

Delaware jury awards Amgen \$70m in patent dispute with Hospira

Amgen has been awarded \$70 million in a dispute over a Pfizer subsidiary's biosimilar of the Epogen treatment for anaemia

A District of Delaware jury has awarded Amgen \$70 million in patent damages against Pfizer subsidiary Hospira, in a case before Judge Richard Andrews

In its verdict, the jury after a five-day trial found infringement of one of the two patents it was asked to rule on. The patents cover Amgen's Epogen treatment for anaemia caused by chronic kidney disease in patients on dialysis. Epogen is a brand name for the erythropoietin alfa (EPO) glycosylated protein produced in genetically engineered mammalian cells.

The case is one of the first lawsuits under the Biologics Price Competition and Innovation Act to reach trial.

The FDA in 2015 accepted Hospira's abbreviated Biologics License Application for a biosimilar version of EPO. Amgen sued Hospira asserting two patents, one covering EPO isoforms and methods of selecting them and the other covering a cell line suitable for making EPO.

Hospira argued its production of EPO was protected by the safe harbour of 35 USC § 271(e)(1), which allows for use of patented processes for the purpose of gaining FDA approval. Amgen argued that the EPO batches were produced to create a stockpile of commercial product.

The jury found that 14 of Hospira's 21 EPO batches of the biosimilar were not protected by the safe harbour and awarded Amgen \$70 million in damages. When the lawsuit was filed, the isoforms patent was close to expiry while the cell line patent had already expired. The isoforms patent,

Patent No. 5,856,298, was the one the jury found to have been infringed.

"Notably, the award comes prior to any actual biosimilar sales in the United States, as FDA has yet to approve Hospira's aBLA due to FDA's concerns with a manufacturing facility for the biosimilar," commented Patterson Belknap Webb & Tyler attorneys Andrew Cohen and Irena Royzman on the Biologics Blog.

Cohen and Royzman commented that the case is a lesson to innovators and biosimilar makers on the value of expired or soon-to-expire patents.

"In deciding which patents to assert in BPCIA litigation, innovators should consider their entire patent portfolio, including recently expired manufacturing patents. Biosimilar makers similarly should be aware that pre-approval batches will not necessarily be exempt from infringement, even if the relevant patents are due to expire prior to FDA approval. Such patents not only are in play, but also – especially in the high-stakes biologics market – may result in significant damages awards," wrote the Belknap attorneys.

Amgen was represented by Marshall Gerstein & Borun, as well as Morris Nichols Arshat & Tunnell, Paul Weiss Rifkind Wharton & Garrison and Richards Layton & Finger. John Labbé of Marshall Gerstein & Borun argued before the court.

Hospira was represented by Wilkie Farr & Gallagher, as well as Heyman Enerio Gattuso & Hirzel. Thomas Meloro of Willkie Farr & Gallagher argued before the court.