# Haynes and Boone in Law360: Stockpiling Biologics Under Hatch-Waxman Protection

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A recent biosimilars litigation raises issues regarding the scope of the 35 U.S.C. § 271(e)(1) safe harbor provision and whether it protects commercial stockpiling. *Amgen Inc. et al. v. Hospira Inc.*, No. 1:15-cv-839 (D. Del., Sept. 25, 2017). Hospira is seeking approval to market a biosimilar version of Amgen's erythropoeietin ("EPO") anemia treatment. Hospira had manufactured 21 lots of EPO between 2013 and 2015. These lots numbered in the tens of millions of doses. Prior to trial, Hospira filed a motion for summary judgment arguing that its activities were protected by the safe harbor provisions of 35 U.S.C. § 271(e)(1).

The district court denied Hospira's motion for summary judgment. The court held that there were genuine disputes of material fact as to whether Hospira's manufacturing activities were "solely for uses reasonably related to the development and submission of information" to the U.S. Food & Drug Administration. *Amgen Inc. v. Hospira Inc.*, 1:15-cv-839, slip op. at 4 (D. Del. Sept. 7, 2017 (order denying summary judgment) (emphasis in original). The district court, in denying the motion for summary judgment, noted that Hospira's own documents and statements to the FDA indicated that the manufacture of some of the lots was for "commercial inventory." "Thus, although Hospira has evidence that its EPO was manufactured and used to gather information for FDA submissions pursuant to FDA guidelines and information requests, that is insufficient to show that there is no genuine dispute of material fact that the quantity of EPO produced was reasonably related to the development and submission of information to the FDA." Id.

The case proceeded to trial, and a jury found that batches of Hospira's biosimilar EPO product erythropoietin infringed Amgen's patents and awarded Amgen $70 million in damages. At trial, the jury rejected Hospira's argument that it was protected by the safe harbor provision, at least for 14 of the 21 batches.

Hospira has filed a motion for judgment as a matter of law on, inter alia, the issue of the safe harbor protection. Hospira's motion stresses that all of its batches were manufactured and used for purposes reasonably related to obtaining FDA approval, and, thus, were entitled to exemption under the safe harbor provision of § 271(e)(1). *Amgen Inc. v. Hospira Inc.*, 1:15-cv-839 (D. Del. Sept. 27, 2017) (motion for judgment as a matter of law). Hospira further argues that any "intent or ulterior motives in undertaking allegedly infringing activities are irrelevant to whether Hospira is entitled to Safe Harbor protection." Id. at 2. Hospira's motion is currently pending.

Excerpted from *Law360*. To read the full article, click here.