IRWIN IP
INTELLECTUAL PROPERTY LITIGATION
IP CASE OF THE WEEK

"Consisting of" Consequences: Prosecution Disclaimers Outweigh Pretrial Stipulations

***Azurity Pharms., Inc. v. Alkem Labs., Ltd.*, No. 23-1977 (Fed. Cir. 2025)**

Authors: Lisa Holubar & Katie Schelli | Edited by: Jason Keener | April 15, 2025

The Federal Circuit recently opined on whether a stipulation in litigation can overcome a disclaimer made during the prosecution history of a patent. The Hatch-Waxman Act allows generic drug companies to use clinical results from brand-name drugs in the FDA approval process. In exchange, the brand-name drug companies get a short-term monopoly before the FDA approves any generics. Alkem filed an Abbreviated New Drug Application ("ANDA") with the FDA, and Azurity alleged the ANDA showed a generic drug that infringed its patent, U.S. Patent No. 10,959,948 (the "'948 Patent"). Alkem argued there was no infringement because its drug contained propylene glycol, which Azurity disclaimed during prosecution. The District Court ruled in favor of Alkem, and the Federal Circuit affirmed.

The '948 Patent claims a liquid formulation of vancomycin (oral antibiotics) "consisting of" a number of ingredients including a "flavoring agent." The '948 Patent is a continuation of U.S. Patent Application No. 15/126,059 (the "'059 Application"), which disclosed a similar liquid formulation of vancomycin. Although the '948 Patent was issued without rejection, the District Court and Federal Circuit relied heavily on the prosecution history of the '059 Application, which applies to the '948 Patent as a continuation. During that prosecution, the application was rejected four times over the prior art reference Palepu, which discloses a liquid formulation of vancomycin for intravenous use, and in relevant part, included "a polar solvent comprising propylene glycol…." Azurity's amendments and statements during prosecution of the '059 Application included remarks that "[t]he absence of propylene glycol and polyethylene glycol in the claimed invention, in part, distinguish it from [Palepu]." And notably, Azurity replaced "comprising" with "consisting of" in the preamble of the independent claims, which limited the scope of the patent to cover a liquid formulation having only the listed ingredients, and nothing else.

Azurity argued on appeal that even if there was a disclaimer, it did not apply to the "flavoring agent" limitations of the '059 Application and '948 Patent, only to the "carrier" claims. The Court disagreed and noted that "Azurity tried multiple routes to satisfy the examiner that unlike Palepu, its claimed invention lacked propylene glycol…. Azurity acquiesced by abandoning the 'carrier' distinction and adopting the 'consisting of' transition." Thus, the claims were allowed only because they excluded propylene glycol. Azurity also argued that a pretrial stipulation with Alkem stating "[s]uitable flavoring agents for use in the Asserted Claims include flavoring agents with or without propylene glycol" meant flavoring agents with propylene glycol could infringe the asserted claims, and that Alkem's stipulation surrendered any argument that propylene glycol was disclaimed. Alkem argued that the stipulated fact did not waive any argument; it merely confirmed a flavoring agent as known in the industry need not have propylene glycol. The Court agreed that Alkem's interpretation was consistent with the rest of the case whereas Azurity's interpretation conflicted with Alkem's noninfringement arguments and the structure of other stipulated facts.

The Federal Circuit noted the importance and binding nature of statements made during prosecution: holding a party to its statements protects the public and promotes the notice function of patents. Thus, patentees should be wary of sweeping statements made during prosecution when distinguishing over prior art, and must recognize that they cannot stipulate their way around such positions in the event they become engaged in adverse proceedings once their patent issues.