Edwards Lifesciences Corp. v. Meril Life Sciences Pvt. Ltd.: Should "Intent" Be Reconsidered in 271(e)(1)?

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Edwards Lifesciences Corp. v. Meril Life Sciences Pvt. Ltd., Appeal No. 22-1877 (Fed. Cir. March 25, 2024) Considerations of 271(e)(1), a 2-1 decision on appeal from a grant of summary judgement of non-infringement, addressed the question of whether 35 U.S.C. § 271(e)(1)'s safe harbor applies to the importation of two medical devices (transcatheter heart valve systems) into the U.S. for purposes of exhibiting the devices at a prominent medical conference that reported on the latest developments in cardiovascular medicine.

The devices imported by the defendant had been approved in India and received CE certification (conformed with health and safety standards) in Europe. Prior to the conference, Meril had started work on a premarket submission and contacted the FDA concerning the preliminary requirements for filing the premarket submission. At the conference, Meril's exhibitor presented displays and presentations describing the devices, but did not actually show the imported devices. However, Meril provided instructions to its exhibitor, stating that sales of the devices outside of the U.S. could be solicited.

On appeal, the majority concluded that the importation was reasonably related to recruiting clinical investigators at the conference for a clinical trial to support FDA approval of the devices. Edwards could not demonstrate that any sales or offers for sale actually occurred, and the court further concluded that "§271(e)(1) applies the safe harbor regardless of the defendant's intent or purpose behind the otherwise infringing act" – here, the importation of the devices.

Judge Alan Lourie dissented, calling for *en banc* rehearing. He explained that the majority's decision continues to perpetuate "the error of *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir.), *opinion amended on reh'g*, 131 F.3d 1009 (Fed. Cir. 1997), and its progeny

that the purposes of the infringing act do not matter in evaluating the safe harbor." Judge Lourie pointed out that §271(e)(1) expressly states that the safe harbor is exclusively available only for uses, sales, and importations that are solely for, as the statute says, development of information for the FDA. Hence, "the purpose of the infringing act is meaningful and important to determining the safe harbor."

A petition for rehearing *en banc*, if sought, will be filed soon. Gibbons, as always, will keep you advised.

FBT Gibbons