Hospira must pay Amgen $70 million in biosimilar patent case - jury

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(Reuters) - A federal jury has awarded Amgen Inc $70 million after finding that Hospira's production of a biosimilar version infringed Amgen's patent covering its anemia drug Epogen.

The verdict by a federal jury in Wilmington, Delaware, on Friday came in what Amgen has said was one of the first patent lawsuits to be filed in the wake of the 2010 Biologics Price Competition and Innovation Act.

Biologic drugs like Epogen are made by using living cells and cannot be copied exactly to make generic versions. The 2010 law created a process for the approval of near-copies or "biosimilars."
Amgen in its complaint said the lawsuit was seeking to give force to a provision of the law requiring biosimilar makers to give 180 days' notice after receiving Food and Drug Administration approval before launching their products.

"Amgen is very pleased with the verdict," Amgen said in a statement on Monday. "Enforcing our patents against infringement is critical to our mission of developing new therapeutics to treat serious illnesses for patients who need them."

Hospira, a unit of Pfizer Inc, said in a statement it plans to continue to defend itself and appeal.
"The company remains committed to making this important treatment option available to patients and physicians as quickly as possible," Hospira said.

Along with establishing the 180-day notice requirement, the 2010 law created a process to streamline disputes over patents between biologic makers and biosimilar applicants.
In a lawsuit filed in September 2015, Amgen claimed Hospira's proposed copycat drug and its manufacturing process would infringe a patent Amgen held for Epogen and had failed to follow the biosimilar process in good faith.

Amgen said Hospira refused to provide it with enough information to decide what patents to litigate and that Hospira said it would not give 180 days' notice after FDA approval before launching the copycat of Epogen.

Hospira denied infringing Amgen's patent, citing a safe harbor that it said would protect companies seeking FDA approval for biosimilars from liability. It also argued the patent was invalid.
The litigation led to an August 2016 ruling by U.S. District Judge Richard Andrews that was the first to hold that the 2010 law created a private right of action to enforce the 180-day notice requirement, despite Hospira's arguments to the contrary.

The case is Amgen Inc et al v. Hospira Inc, U.S. District Court, District of Delaware, No. 15-cv-00839.

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For Hospira: Thomas Meloro of Willkie Farr & Gallagher