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Federal Circuit Patent Bulletin: *Intendis GmbH v. Glenmark Pharm. Ltd.*

May 16, 2016

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On May 16, 2016, in *Intendis GmbH v. Glenmark Pharm. Ltd.*, the U.S. Court of Appeals for the Federal Circuit (Prost, Moore,* Taranto) affirmed the district court's judgment that Glenmark's Abbreviated New Drug Application infringed U.S. Patent No. 6,534,070, which related to azelaic acid compositions marketed as Finacea® Gel, under the doctrine of equivalents. The Federal Circuit stated:

Even when an accused product does not meet each and every claim element literally, it may nevertheless be found to infringe the claim "if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." One way to show equivalence is by showing on an element-by-element basis that "the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product," often referred to as the function-way-result test. . . .

Glenmark's argument on appeal is limited to the district court's determination that Glenmark's isopropyl myristate performed substantially the same function as the claimed triglyceride and lecithin. . . . To be clear, we are not presented with the issue of the substantiality of the differences between the chemical structures of isopropyl myristate, triglyceride, and lecithin. This appeal is limited to whether the district court clearly erred when it determined that triglyceride and lecithin function as penetration enhancers in the claimed compounds. . . .

We see no clear error in the district court's finding of infringement under the doctrine of equivalents. As an initial matter, we disagree that the lack of disclosure of the claimed excipients as penetration enhancers in the '070 patent is fatal to Appellees' infringement case. We have never held that a patent must spell out a claim element's function, way, and result in order for the doctrine of equivalents to apply as to that element. . . . Glenmark is correct that the proper analysis focuses on the claimed element's function in the claimed composition, not a function that element could perform in the abstract divorced from the claimed composition. But Glenmark is wrong to the extent that it argues that a determination of the claimed element's function is limited to a review of the intrinsic record. The relevant inquiry is what the claim element's function in the

claimed composition is to one of skill in the art, and a fact finder may rely on extrinsic evidence in making this factual determination.

Glenmark argues that the district court erred in its determination that the claimed excipients function as penetration enhancers in light of the evidence of record. We see no clear error in this district court fact finding. Fatal to Glenmark's argument is its own ANDA submission to the FDA repeatedly referring to the claimed excipients (triglyceride and lecithin) as penetration enhancers. . . . Glenmark's repeated statements to the FDA that the claimed excipients function as penetration enhancers tend to show that one of skill in the art would understand the claimed excipients to function as penetration enhancers. We see no reason why a district court acting as a fact finder should ignore a party's representation to a federal regulatory body that is directly on point. Based on this record, the district court's finding regarding the function of the claimed excipients is not clearly erroneous. . . .

A patentee may not assert "a scope of equivalency that would encompass, or ensnare, the prior art." . . . In short, we ask if a hypothetical claim can be crafted, which contains both the literal claim scope and the accused device, without ensnaring the prior art. . . .

Glenmark argued that finding infringement under the doctrine of equivalents would ensnare a prior art reference entitled "In vitro permeation of azelaic acid from viscosized microemulsions" ("Gasco"), which disclosed a microemulsion containing azelaic acid as the active ingredient and DMSO as a penetration enhancer. The parties agreed that Gasco did not disclose isopropylmyristate, lecithin, or triglyceride. . . . Hypothetical claims extend the actual claim to literally recite the accused product. The district court adopted a proper hypothetical claim, one that includes triglycerides and lecithin or alternatively isopropyl myristate. It correctly rejected as too broad Glenmark's proposed hypothetical claim which would cover all penetration enhancers. The district court's infringement finding was that the excipient in Glenmark's product (isopropyl myristate) was equivalent to the claimed excipients (lecithin and triglycerides); it was not a finding that any penetration enhancer would be equivalent to the claimed excipients. . . .

[P]rosecution history estoppel limits the broad application of the doctrine of equivalents by barring an equivalents argument for subject matter relinquished when a patent claim is narrowed during prosecution. We have recognized that prosecution history estoppel can occur during prosecution in one of two ways, either (1) by making a narrowing amendment to the claim ("amendment-based estoppel") or (2) by surrendering claim scope through argument to the patent examiner ("argument-based estoppel"). . . . There are some cases, however, where the amendment cannot reasonably be viewed as surrendering a particular equivalent. The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. In those cases the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence. . . .

The district court correctly determined that prosecution history estoppel did not preclude the capture of Glenmark's lecithin-free composition as an equivalent. Argument-based estoppel only applies when the prosecution history "evince[s] a clear and unmistakable surrender of subject matter." Applicants' clarifying statement, "Since the dependent claims must limit the independent claims, the meaning is clear that zero amounts are not included," did not clearly and unmistakably disavow claim scope to distinguish prior art. Amendment-based estoppel does not apply because the amendment was not a narrowing amendment made to obtain the patent.