

Fed. Circ. Affirms Hospira's Generic Adrenalin Loss To Par

By **Britain Eakin**

Law360 (November 23, 2020, 10:21 PM EST) -- The Federal Circuit on Monday affirmed a Delaware federal judge's ruling that Hospira's generic version of Par Pharmaceutical's epinephrine emergency allergy product Adrenalin infringes two valid patents covering the drug, leaving in place an injunction blocking Hospira's generic.

Pfizer unit Hospira had argued on appeal in the Hatch-Waxman Act case that the district court wrongly found infringement, saying its abbreviated new drug application could not infringe because the claims in Par's patents require "about" six to eight milligrams of a certain compound, while Hospira's generic contains nine milligrams. But the Federal Circuit agreed with Par in a nonprecedential opinion that Hospira's generic infringes and found that the district court "reasonably concluded" that the amounts in the generic fall within the claimed range in Par's patents.

The three-judge panel said that when "about" is used in a numeric range, it "avoids a strict numerical boundary to the specified parameter." Since Hospira agreed to the district court's adoption of the plain and ordinary meaning of "about" to mean "approximately," the panel said it could find no clear error in the district court's analysis that Hospira's generic infringes.

Hospira had asserted that Par made public statements years after the patents were issued that 8.5 milligrams would be too high to fall within the "about" range. But the court said that was irrelevant since Hospira had agreed to the plain and ordinary meaning of the term at the district court.

As a result, the panel said the only thing at issue before the district court was what a skilled artisan would have reasonably understood to fall within the range claimed in Par's patents. The Federal Circuit said that under its precedent, the evidence in the district court case "supported a finding that 'about 8' encompasses 9."

"Hospira has cited no authority that would make Par's later statements, made in a different context, controlling over the evidence that the district court relied on here to find in Par's favor on this claim limitation," the opinion said.

U.S. District Judge Joseph F. Bataillon of Nebraska, sitting in Delaware, ruled in favor of Par and its parent company Endo in Nov. 2019, finding that Hospira's abbreviated new drug application infringes. The judge issued an injunction barring Hospira from making or selling a generic version of the emergency allergy treatment until the patents expire.

According to Par's 2019 annual report, the patents covering Adrenalin expire in 2035. The drug brought in more than \$179 million last year — a 25% increase from 2018 — which the report attributed to increased price and volume.

Hospira argued at the district court that Par's two patents would have been obvious based on prior art, but Judge Bataillon determined that the Pfizer unit failed to show that a skilled artisan would have been motivated to combine the prior art references or that they would have reasonably expected to be successful if they did so.

The case has an unusual back story since both companies started selling epinephrine products before the current regulatory approval structure was in place and were given an exception to stay on the market.

In 2006, the U.S. Food and Drug Administration started increasing requirements for these unapproved drugs, leading Par's predecessor JHP Pharmaceuticals LLC to work on a product that met the modern requirements. The FDA ended up approving Adrenalin, but told JHP to address concerns over stability and shelf life.

Par eventually succeeded and filed a supplemental new drug application — approved in 2016 — receiving the two patents at issue in Monday's decision, which were tied to those improvements. In 2007, Hospira agreed to fix its unapproved products but the company was unsuccessful and instead sought approval of an Adrenalin generic in 2017 that prompted Par's infringement suit.

Counsel and representatives for the parties did not return a request for comment.

The patent-in-suits are U.S. Patent Nos. 9,119,876 and 9,295,657.

U.S. Circuit Judges Timothy B. Dyk, Richard G. Taranto and Kara Farnandez Stoll sat on the panel for the Federal Circuit.

Par is represented by Daniel G. Brown, Jennifer Koh and Gabriel K. Bell of Latham & Watkins LLP.

Hospira is represented by Thomas J. Meloro, Matthew S. Freimuth and Devon W. Edwards of Willkie Farr & Gallagher LLP.

The case is Par Pharmaceutical Inc. v. Hospira Inc., case number 20-1273, before the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Dani Kass. Editing by Steven Edelstone.