



## Federal Circuit: Statements Made During Prosecution of Parent Application Disavow Claim Scope in Subsequent Patents

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The Federal Circuit affirmed a District of Delaware finding of non-infringement in an ANDA litigation due to the patentee's clear and unmistakable disavowal of claim scope during prosecution. Specifically, the court held that statements made during prosecution of a parent application before the asserted claims were allowed amounted to a prosecution disclaimer that extended to subsequent patents in the family. In reaching this conclusion, the court rejected an attempt by the patentee to resurrect the claim scope through a unilateral, self-serving statement made in later applications in the family.

Azurity Pharmaceuticals, Inc. sued Alkem Laboratories Ltd. for infringing certain claims of U.S. Patent No. 10,959,948 ("948 patent") in an ANDA litigation. The '948 patent claimed liquid formulations "**consisting of**" vancomycin hydrochloride and a list of additional ingredients. Notably, propylene glycol was not included in that list. Alkem argued that it did not infringe because its product included propylene glycol and Azurity disclaimed compositions including propylene glycol during prosecution to distinguish prior art. Azurity disputed the disclaimer. As support, Azurity pointed to a statement it made during prosecution of a later-filed application, which indicated that "For the record, Applicant did not disclaim propylene glycol when submitting the arguments in [the parent application], and reserves the right to claim propylene glycol in the instant and future cases in this patent family." The district court agreed with Alkem and found that Azurity disclaimed propylene glycol in its claimed formulations when it amended its claims to use the transition "consisting of" and distinguished prior art based on the absence of propylene glycol in its claims. As a result, the

district court found that Alkem did not infringe because its ANDA product undisputedly contained propylene glycol.

On appeal, the Federal Circuit affirmed the district court's decision, focusing primarily on the patentee's statements and amendments during prosecution of the parent application of the asserted patent. During prosecution of the parent, the examiner repeatedly rejected Azurity's proposed "comprising" claims based on a prior art reference that disclosed oral solutions of vancomycin hydrochloride that included "a polar solvent including propylene glycol." In response, Azurity first proposed adding negative claim limitations—such as a "liquid solution" that "does not comprise a propylene glycol"—to distinguish the prior art. Azurity also submitted a declaration from its Chief Scientific Officer stating that the claimed "solutions do not have propylene glycol." The examiner rejected the negative limitations for lack of support in the specification. Azurity then amended the claims to use the transition "consisting of" in the preamble, again arguing that the absence of propylene glycol from the "closed 'consisting of'" claims distinguished them from the prior art. The examiner then allowed the claims because they "exclude[d] the presence of propylene glycol."

Based on this history, the Federal Circuit held that Azurity disclaimed propylene glycol from the asserted claims, explaining that arguments from the parent application "apply directly" to the '948 patent because it was a continuation of the parent and "included the same 'consisting of' preambles" that distinguished the prior art.

Azurity attempted to get around this history by pointing to its express reservation of rights statement made in a related application after the asserted claims issued. But the Federal Circuit found that argument unpersuasive. While acknowledging that "statements in the prosecution histories of patents descended from a common ancestor application may be relevant for interpreting the claims in the related patents," the court clarified that its prior cases addressing the issue "focused on how such statements have been relevant to **later** issued patents." Here, Azurity relied on an unprovoked statement made during prosecution of an application that was not part of the direct line of applications that led to the asserted patent after the asserted patent issued. Thus, viewed "through the lens of public notice," Azurity's "unilateral and belated statement carrie[d] no weight."

The Court was also unpersuaded by Azurity's alternative argument that Alkem infringed despite any alleged disclaimer because, according to Azurity, the disclaimer would not apply to Alkem's specific use of "propylene glycol" as a "flavoring agent." Azurity argued that the

disclaimer would only exclude the use of propylene glycol as a “carrier” agent because that was how the compound functioned in the prior art. The Court remarked that, regardless of any particular function, “what matter[ed] most was the broad language that Azurity used to distinguish” the prior art during prosecution. According to the Court, “Azurity’s repeated, sweeping statements—endorsed by the examiner—return an equally sweeping disclaimer.” The Court therefore rejected Azurity’s attempt to narrow the disclaimer and affirmed non-infringement accordingly.

**Practice Tip:** Practitioners should carefully consider the potential impact of statements and amendments made during prosecution, especially because, as this case makes clear, it is possible to surrender more than what may be necessary to distinguish the prior art. For example, in *Azurity*, the patentee’s adoption of “consisting of” language was construed as a broad disclaimer of propylene glycol, even though the patentee may have only intended to disclaim propylene glycol used in a particular way. To avoid a similar outcome, patentees should consider strategies for distinguishing prior art that are narrow and focused on the precise disclosures in the reference. Moreover, practitioners should endeavor to address any unintentional disclaimer before the relevant claims issue because it is unlikely to be corrected later.

*Azurity Pharms., Inc. v. Alkem Lab’s Ltd.*, No. 2023-1977 (Fed. Cir. Apr. 8, 2025)

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