United States Court of Appeals for the Federal Circuit

INTENDIS GMBH, INTRASERV GMBH & CO. KG, BAYER HEALTHCARE PHARMACEUTICALS INC.,
Plaintiffs-Appellees

v.

GLENMARK PHARMACEUTICALS INC., USA, GLENMARK PHARMACEUTICALS LTD.,
Defendants-Appellants

2015-1902

Appeal from the United States District Court for the District of Delaware in No. 1:13-cv-00421-SLR, Judge Sue L. Robinson.

Decided: May 16, 2016

BRADFORD J. BADKE, Sidley Austin LLP, New York, NY, argued for plaintiffs-appellees. Also represented by SONA DE.

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, argued for defendants-appellants. Also represented by BRIAN TIMOTHY BURGESS; ELIZABETH HOLLAND, LINNEA P. CIPRIANO, HUIYA WU, New York, NY; DAVID ZIMMER, San Francisco, CA.

Before PROST, *Chief Judge,* MOORE and TARANTO, *Circuit Judges.*

MOORE, *Circuit Judge.*

This case arises under the Hatch–Waxman Act,[1] and involves Glenmark Pharmaceuticals Ltd. and Glenmark Pharmaceuticals Inc., USA's (collectively, "Glenmark")[2] proposed generic version of Finacea® Gel, a topical medication for various skin disorders. Glenmark appeals the United States District Court for the District of Delaware's final judgment entered in favor of Intendis GmbH, Intraserv GmbH & Co. KG, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Appellees"). For the reasons set forth below, we affirm.

BACKGROUND

Appellee Bayer HealthCare Pharmaceuticals Inc. holds approved New Drug Application ("NDA") No. 21470 for Finacea® Gel, which contains azelaic acid as the therapeutically active ingredient in a concentration of 15% by weight and is indicated for the topical treatment of inflammatory papules and pustules of mild to moderate rosacea. Finacea® Gel's inactive ingredients, known as excipients, include triglycerides and lecithin. Finacea® Gel is manufactured in the form of a "hydrogel," which the

---

[1] The Hatch–Waxman Act is the name commonly used to refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified in relevant part at 21 U.S.C. § 355), as amended, which governs the Food and Drug Administration's approval of new and generic drugs.

[2] Glenmark Pharmaceuticals Ltd. and Glenmark Pharmaceuticals Inc., USA were formerly known as Glenmark Generics Ltd. and Glenmark Generics Inc., USA, respectively.

district court construed to mean "a semisolid dosage form that contains water and a gelling agent to form a gel, which may contain dispersed particles and/or insoluble liquids." *Intendis GmbH v. Glenmark Pharm. Ltd.*, 117 F. Supp. 3d 549, 567–68 (D. Del. 2015).

The Food and Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluation, commonly known as the Orange Book, lists U.S. Patent No. 6,534,070 ("the '070 patent") as covering Finacea® Gel. The '070 patent, entitled "Composition with Azelaic Acid," is assigned to Appellee Intraserv GmbH & Co. and exclusively licensed to Appellee Intendis GmbH. The patent issued in March 2003 and claims priority to a provisional application filed on February 12, 1998. Sole independent claim 1 of the '070 patent recites:

> 1. A composition that comprises:
>
> (i) azelaic acid as a therapeutically active ingredient in a concentration of 5 to 20% by weight,
>
> (iii) at least one *triacylglyceride*[3] in a concentration of 0.5 to 5% by weight,
>
> (iv) propylene glycol, and
>
> (v) at least one polysorbate, in an aqueous phase that further comprises water and salts, and the composition further comprises
>
> (ii) at least one polyacrylic acid, and
>
> (vi) *lecithin*,

---

[3] The parties agree that the claim term "triacylglyceride" means "triglyceride."

> wherein the composition is in the form of a hydrogel.

'070 patent, col. 6, lines 28–39 (emphases added).

Glenmark Pharmaceuticals Ltd. submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking to market a generic version of Finacea® Gel. The submission included a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '070 patent is invalid and not infringed. Unlike Finacea® Gel, the proposed generic product substituted isopropyl myristate for the claimed triglyceride and lecithin. Pursuant to 21 U.S.C. § 505(j)(2)(B)(ii), Glenmark Pharmaceuticals Inc., USA informed Appellees that an ANDA had been filed. In response, Appellees filed a complaint against Glenmark in the United States District Court for the District of Delaware, alleging that Glenmark's submission of the ANDA infringed the '070 patent under 35 U.S.C. § 271(e)(2)(A).

The district court held a Markman hearing on January 21, 2015, and a five-day bench trial from February 5–11, 2015 on the issues of infringement and validity. On July 27, 2015, the district court issued an opinion concluding that claims 1–12 of the '070 patent were infringed under the doctrine of equivalents and not invalid.

With respect to infringement, the central dispute was whether isopropyl myristate in Glenmark's generic product met the claim elements triglyceride and lecithin under the doctrine of equivalents. The district court found that it did, relying on the function-way-result test. The district court rejected Glenmark's arguments that infringement under the doctrine of equivalents (i) would encompass the prior art and (ii) was barred by prosecution history estoppel.

With respect to validity, the district court found that none of the prior art references raised by Glenmark

disclosed every element of independent claim 1 and rejected Glenmark's argument that the claims would have been obvious. Prior to Finacea® Gel, Bayer marketed and sold a topical 20% azelaic acid cream known as Skinoren®, which is prior art to the '070 patent. The district court agreed with Glenmark that a person of ordinary skill in the art would pursue a hydrogel formulation of azelaic acid because the Skinoren® formulation had undesirable qualities such as phase separation of the emulsion, whitening effect, and spreadability problems. However, the district court determined that Glenmark failed to show by clear and convincing evidence that a person of ordinary skill would have been motivated to combine the prior art references in a manner that would render claim 1 of the '070 patent obvious. It determined that even if Glenmark had, Glenmark failed to show a reasonable expectation of success in making such combination. Finally, the district court found that the objective indicia of nonobviousness, namely, unexpected results of the claimed formulations and commercial success of Finacea® Gel, weighed in favor of nonobviousness.

On August 14, 2015, the district court entered a final judgment in favor of Appellees and directed the FDA not to approve Glenmark's ANDA until after the November 18, 2018, expiration of the '070 patent. This appeal followed.

DISCUSSION

On appeal, Glenmark argues that (i) the district court erred in its application of the function prong of the function-way-result test for infringement under the doctrine of equivalents, (ii) infringement under the doctrine of equivalents would encompass the prior art, (iii) Appellees expressly disavowed and disclaimed a formulation without lecithin, and (iv) the district court erred in its obviousness analysis. We address each argument in turn.

I. Infringement Under the Doctrine of Equivalents

Infringement under the doctrine of equivalents is a question of fact that we review for clear error following a bench trial. *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1311 (Fed. Cir. 2015). 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." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950)). 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. *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1312 (Fed. Cir. 2009). Each prong of the function-way-result test is a factual determination. In this case, neither party objects to employing the function-way-result test as a means to determine equivalency of these chemical compounds.

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. We review the district court's determination that they perform substantially the same function, a question of fact, for clear error. *Biovail Corp. Int'l v. Andrx Pharm., Inc.*, 239 F.3d 1297, 1300 (Fed. Cir. 2001). 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.

Glenmark's non-infringement argument was based on the claim elements triglyceride and lecithin (collectively, "claimed excipients"), which are recited in the sole independent claim 1. Even though Glenmark's generic product did not physically contain triglyceride or lecithin, the district court found that the claimed excipients were met under the doctrine of equivalents. First, the court found that isopropyl myristate in Glenmark's generic product ("Glenmark's excipient") performs substantially the same function as the claimed excipients—namely, enhancing azelaic acid's penetration of the skin. It reasoned that several experts testified that the claimed excipients could act as penetration enhancers and that "nothing in the record" indicated they could not. It also reasoned that Glenmark's ANDA included repeated statements that both Glenmark's excipient and the claimed excipients function as penetration enhancers. It noted that Glenmark "should not be permitted to liken their product to the claimed composition to support their bid for FDA approval, yet avoid the consequences of such a comparison for purposes of infringement." *Intendis*, 117 F. Supp. 3d at 573. Second, the court found that Glenmark's excipient performed in substantially the same way as the claimed excipients—namely, by disrupting the lipids in the skin's outermost layer, known as the stratum corneum. It based its finding on testimony by various experts, as supported by scientific literature. Third, the court found that Glenmark's excipient obtained substantially the same result as the claimed excipients—namely, a therapeutically effective azelaic acid composition that is able to penetrate the skin in order to deliver the active ingredient. It relied on data from the '070 patent, Glenmark's own patent application, a skin penetration study, and a clinical trial.

On appeal, Glenmark argues that the district court erred in its finding regarding the function prong because Appellees failed to prove that the claimed excipients function as penetration enhancers in the claimed composi-

tion. It argues that "[t]he '070 patent itself is silent on the question of whether lecithins or triglycerides function as penetration enhancers." *Intendis*, 117 F. Supp. 3d at 572. According to Glenmark, this absence of support in the patent itself for the notion that the claimed excipients function as penetration enhancers is fatal to Appellees' infringement case. Glenmark argues that Appellees' theory is also contradicted by evidence outside the patent. It points to Appellees' FDA filings and development reports as such examples, which identified the claimed lecithin and triglyceride as an emulsifier and an emollient, respectively. It argues that not a single literature reference in evidence identified lecithin or triglyceride as a penetration enhancer, and Appellees' expert testimony was rejected by the district court. According to Glenmark, the district court justified its finding that the claimed excipients function as penetration enhancers on the basis that the evidence did not exclude that possibility, despite the lack of any affirmative evidence.

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. To the contrary, we have held that "[w]hen the claims and specification of a patent are silent as to the result of a claim limitation, . . . we should turn to the ordinary skilled artisan." *Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1365 (Fed. Cir. 2007).

Certainly, a patent's disclosure is relevant and can at times be dispositive of the function. 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. *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1425 (Fed. Cir. 1994).

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. For example, Glenmark stated in its filing to the FDA that "[i]sopropyl myristate was selected as [a] penetration enhancer instead of lecithin and medium chain triglyceride" under the heading "Selection of penetration enhancer." J.A. 5865. 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.

In a strange turn of events, Glenmark argued at oral argument to this court that its statements in its FDA submissions about the claimed excipients (triglyceride and lecithin) functioning as penetration enhancers should be rejected and cannot be evidence to support the district court's finding. It argued that "lecithin and triglycerides are not known to the art as penetration enhancers" and

that its representation to the FDA that they do function as penetration enhancers was a "guess" and "wrong." Oral Argument at 10:49–13:38, *Intendis GmbH v. Glenmark Pharm. Inc.*, No. 2015-1902 (Fed. Cir. Jan. 8, 2016), *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-1902.mp3. These seemingly extemporaneous arguments do not persuade us that there is clear error in the district court's decision that isopropyl myristate in Glenmark's generic product and the claimed triglyceride and lecithin perform substantially the same function. No such arguments were made by Glenmark in any of its briefing to this court. And when asked whether Glenmark had notified the FDA of these purported inaccurate representations to the FDA, Glenmark's counsel was unaware of such notification. *Id.* at 11:53–12:25.

The district court did not clearly err in its findings regarding the doctrine of equivalents.

II. Encompassing the Prior Art

A patentee may not assert "a scope of equivalency that would encompass, or ensnare, the prior art." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1322 (Fed. Cir. 2009) (quotation marks omitted). Even if an accused element meets the function-way-result test, no equivalent will be found if the scope of equivalency would capture the prior art. Hypothetical claim analysis is a practical method to determine whether an equivalent would impermissibly ensnare the prior art. *See Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1364 (Fed. Cir. 2000). Hypothetical claim analysis is a two-step process. The first step is "to construct a hypothetical claim that literally covers the accused device." *DePuy Spine*, 567 F.3d at 1324. Next, prior art introduced by the accused infringer is assessed to "determine whether the patentee has carried its burden of persuading the court that the hypothetical claim is patentable over the prior art." *Id.* at 1325. 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. We review a district court's conclusion that a hypothetical claim does not encompass the prior art de novo and resolution of underlying factual issues for clear error. *Id.* at 1324.

The district court determined that a proper hypothetical claim included the claimed excipients and Glenmark's excipient, namely, the hypothetical claim includes isopropyl myristate as an alternative to the claimed triglyceride and lecithin. 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 isopropyl myristate, lecithin, or triglyceride. The district court determined that the hypothetical claim was not anticipated or rendered obvious by Gasco, and rejected Glenmark's argument that finding infringement under the doctrine of equivalents would ensnare Gasco. It reasoned, based on expert testimony, that a skilled artisan (i) would not necessarily have substituted the hypothetical claim excipient (isopropyl myristate or lecithin and triglyceride) for Gasco's DMSO, and (ii) would not have had a reasonable expectation of success in doing so.

Glenmark argues that the district court erred in determining that the doctrine of equivalents was not precluded by ensnarement. It argues that the district court's hypothetical claim was "inexplicably narrower" than Appellees' range of equivalents. It argues that a proper hypothetical claim should have matched Appellees' theory of infringement and thus included *any penetration enhancer*. It argues that a proper hypothetical claim would have been anticipated by or obvious over the prior art and thus the doctrine of equivalents should be precluded.

We agree with the district court's determination that its infringement finding under the doctrine of equivalents did not impermissibly read on the prior art. 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. *See Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950) ("What constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case. . . . In determining equivalents, things equal to the same thing may not be equal to each other and, by the same token, things for most purposes different may sometimes be equivalents."). The district court properly rejected Glenmark's argument that the hypothetical claim must be constructed to capture all penetration enhancers. Glenmark does not challenge the district court's determination that the hypothetical claim as constructed would have been patentable. Thus, we see no reversible error in the district court's conclusion that Gasco does not bar the application of the doctrine of equivalents to find Glenmark's generic version to infringe the asserted claims.

III. Prosecution History Estoppel

We have summarized the doctrine of prosecution history estoppel as follows:

> [P]rosecution history estoppel limits the broad application of the doctrine of equivalents by barring an equivalents argument for subject matter relin-

> quished 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").

Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1363 (Fed. Cir. 2006) (citations omitted). With respect to the amendment-based estoppel, the Supreme Court has explained:

> A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim. 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.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722, 740–41 (2002). We review de novo issues relating to the application of prosecution history estoppel. *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1375 (Fed. Cir. 2007).

The district court rejected Glenmark's argument that the '070 patent applicants surrendered a lecithin-free composition (e.g., Glenmark's proposed generic product)

as an equivalent during prosecution. During prosecution, the examiner noted that two dependent claims, which recited a lecithin "concentration of up to 1%" and "concentration of up to 3%," respectively, could include zero lecithin. Applicants responded that those range limitations clearly did not include zero because they "are only in claims dependent on independent claims, which clearly require [lecithin]." J.A. 4386–87 (noting that the examiner's argument "is not well taken."). Regardless, applicants amended the two dependent claims to recite a lecithin "concentration of from more than 0 to 1%" and "concentration of from more than 0 to 3%," respectively, noting that they were "amended to expressly state what has already been made clear on the record." The district court determined that "taken in context," the amendments were for clarification purposes, "not to disclaim formulations with zero lecithin." It noted that Glenmark did not dispute that independent claim 1 always required lecithin, and consequently, both dependent claims also always required lecithin.

Glenmark argues that the district court erred in determining that prosecution history estoppel did not apply to bar the doctrine of equivalents. It argues that applicants expressly disavowed and disclaimed formulations without lecithin.

We see no error in the district court's analysis. 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." *Deering Precision Instruments, LLC v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1326 (Fed. Cir. 2003) (citation and punctuation omitted). Applicants' clarifying statement, "Since the dependent claims must limit the independent claims, the meaning is clear that zero amounts are not included," J.A. 4387, 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. Rather, this record demonstrates that the amendment to the dependent claims was a clarifying amendment. As dependent claims can never be broader than the independent claim from which they depend, the dependent claims as originally written could not have included 0% lecithin. The amendment was, as the comments themselves make clear, a clarifying amendment and it does not give rise to prosecution history estoppel. We see no error in the district court's determination that prosecution history estoppel does not apply.

IV. Obviousness

The district court determined that the asserted claims would not have been obvious over the previously-marketed Skinoren® cream in combination with (i) references disclosing formulations containing the claimed excipients ("non-azelaic acid art"), and (ii) references disclosing formulations containing azelaic acid ("azelaic acid art").[4] Skinoren® cream contained 20% azelaic acid and was marketed for skin conditions. The district court found that Skinoren®'s formulation had certain undesirable qualities, and that a skilled artisan would consider developing an alternative to Skinoren® in a different dosage form given the market forces and the deficiencies of Skinoren®. It also found that a skilled artisan would have been motivated to pursue a hydrogel formulation of azelaic acid based on Maru, one of the pieces of azelaic acid art, which the district court found to

---

[4] The non-azelaic acid art was PCT Application Pub. Nos. WO 93/18752 and WO 95/05163. The azelaic acid art was articles by Maru, Gasco, and Pattarino; U.S. Patent No. 5,385,943; and PCT Application Pub. No. WO 93/39119.

disclose a hydrogel formulation containing azelaic acid. It found, however, that the record did not show that the artisan would have been motivated to use the claimed excipients (triglyceride and lecithin). It noted that Glenmark's only support to combine Maru with either of the two references that disclose the claimed excipients was the testimony by Glenmark's expert that a skilled artisan "could have put . . . information together from another two publications" to render claim 1 obvious. It reasoned that this cursory statement was insufficient to meet Glenmark's burden of showing by clear and convincing evidence a motivation to combine Maru with other prior art to render the claims obvious. It also found that even if Glenmark had presented evidence to show motivation to combine, Glenmark failed to carry its burden to demonstrate a reasonable expectation of success in making the combination. It found—based on fact and expert testimony—that "swapping ingredients in complex chemical formulations is anything but 'routine.'" J.A. 65. It wrote that Glenmark did not present testimony or other evidence regarding an expectation of success. It also determined that the objective indicia of unexpected results and commercial success supported its conclusion of nonobviousness.

Glenmark argues that the district court erred in concluding that the asserted claims would not have been obvious. It argues that a skilled artisan would have known how to "successfully" combine the non-azelaic acid art with the azelaic acid art. It argues that the objective indicia do not overcome its "strong" prima facie case of obviousness. According to Glenmark, the district court erred in finding that the claimed compositions demonstrated unexpected results. It also argues Appellees' "equivocal" evidence concerning commercial success does not support the district court's nonobviousness conclusion.

The district court correctly concluded that the asserted claims would not have been obvious. We discern no

clear error in the district court's finding that a skilled artisan would not have been motivated to combine the prior art or in finding no reasonable expectation of success based on the evidence of record. Moreover, we see no clear error in the district court's findings with respect to objective indicia of nonobviousness.

CONCLUSION

The district court did a commendable job in rendering its detailed and thorough opinion. Because we see no reversible error in the district court's decision that Glenmark's generic product infringed the asserted claims and that the asserted claims are not invalid, the district court's judgment is affirmed.

AFFIRMED

COSTS

Costs to the Appellees.