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Section 271(e)(1) Safe Harbor Applies to Importation Regardless of Intent or Actual Use

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A divided panel of the Federal Circuit affirmed a district court's grant of summary judgment of noninfringement, holding that importation of two product samples into the U.S. was reasonably related to obtaining FDA approval based on the particular facts of this case. In dissent, Judge Lourie disagreed, suggesting that summary judgment was not appropriate where factual disputes existed as to whether the importation was "solely" for purposes related to FDA approval.

At issue in this case was the importation of two sample heart valve systems. The accused infringer brought the samples into the U.S. in connection with a medical trade show. It was undisputed, however, that the samples were never shown at the trade show. It was also undisputed that the accused infringer never offered for sale or sold the samples. And in advance of the trade show, the accused infringer instructed its employees that they could not make offers for sale in the U.S. But the employees were permitted to make offers for other countries where the systems were already approved for human use. According to the accused infringer, it brought the samples to the U.S. trade show to identify potential clinicians for its premarket approval application who were known to attend the trade show. In support of this assertion, the accused infringer presented evidence that it started work on a premarket approval submission, began planning a "Landmark Trial" to include in future submissions to the FDA, contacted the FDA about the requirements for a premarket submission and retained a medical device consulting company to assist with its premarket submission.

Based on these facts, the district court found the accused infringer's activities were protected by the Safe Harbor provision, and granted summary judgment of non-infringement.

On appeal, the patentee argued the district court failed to apply an objective standard to the Safe Harbor and instead improperly relied on the accused infringer's intent. The Federal Circuit rejected this argument, explaining that "the relevant inquiry is not *why*" the accused infringer imported the samples "or *how*" it used the samples, "but whether the act of importation was for a use reasonably related to submitting information to the FDA." In view of the undisputed evidence that no offers for sale were made, the court held that no reasonably minded juror could have concluded the importation was "solely to support commercial sales, rather than to recruit clinical investigators." According to the majority, "solely" as used in the Safe Harbor modifies uses and means, for each act of infringement, the safe harbor is available where the acts or uses that constitute infringement bear a reasonable relation to the development and submission of information to the FDA.

On this point, Judge Lourie dissented. In Judge Lourie's view, the majority opinion and the Federal Circuit precedence on which it relies read the word "solely" out of the Safe Harbor. Judge Lourie believes that solely limits the application of the Safe Harbor to acts that have no purpose other than the development of information for the FDA. In other words, the Safe Harbor does not exist to protect acts that have a dual purpose, one of which is commercial. And here, factual disputes existed at least as to whether the accused infringer's importation served a dual purpose—FDA approval and sales. Judge Lourie urged that consideration by the Federal Circuit en banc is warranted to consider the proper construction of the Safe Harbor provision.

Practice Tip: Parties who are actively developing products for which FDA approvals are required prior to commercial use should take care to ensure that any potential act of infringement preceding FDA approval is tied to the development of information that will be submitted to the FDA. Such activity is protected if it is reasonably related to an FDA submission; whereas activity that is solely commercial in nature is exempt from the Safe Harbor.

Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd., No. 2022-1877, 2024 WL 1243032 (Fed. Cir. Mar. 25, 2024)

Categories

Patent Infringement