

AMGEN INC. v. SANDOZ INC., Appeal No. 2018-1551 (Fed. Cir. May 8, 2019). Before Lourie, O'Malley, and Reyna. Appealed from N.D. Cal. (Judge Seeborg).

Background:

Amgen created and commercialized two related biologic products, filgrastim (marketed as Neupogen®) and pegfilgrastim (marketed as Neulasta®), indicated for treating neutropenia, which is a deficiency of white blood cells. Neupogen® also mobilizes stem cells from the bone marrow into the bloodstream for collection for stem cell transplantation.

Sandoz submitted abbreviated Biologics License Applications to market biosimilar products of filgrastim and pegfilgrastim. Amgen filed a declaratory judgment action alleging that the biosimilars would infringe its patent, which related to a method of manufacturing the products.

When construing the method steps, the district court construed the claim to mean that the steps must be performed as separate steps requiring separate solutions, and must be performed in the order recited. Amgen stipulated to non-infringement because Sandoz's process only involves a one-step, one-solution process. Summary judgment was granted, and Amgen appealed.

Issue/Holding:

Was the claim correctly constructed? Yes – affirmed.

Discussion:

On appeal, Amgen argued that the steps in the claim at issue are functional features, rather than actual process steps. Amgen argued that in Sandoz's one-step, one-solution process, functionally, the steps occur in the same order as Amgen's claim.

However, the Federal Circuit agreed with Sandoz that the recited claim language logically required that the process steps, which were lettered (a) through (g), be performed in sequence. There was no indication in the claim that the steps should be treated differently. In addition, the specification consistently described each step as separate steps performed with different solutions.

Amgen also argued that Sandoz infringes the claim through the doctrine of equivalents. Amgen argued that Sandoz's one-step, one-solution process is insubstantially different from the claimed multistep, multi-solution process because it achieves the same functions, in substantially the same way, to achieve the same result.

However, the Federal Circuit again agreed with Sandoz that the one-step, one-solution process does not function in the same way as the claimed process, that the doctrine of equivalents cannot override the natural language of Amgen's claim, and cannot be used to effectively read out claim limitations.

Therefore, the Federal Circuit affirmed the district court's claim construction and the finding of no infringement.