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Judge Lourie's Dissent Revives Debate Over FDA Safe Harbor

By **Dani Kass**

Law360 (April 5, 2024, 8:55 PM EDT) -- U.S. Circuit Judge Alan Lourie has urged the Federal Circuit to reconsider its precedent over a safe harbor that allows infringement when companies are developing products regulated by the U.S. Food and Drug Administration, and many attorneys agreed with him that the appeals court has been improperly expanding the safe harbor for decades.

The Federal Circuit on March 25 ruled 2-1 that Meril Life Sciences **could invoke the safe harbor** after being sued by Edwards Lifesciences over transcatheter heart valve systems, even if only part of its allegedly infringing behavior was tied to Meril pursuing FDA approval. In response, Judge Lourie issued a fiery dissent, saying the Federal Circuit has effectively made the safe harbor meaningless by allowing it to apply in a situation that wasn't limited to FDA approval.

Judge Lourie said the majority correctly applied precedent, but he argued that case law went against the meaning and intent of the statute, and attorneys who spoke to Law360 agreed with the overall argument in his dissent. The judge also invited requests for en banc review, which the Federal Circuit rarely grants in patent cases.

"I'm not sure ultimately which way an en banc Federal Circuit would go, but I do think this is something important enough that it should be heard en banc," said Nutter McClennen & Fish LLP partner Ben Stern, who said the appeals court has strayed from the statute's language.

The suit stems from India-based Meril importing two transcatheter heart valve systems that allegedly infringe Edwards' patents. Meril brought those products to a medical conference in California while still preparing a submission for FDA approval, and it tried to recruit investigators for clinical trials. The company did not present the physical product at the conference.

The Federal Circuit panel was torn on whether Meril's intent behind that importation matters. The majority held that the safe harbor applies "regardless of the defendant's intent or purpose behind the otherwise infringing act." The dissent warned that ignoring intent undermines why the law was crafted — to get products on the market quickly after patents expire — and harms patent owners.

"The statute has been interpreted so broadly that a patent owner doesn't really stand a chance to stop importation of a product that's imported for multiple purposes, if at least one purpose is related to FDA submission," said Kilpatrick Townsend & Stockton LLP partner Justin Krieger.

The facts of Meril's specific case, though, show there was no doubt the company was focused on safe-harbor-related activity, said Sterne Kessler Goldstein & Fox PLLC director Dennies Varughese, who strongly disagreed with Judge Lourie.

Meril's representative carried the samples alongside a note in all capitals, which stated "Non-sterile. Not For Human Use. Not For Sale. Not Approved For Sale In United States. For Demo Purpose Only At [Conference]," Varughese quoted from the majority opinion.

"When you look at the statute, I can't understand how anyone could reasonably look at that and not conclude that those two models were not solely for purposes that were reasonably related to getting FDA approval," he said.

The statute states: "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."

The main tension tied to whether intent matters is the use of the word "solely" in the statute, which some judges have read to be part of a larger clause for activity being "reasonably related" to obtaining FDA approval, while others have read it alone as only to obtain FDA approval.

The safe harbor itself was passed shortly after a 1984 Federal Circuit decision, Roche Products v. Bolar Pharmaceutical, where the court said no infringement is allowed before the patent expires, even for circumstances like drug development.

In the last 30 years, at least three Federal Circuit decisions and one U.S. Supreme Court ruling inform how courts interpret the safe harbor.

"For a long time, almost every court decision broadened the scope of the safe harbor," said Foley & Lardner LLP partner Courtenay C. Brinckerhoff.

In 1997's AbTox v. Exitron, the Federal Circuit ruled firmly in favor of the "reasonably related" camp, explicitly **rejecting** the more limited view of the statute raised by Judge Lourie.

The Supreme Court **held** in Merck v. Integra Lifesciences in 2005 that the safe harbor "provides a wide berth for the use of patented [inventions] in activities related to the federal regulatory process."

The Federal Circuit expanded upon Merck a decade later with Momenta Pharmaceuticals v. Teva Pharmaceuticals , **holding** in 2015 that the safe harbor allows for promotional use when it's consistent with collecting data for FDA applications.

Then in 2019's Amgen v. Hospira , the Federal Circuit **found** that batches of a drug made for testing were covered by a safe harbor, but that those stockpiled only for future sales were not.

"The investigation of this safe harbor has been slow but very well-defined," said Hoffmann & Baron LLP managing partner Dan Scola, who also expressed support for an en banc hearing in the Edwards case, arguing the court has veered from Congress' intent.

Some decisions trying to rein in the safe harbor were more about what products are covered, rather than intent or purpose, Brinckerhoff said.

Scola similarly said, "You start off first with [the safe harbor] applies to drugs, then medical devices, then to people making ingredients for research tools, and then to information that is solely reasonably related."

But how decades of rulings over the definition of "solely" started is questionable, Krieger said, given how small of a role the word had in AbTox.

In one paragraph, the Federal Circuit's ruling said that "contrary" to arguments from AbTox, "[the statute] requires only that the otherwise infringing act be performed 'solely for uses reasonably related to' FDA approval."

The ruling continues: "As long as the activity is reasonably related to obtaining FDA approval, [the patent owner's] intent or alternative uses are irrelevant to its qualification to invoke the [safe harbor]."

Krieger said he cannot understand how that interpretation of "solely" came about.

"It seems so bizarre and conclusory," he said. "It's unfortunate that one paragraph of one opinion can lead to such disarray in terms of the scope, the understanding, the meaning of the safe harbor, and how broad or narrow it could be."

"Ultimately," Stern said, "this is a grammar exercise. What does the word 'solely' and the phrase 'reasonably related' mean in terms of what modified what?"

The interpretation focusing on "reasonably related" calls for the law allowing the safe harbor to be broadly viewed, while the strict use of "solely" would be more of a bright-line rule, Stern said.

"I think both Judge Lourie and the majority recognize those two possibly contrasting poles," he added.

But if Judge Lourie's position were to win over an en banc panel, those relying on the safe harbor will need to be extra careful to stick within the right bounds, according to Krieger. Patent owners would likely grab onto the narrowed law and sue those who had hoped the safe harbor would be viewed in a broader light, he said.

"It has the great potential of increasing the floodgates into a tremendous amount of litigation in this area," Krieger said.

--Editing by Adam LoBelia.
