EDWARDS LIFESCIENCES CORP. v. MERIL LIFE SCIENCES PVT. LTD., Appeal No. 2022-1877 (Fed. Cir. March 25, 2024). Before Lourie, Stoll, and Cunningham. Appealed from N.D. Cal. (Judge Gilliam, Jr.).

Background:

Meril is an India-based medical device company that created heart valves to treat heart disease. The heart valves are regulated as "Class III" medical devices, meaning that the devices are "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C)(ii)(1). Meril cannot market or sell the heart valves in the United States without first receiving premarket approval from the Food and Drug Administration (FDA).

To obtain FDA premarket approval, Meril needed to identify clinical investigators to implant the device in human subjects, collect data from those subjects, and then submit the data to the FDA. Meril sought out such clinical investigators at a scientific conference hosted in California, which was attended by researchers and clinicians. A Meril employee brought two sample heart valves to the conference, but never removed them from their storage bag. Instead, the employee provided information on the heart valves with displays and presentations without actually showing the heart valves to anyone. The employee informed conference attendees that the heart valves were "NOT FOR SALE. NOT APPROVED FOR SALE IN UNITED STATES. FOR DEMO PURPOSE ONLY."

Edwards, one of Meril's competitors, sued Meril for infringement based on the importation of the two demo heart valves. Meril moved for summary judgment of noninfringement, and the district court granted the motion, determining that Meril's importation of the heart valves was exempt from patent infringement under the safe harbor of 35 U.S.C. § 271(e)(1).

Issue/Holding:

Did the district court err in finding that the §271(e)(1) safe harbor applied? No, affirmed.

Discussion:

The § 271(e)(1) safe harbor sets forth that "[i]t shall not be an act of infringement to . . . 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." Consistent with its earlier precedent, the Federal Circuit interpreted the word "solely" as modifying "for uses," and thus the safe harbor applies only to acts or uses that "bear a reasonable relation to the development and submission of information" to the FDA. The safe harbor extends to such "reasonably related" uses regardless of the defendant's actual intended use of the patented invention, and even if the information was never actually submitted. *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030, 1038-39 (Fed. Cir. 1997). In the present case, the Federal Circuit held that Meril's importation of the heart valves was "reasonably related" to selecting qualified investigators for clinical testing in an effort to develop information to submit to the FDA, even if Meril also intended to commercially promote the heart valves during the conference.

In dissent, Judge Lourie argued that the term "solely" creates a safe harbor only for importations that "solely are for . . . the development of information" for the FDA.