INTENDIS GMBH v. GLENMARK PHARMACEUTICALS INC., USA, Appeal No. 15-1902 (Fed. Cir. May 16, 2016). Before Prost, Moore, Taranto. Appealed from D. Del. (Judge Robinson).

Background:

Glenmark Pharmaceuticals submitted an Abbreviated New Drug Application (ANDA) to the Food and Drug Administration (FDA) to market a generic version of Finacea® gel, a topical medication for various skin disorders. Finacea® gel includes azelaic acid as an active ingredient and triglyceride and lecithin as excipients. The proposed generic product substituted isopropyl myristate for the triglyceride and lecithin. The submission included a paragraph IV certification asserting that the patent listed as covering Finacea® gel is invalid and not infringed.

Intendis filed a complaint against Glenmark, asserting that Glenmark's ANDA submission infringed the patent covering Finacea® gel. The district court held that, even though the excipients were different, the patent was infringed under the doctrine of equivalents. Glenmark appealed.

Issue/Holding:

Did the district court err in finding infringement under the doctrine of equivalents? No, affirmed.

Discussion:

The Federal Circuit agreed with the district court that the isopropyl myristate in Glenmark's generic product met the claim elements, triglyceride and lecithin, under the doctrine of equivalents. In particular, using the function-way-result test, the district court first found that Glenmark's isopropyl myristate performed a substantially identical function as the claimed triglyceride and lecithin, namely enhancing azelaic acid's penetration of the skin.

The Federal Circuit opined that the district court properly reached this conclusion based on expert testimony and scientific literature that Glenmark's excipient and the claimed excipients act as penetration enhancers in substantially the same manner by disrupting the lipids in the skin's outermost layer, the stratum corneum. Additionally, Glenmark's composition containing isopropyl myristate achieved substantially the same result as the claimed composition containing triglyceride and lecithin, namely penetration of the stratum corneum to deliver the active agent, azelaic acid.

The Federal Circuit rejected Glenmark's argument that the patent's lack of disclosure regarding the function of lecithins or triglycerides as penetration enhancers was fatal to Intendis' infringement case. The Federal Circuit held that there is no requirement that a patent must disclose a claim element's function for the doctrine of equivalents to apply. Moreover, the Federal Circuit opined that, when the claims and specification are silent as to the function of a claim element, extrinsic evidence should be used to determine what the claim element's function in the claimed composition is to one of ordinary skill in the art. Furthermore, the Federal Circuit opined that Glenmark's own ANDA submission, which repeatedly stated that Glenmark's isopropyl myristate and the claimed triglyceride and lecithin all function as penetration enhancers, fatally undercut Glenmark's argument.