NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

AZURITY PHARMACEUTICALS, INC.,
Plaintiff-Appellant

v.

ALKEM LABORATORIES LTD.,
Defendant-Appellee

2023-1540

Appeal from the United States District Court for the District of Delaware in No. 1:19-cv-02100-MSG, Judge Mitchell S. Goldberg.

Decided: September 14, 2023

TUNG ON KONG, Wilson, Sonsini, Goodrich & Rosati, PC, San Francisco, CA, argued for plaintiff-appellant. Also represented by WENDY L. DEVINE, KRISTINA M. HANSON; KELSEY CURTIS, RICHARD TORCZON, Washington, DC.

TIMOTHY H. KRATZ, Kratz & Barry LLP, Atlanta, GA, argued for defendant-appellee. Also represented by GEORGE BARRY, III; MICHAEL PATRICK HOGAN, Philadelphia, PA; R. TOUHEY MYER, Wilmington, DE.

Before DYK, HUGHES, and STOLL, *Circuit Judges*.

DYK, *Circuit Judge*.

Azurity Pharmaceuticals, Inc. ("Azurity") appeals a decision of the United States district court for the District of Delaware determining that claims 16, 18, 22, 23, and 28 of U.S. Patent No. 10,786,482 and claims 4, 7, 17, and 18 of U.S. Patent No. 10,918,621 were invalid. We *affirm*.

BACKGROUND

The '482 and '621 patents claim liquid formulations of enalapril. Enalapril treats high blood pressure and has long been used in tablet form. Children and elderly patients can have difficulty swallowing tablets, making the liquid form a useful alternative. The difficulty with a liquid form is that enalapril degrades in water. The '482 and '621 patents aim to remedy this and claim a liquid formulation that "maintains about 95% w/w or greater of the initial enalapril amount at the end of a storage period of at least 12 months at about 5±3° C." '482 patent, col. 42 ll. 21–23.

Alkem Laboratories, Ltd. ("Alkem") submitted an Abbreviated New Drug Application ("ANDA"). Azurity brought suit claiming the ANDA infringed the '482 and '621 patents. The district court agreed that the ANDA infringed, and that determination is not challenged on appeal. However, the district court also found the '482 and '621 patents were invalid due to obviousness and insufficient written description. Azurity appeals.

DISCUSSION

"Obviousness is a mixed question of fact and law." *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1327 (Fed. Cir. 2017). The district court's legal conclusion of obviousness is subject to de novo review, while "subsidiary factual findings are reviewed for substantial evidence." *Id.* Substantial evidence is "such relevant evidence as a

reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

We see no legal error in the district court's obviousness determination and conclude that it was supported by substantial evidence. Because we affirm the district court's obviousness determination, we decline to reach the issue of written description.

AFFIRMED