

AMGEN INC. v. AMNEAL PHARM. LLC, Appeal No. 2018-2414 (Fed. Cir. Jan. 7, 2020).
Before Newman, Lourie, and Taranto. Appealed from D. Del. (Judge Goldberg).

Background:

Amgen has a patent covering its drug Sensipar®, which is a formulation of cinacalcet hydrochloride used to treat hyperparathyroidism in patients with chronic kidney disease or cancer. Defendants Amneal and Primal each filed an ANDA for a generic version of Sensipar®, and Amgen brought suit against each of them for infringement.

At issue in the district court was the construction of a Markush group and whether the acceptance of an Examiner's Amendment to add the Markush group triggered prosecution history estoppel to bar infringement based on the doctrine of equivalents.

Claim 1 of the patent used the transitional phrase "comprising" and the Markush group recited "at least one binder selected from the group consisting of" (emphasis added). The district court construed the claim as being closed to unrecited binders based on the "consisting of" language. Therefore, because Amneal's formulation included both a recited binder and an unrecited binder, Amneal did not literally infringe Amgen's patent.

Further, the district court concluded that the acceptance of the Examiner's Amendment was for reasons relating to patentability, and thus prosecution history estoppel barred the application of the doctrine of equivalents to a formulation that only used an unrecited binder. Therefore, Primal did not infringe because its formulation only used an unrecited binder.

Issues/Holdings:

Was the claim correctly construed? No, reversed and remanded in part. Did prosecution history estoppel apply? Yes, affirmed in part.

Discussion:

The Federal Circuit concluded that there is no language in Amgen's claim indicting that every binder must be within the Markush group and there was no sufficient basis in the specification or prosecution history to conclude otherwise. The Federal Circuit relied on the transitional phrase "comprising" and the modifying phrase of "at least one" to construe the claim to mean that one of the recited binders must be present without precluding the presence of an additional unrecited binder.

The Federal Circuit also concluded that prosecution history estoppel applies. During prosecution, Amgen amended the claims to attempt to overcome the Examiner's rejection. However, Amgen later agreed to further amendments proposed by the Examiner to obtain allowance. The Federal Circuit reasoned that, if Amgen's original amendments were sufficient to overcome the rejection, then there would have been no reason for the Examiner to propose further amendments. Amgen's boilerplate language in a subsequent filing that the amendments were not added in "response to a prior art rejection but rather to place the claims in proper format and to better define the claimed subject matter, including equivalents" was insufficient to overcome the presumption that the amendments were made for reasons relating to patentability.