Pfizer generic epinephrine shot would infringe Endo patents - Fed Circuit

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(Reuters) - Pfizer Inc unit Hospira's proposed generic version of Endo International PLC's emergency allergy treatment Adrenalin would infringe two of Endo's patents, a federal appeals court has ruled, affirming a lower court ruling blocking the generic drug from the market.

Circuit Judge Richard Taranto, writing for a three-judge panel of the Federal Circuit U.S. Court of Appeals, said that slight changes in Pfizer's proposed formulation of the injection were not enough to avoid infringing the patents.

Thomas Meloro of Willkie Farr & Gallagher, a lawyer for Pfizer, and Daniel Brown of Latham & Watkins, a lawyer for Endo, did not immediately respond to requests for comment.

Adrenalin is an injection containing the hormone adrenaline, also known as epinephrine, and agents including antioxidants used to extend shelf life. The medicine, which is indicated for emergency treatment of allergic reactions, generates about $140 million in annual revenue for Endo, which has its operational headquarters in Malvern, Pennsylvania.

Adrenalin was developed by Par Pharmaceuticals, which Endo acquired in 2015 for $8 billion. Par obtained patents covering the specific formulation of compounds in Adrenalin.

In 2017, Pfizer sought approval from the Food and Drug Administration to market a generic version of Adrenalin.

Endo sued Pfizer that year in Delaware, alleging the latter's proposed generic infringed the patents. Pfizer countered that its generic did not infringe, noting that the product had a slightly different formulation than the one claimed in Endo's patent.

Pfizer also argued that the patents were invalid because they described a formulation that was obvious in light of decades-old medical research.

Following a bench trial in June 2019, U.S. District Judge Joseph Bataillon in Wilmington, Delaware ruled that Pfizer's generic infringed the patents despite the tweaks to the formulation, calling the two versions functionally equivalent.

Bataillon also rejected Pfizer's obviousness argument, saying the shelf life, or stability, of the formulation in Adrenalin represented an important advancement.

Pfizer appealed the finding as to infringement. It argued that Bataillon had been wrong to find that the concentration of sodium chloride in its proposed product, at nine milligrams per milliliter, infringed an Endo patent claim calling for "about" six to eight milligrams per milliliter.

Taranto rejected that argument, writing that "evidence supported a finding that 'about eight' encompasses nine, considering the purpose of the upper limit."

Pfizer also argued that it Bataillon had been wrong to conclude that the presence of citric acid in its proposed product satisfied two separate limitations of Endo's patents, that of an agent that prevents degradation and an agent that lowers the solution's pH value. But Taranto said nothing in the language of the patent prevented the same component from fulfilling both limitations.

Taranto was joined by Circuit Judges Timothy Dyk and Kara Stoll.

The case is Par Pharmaceutical Inc et al v. Hospira Inc, Federal Circuit U.S. Court of Appeals, No. 20-1273.

For Endo: Daniel Brown of Latham & Watkins

For Pfizer: Thomas Meloro of Willkie Farr & Gallagher

References

ENDO INTERNATIONAL PLC; HOSPIRA INC; LATHAM AND WATKINS LLP; PAR PHARMACEUTICAL INC; PFIZER INC; WILLKIE FARR AND GALLAGHER LLP