

AZURITY PHARMACEUTICALS, INC., v. ALKEM LABORATORIES LTD., Appeal No. 2023-1977 (Fed. Cir. April 8, 2025). Before Moore, Chen, and Murphy. Appealed from D. Del. (Judge Goldberg).

Background:

Alkem filed an Abbreviated New Drug Application with the U.S. Food and Drug Administration seeking market approval to sell a formulation for a drinkable antibiotic. Azurity filed suit under the Hatch-Waxman Act seeking an injunction based on patent infringement.

The patent at issue recites a formulation "consisting of" various ingredients including "a flavoring agent." Alkem argued that their alleged flavoring agent contains propylene glycol and that propylene glycol was disclaimed by Azurity during prosecution.

During prosecution of the parent application, the examiner rejected the parent over a reference which taught a composition including propylene glycol. In response, amendments were introduced which explicitly excluded propylene glycol from one of the components of the claimed formulation. The examiner rejected the negative limitation for a lack of written description and further asserted that it is unclear if the propylene glycol can be present at all. Azurity then amended the preamble to recite "consisting of" and argued that the claimed composition is distinguished because the reference composition includes propylene glycol. The examiner confirmed in the reasons for allowance that the exclusion of propylene glycol by the consisting of language resulted in the allowance. After the parent was allowed, the patent at issue was filed and granted. The patent at issue recites the same "consisting of" in the preamble of the independent claim.

Based on the above, the district court agreed with Alkem that propylene glycol was disclaimed and determined that Alkem's product does not infringe because it contains the chemical. Azurity appealed.

Issue/Holding:

Did the district court err in holding that propylene glycol was disclaimed during the prosecution history of the patent at issue? No, affirmed.

Discussion:

The Federal Circuit agreed that Azurity disclaimed propylene glycol. In reviewing the prosecution history of the parent application, the court held that the "examiner insisted on clarity, and Azurity acquiesced by abandoning the [] distinction and adopting the 'consisting of' transition." The court noted that the scope of the surrender is not limited to what is absolutely necessary to distinguish from the reference, and what matters here is the broad language used to distinguish over the reference.

Azurity also argued that a statement during prosecution in another related application—that propylene glycol was not disclaimed—is relevant for determining the scope of the claims. However, the Federal Circuit disagreed because the patents, while related, are not part of the same lineage and have different parent applications. Moreover, this statement was made after allowance of the patent at issue. Therefore, through the lens of public notice, the statement carries no weight.