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How Safe is the Safe Harbor for Methods of Manufacturing Biosimilar Products—It Depends on Why Each Batch is Made

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Amgen sued Hospira for infringing U.S. Patent No. 5,856,298 ("the '298 Patent"), which covers methods of producing certain forms of the glycoprotein erythropoietin (EPO) after Hospira sought FDA approval of its biosimilar version of Amgen's Epogen. A jury found the '298 Patent infringed and was not invalid. It also found that only seven of Hospira's 21 batches of drug product fell under § 271(e)(1)'s safe harbor. The district court denied Hospira's motions for judgment as a matter of law and a new trial.

On appeal, Hospira challenged the district court's safe harbor jury instructions. Those instructions explained that if the manufacture of a batch of drug substance was reasonably related to development and submission of information to the FDA, additional underlying purposes for the manufacture and use of the drug do not remove the batch from the safe harbor. In Hospira's view that instruction improperly focused the jury on the reasons **why** each batch was manufactured—it should have focused on **how** each batch was used and whether that use was reasonably related to the development and submission of information to the FDA. Amgen disagreed. According to Amgen, because the '298 patent claims methods of manufacturing EPO, the instructions properly focused on each act by Hospira to manufacture the drug and whether that manufacture was reasonably related to seeking FDA approval.

The Federal Circuit agreed with Amgen. The safe harbor exemption applies if there is a reasonable basis for believing that use of the patented invention will produce information relevant to an FDA submission. Here, the patented inventions were methods of

manufacturing EPO. The accused activity was Hospira's act of manufacturing its EPO product. Thus, the relevant inquiry is not how Hospira used the resulting batches, but whether each act of manufacture was for uses reasonably related to submitting information to the FDA, notwithstanding any additional underlying purposes.

Hospira also challenged the reasonableness of the jury's verdict that 14 of the 21 drug batches were not covered by the Safe Harbor exemption. Specifically, Hospira argued that no reasonable jury could have concluded that only some batches were covered where, as here, all of the batches were used to develop information for the FDA. The Federal Circuit disagreed. The jury heard testimony that Hospira made some batches and performed some stability testing not required by the FDA. The jury also saw documentary evidence that parts of some of the batches were intended to be used as commercial inventory. Consequently, the Federal Circuit held that substantial evidence supported the jury's verdict.

Practice tip: If you plan to rely on § 271(e)(1)'s safe harbor as a defense against claims covering a method of manufacture, be sure the evidence shows that each act of manufacturing the product was reasonably related to developing or submitting information to the FDA.

Amgen Inc., Amgen Manufacturing, Limited v. Hospira, Inc., No. 2019-1067 (Fed. Cir. Dec. 16, 2019)

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