AMGEN INC. v. SANDOZ INC., Appeal No. 2015-1499 (Fed. Cir. July 21, 2015). Before Newman, Lourie, and Chen. Appealed from N.D. Cal. (Judge Seeborg).

Background:

Amgen owns a patent directed to a method of using filgrastim (Neupogen). Sandoz filed an abbreviated biologics license application in the FDA under the provisions of the Biologics Price Competition and Innovation Act (BPCIA) seeking approval of a biosimilar filgrastim product (Zarzio). Amgen sued Sandoz for infringement and the state law claims of unfair competition and conversion. The district court found in favor of Sandoz, in part, and entered final judgment in favor of Sandoz on the unfair competition and conversion claims and its counterclaims for declaratory judgment that it correctly interpreted the BPCIA. Amgen appealed.

Issue/Holding:

Did the district court properly interpret the BPCIA? No, vacated and remanded.

Discussion:

The primary issue in the district court was whether Sandoz (i) violated the BPCIA by electing not to disclose the information facially required by §262(l)(2)(A), and (ii) gave a premature, ineffective notice of commercial marketing under § 262(l)(8)(A) before FDA approval of its biosimilar product. The district court found that the information disclosure requirement of the BPCIA is not mandatory as argued by Sandoz, and that Sandoz fulfilled the commercial marketing notice requirement.

Regarding the information disclosure requirement, §262(l)(2)(A) provides that an aBLA applicant "shall provide" to the reference product sponsor a copy of the application submitted to the FDA and other manufacturing information. However, Sandoz never provided Amgen with the required information. Sandoz argued that the information disclosure provision is not mandatory because the BPCIA contemplates the consequences of a failure to disclose that information by permitting Amgen to then file an infringement action. The Federal Circuit agreed, finding that the BPCIA contemplates that an applicant might fail to disclose the information and sets forth the consequences for such failure, *i.e.*, an infringement action.

Regarding the commercial notice requirement, Sandoz provided Amgen with notice of commercial marketing before the FDA licensed its biosimilar as well as further notice once licensed. §262(l)(8)(A) provides that an aBLA applicant "shall provide" notice to the reference product sponsor not later than 180 days before the date of first commercial marketing of the biological product "licensed" under the BPCIA. The Federal Circuit held that Sandoz's "pre-licensed" notice did not satisfy §262(l)(8)(A). The Federal Circuit found that the statutory language in §262(l) draws a distinction between licensed and applied-for biosimilars and held that the notice provisions of §262(l)(8)(A) compel that the biosimilar be licensed. However, the Federal Circuit found that Sandoz's further notice once the biosimilar was, in fact, licensed was effective. Regarding the "shall provide" provision of this subsection, the Federal Circuit distinguished over its holding with respect to these same terms in §262(l)(2)(A) finding that the notice disclosure is mandatory to start the 180-day period prior to commercial marketing.

Judge Newman dissented from the holding that the information disclosure requirement of §262(l)(2)(A) is not mandatory, arguing that Sandoz's violation of this requirement should foreclose it from access to the benefits of the BPCIA. Judge Chen dissented from the holding that "shall provide" in §262(l)(8)(A) be treated any differently than in §262(l)(2)(A), arguing that "shall provide" should not require mandatory disclosure in either subsection.