Glaxo Group Limited v. Torpharm Inc.

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Appealed from: United States District Court for the Northern District of Illinois

Judge William T. Hart

97-1556 GLAXO INC. and GLAXO GROUP LIMITED, Plaintiffs-Appellants, v. TORPHARM, INC., APOTEX USA, INC., AND APOTEX INC., Defendants-Appellees.

This is yet another appeal in the ongoing litigation between the holder of patents on a popular medication, Zantac(TM), and a number of generic drug companies who are attempting to sell a generic equivalent of the drug. The original United States patent held by plaintiffs, Glaxo, Inc. and Glaxo Group Limited ("Glaxo"), No. 4,128,658 ("the `658 patent") covering one form of the active ingredient, expired on July 25, 1997. Nevertheless, Glaxo continues to seek to prevent other drug companies from manufacturing and selling a generic version based on two of Glaxo's other United States Patents (Nos. 4,521,431 ("the `431 patent") and 4,672,133 ("the `133 patent")) covering a second form of the active ingredient. In this case, the district court essentially concluded that Glaxo is impermissibly attempting to extend the term of its now expired `658 patent, and granted the defendants, TorPharm, Inc., Apotex USA, Inc., and Apotex Inc. (collectively "TorPharm"), summary judgment of non-infringement of the `431 and `133 patents.

After careful consideration, we conclude that the district court erred in concluding that the defendants were practicing Example 32 of Glaxo's expired `658 patent; and thus the court's resulting Conclusion that the defendants are practicing subject matter that was dedicated to the public upon expiration of the `658 patent is not sustainable. Although the defendants-appellees advance several alternative grounds to affirm, none of them will bear the weight placed on them. We are compelled to vacate and remand this case for further proceedings.

BACKGROUND

Glaxo manufactures and sells the highly successful anti-ulcer medication Zantac(TM). The active ingredient in Zantac(TM) is ranitidine hydrochloride (RHCl), an aminoalkyl furan derivative that can occur in at least two distinct crystalline forms. Glaxo's `658 patent, issued in 1978, claimed the class of aminoalkyl furan derivatives having the desired histamine-blocking activity, and specifically claimed RHCl, the lead compound of the class. At the time the patent application was filed, Glaxo did not know that RHCl could occur in more than one crystalline form. Later, Glaxo determined that the form of RHCl obtained by practicing the `658 patent is a polymorph known as "Form 1." The

`658 patent covering Form 1 expired on July 25, 1997.

In 1980, a new crystalline polymorph of RHCl called "Form 2" was discovered by Glaxo scientists. Form 2 exhibits two distinct advantages over Form 1. Form 2 can be prepared and isolated using concentrated hydrochloric acid instead of hydrogen chloride gas, which was required to produce Form 1. Secondly, Form 2 possesses better drying and filtration characteristics. Both of these advantages make Form 2 easier to manufacture. The physical properties of the Form 2 polymorph provide such advantages that all of Glaxo's Zantac(TM) product sold since 1981 has contained Form 2 RHCl.

Glaxo obtained two patents on Form 2: the `431 patent covering the RHCl crystallized as the Form 2 polymorph per se, and the `133 patent covering specific processes for synthesizing Form 2 RHCl. The claims in both of these patents characterize Form 2 RHCl by means of an infra-red ("IR") spectrum having 29 identifiable main peaks. The `431 patent includes a second, dependent claim describing the x-ray powder diffraction pattern of Form 2 RHCl. The `431 patent covering Form 2 will expire in 2002, and the `133 patent covering the process for making Form 2 will expire in 2004. It is these two Form 2 patents that are the subject of the present suit.

This is not the first time Glaxo has appeared before this court defending its patents related to RHCl. In Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 34 USPQ2d 1565 (Fed. Cir. 1995) ("Novopharm I"), this court affirmed the judgment of the United States District Court for the Eastern District of North Carolina that the claims of the `431 patent were not anticipated by the `658 patent. (For purposes of that litigation the parties had stipulated to infringement by the accused product.) In Glaxo, Inc. v. Novopharm Ltd., 110 F.3d 1562, 42 USPQ2d 1257 (Fed. Cir. 1997) ("Novopharm II"), we affirmed a judgment of the district court that the `431 patent was not infringed by a different Novopharm product.

Even though we affirmed the district court's judgment in Novopharm II, we disagreed with its claim construction. The district court interpreted the claims of the `431 and `133 patents to be limited to "pure Form 2 RHCl." Id. at 1565, 42 USPQ2d at 1260. We held that the claims were not so limited. See id. at 1565-66, 42 USPQ2d at 1260. The constructional issue was not determinative, however, in light of Glaxo's failure to put forward sufficient evidence to prove infringement. See id. at 1566-67, 42 USPQ2d at 1260-61. We explicitly declined to address the question of whether small amounts of Form 2 RHCl in a mixture containing primarily Form 1 RHCl could infringe the `431 patent. See id. at 1566 n.1, 42 USPQ2d at 1260 n.1.

TorPharm filed an abbreviated new drug application ("ANDA") with the U.S. Food & Drug Administration ("FDA") on June 5, 1995, seeking approval to market a generic version of an anti-ulcer medication containing Form 1 RHCl after the `658 patent expired. On August 14, 1995, Glaxo sued TorPharm in the Northern District of Illinois, essentially alleging under 35 U.S.C. § 271(e) that TorPharm's Form 1 RHCl product contains a small amount of Form 2 and, therefore, is

infringing. Glaxo also sought a declaratory judgment that TorPharm infringes the `133 process patent by manufacturing and selling the drug for which TorPharm was seeking approval.

TorPharm filed a motion for summary judgment of non-infringement of the `431 patent. [1] In a memorandum opinion and order dated May 18, 1997, the district court granted-in-part and denied-in-part TorPharm's summary judgment motion. See Glaxo, Inc. v. TorPharm, Inc., 1997 WL 282742, *8 (N.D. Ill. May 18, 1997). The court granted TorPharm's motion for summary judgment of non-infringement of claim 2 of Glaxo's `431 patent on the ground that Glaxo failed to produce evidence that TorPharm's product would exhibit the x-ray diffraction pattern contained in claim 2. In addition, the court, citing Novopharm II, concluded that an expert declaration proffered by Glaxo failed to raise a genuine issue of material fact because the expert failed to use the "Debye Scherrer method" to prove infringement, as required by claim 2.

However, the district court denied TorPharm's motion for summary judgment as to claim 1 holding that the testimony of Glaxo's expert created a triable issue of fact as to whether TorPharm's product demonstrated all 29 main IR peaks. See 1997 WL 282742 at *7. TorPharm's motion for summary judgment as to Glaxo's declaratory judgment action was also denied on the grounds that Glaxo had presented some evidence of infringement by TorPharm's product. Finally, the district court ordered the parties to brief the question left open in Novopharm II, i.e., whether a 0.5% level of Form 2 RHCl in a mixture consisting otherwise of Form 1 RHCl constitutes infringement of the `431 patent. See id. at *8. The holdings in the May 18 opinion are not on appeal.

After the parties had briefed the issue of whether a small amount of Form 2 is infringing, the district court subsequently issued a memorandum opinion and order, granting TorPharm's motion for summary judgment of non-infringement of the `431 patent. See Glaxo, Inc. v. TorPharm, Inc., 1997 WL 535090, *8 (N.D. Ill. Aug. 22, 1997). However, the court did not do so based on the so-called de minimis exception. See, e.g., Spray Refrigeration Co. v. Sea Spray Fishing, Inc., 322 F.2d 34, 36 (9th Cir. 1963). The court concluded that Glaxo was correct in asserting that the de minimis exception has no application to the case at hand. Glaxo, 1997 WL 535090 at *4.

Nonetheless, the district court held that summary judgment was in order. In reaching its Conclusion on infringement, after considering all the evidence put before it, the district court found that TorPharm was attempting to practice Example 32 of the `658 patent to produce Form 1 RHCl. Id. at *8. Because Example 32 was dedicated to the public upon expiration of the `658 patent, according to the court, TorPharm's product could not infringe the Form 2 patents without violating the rule against double patenting. The court also construed the asserted claims of the Form 2 patents in light of the prosecution history, again to avoid double patenting problems, to require that an accused product exhibit improved drying and filtration characteristics in order to infringe. In the district court's view, because TorPharm's product did not possess those improved characteristics, it did not infringe. Glaxo appeals the summary judgment of non-infringement. This court has jurisdiction over Glaxo's appeal pursuant to 28 U.S.C. § 1295(a)(1) (1994).

Discussion

We review the grant of summary judgment of non-infringement without deference to the district court. See Winner Int'l Corp. v. Wolo Mfg. Corp., 905 F.2d 375, 376, 15 USPQ2d 1076, 1077 (Fed. Cir. 1990). Accordingly, we apply anew the summary judgment standard set forth in Rule 56(c) of the Federal Rules of Civil Procedure. Under that standard, summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); see Winner, 905 F.2d at 376, 15 USPQ2d at 1077. Under this standard, all reasonable inferences must be drawn and all factual disputes resolved in favor of the non-movant, see Lane Bryant, Inc. v. United States, 35 F.3d 1570, 1574 (Fed. Cir. 1994), who in this case is Glaxo. A dispute is genuine if a reasonable jury could return a verdict in favor of the non-movant. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 2510 (1986); Robotic Vision Sys., Inc. v. View Eng'g, Inc., 112 F.3d 1163, 1165, 42 USPQ2d 1619, 1621 (Fed. Cir. 1997); Lifescan, Inc. v. Home Diagnostics, Inc., 76 F.3d 358, 362, 37 USPQ2d 1595, 1599 (Fed. Cir. 1996). We must reverse a summary judgment if any errors of law were made, see Quad Envtl. Tech. Corp. v. Union Sanitary Dist., 946 F.2d 870, 872, 20 USPQ2d 1392, 1396 (Fed. Cir. 1991), unless an independent legal ground exists in the record upon which we can affirm, see Fireman's Fund Ins. Co. v. United States, 909 F.2d 495, 499 (Fed. Cir. 1990).

I.

Glaxo claims that at least two fundamental errors were made by the district court in granting summary judgment. First, Glaxo argues that the court's factual predicate-that TorPharm is practicing Example 32-is clearly erroneous. Second, Glaxo argues that the court's legal assumption-that TorPharm is free to practice the subject matter of an expired patent, regardless of the existence of any other patent, is an erroneous interpretation of the law.

On appeal, TorPharm does not make much of an effort to support the district court's reasoning. Instead, it devotes the majority of its brief urging us to adopt one of several alternative grounds on which to affirm-even though those grounds were not adopted by the district court.

Although TorPharm has abandoned the district court's ratio decidendi, we must nonetheless consider the court's Conclusions and analysis in order to determine whether any errors of law or fact were made. The linchpin of the district court's analysis is its Conclusion that TorPharm was practicing Example 32 of the `658 patent. On appeal, TorPharm effectively concedes that the evidence does not support that conclusion. TorPharm's president testified that he had no specific knowledge about the process employed by its supplier, Signa S.A., to manufacture RHCl for TorPharm. He did admit, however, that the process used by Signa is set forth in U.S. and Canadian patents assigned to ACIC (Canada) Inc. Those patents admittedly disclose a process that is significantly different from the process disclosed in Example 32 of the `658 patent. Because, at the

very least, a reasonable jury could find that TorPharm is not practicing Example 32 of the `658 patent, the summary judgment must be vacated. See Robotic Vision, 112 F.3d at 1165, 42 USPQ2d at 1621; Lifescan, 76 F.3d at 362, 37 USPQ2d at 1599.

Glaxo also asserts that the district court erred as a matter of law when it concluded that after the expiration of the `658 patent TorPharm could practice the subject matter of the patent. Because we have concluded that the summary judgment cannot stand due to clear errors of fact, we need not and do not reach this issue.

II.

TorPharm advances several grounds upon which it argues we can affirm, despite the fact that the district court did not rely upon or adopt them. Glaxo argues that we should not entertain these arguments because they were rejected by the district court. Considering these issues, according to Glaxo, would in effect amount to an impermissible interlocutory review of the denial of a summary judgment. Not content to rely on its procedural argument, Glaxo also engages the issues on the merits.

As a general proposition, an appellate court may affirm a judgment of a district court on any ground the law and the record will support so long as that ground would not expand the relief granted. See A- Transport Northwest Co. v. United States, 36 F.3d 1576, 1580 n.7 (Fed. Cir. 1994); Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555, 1561- 62, 31 USPQ2d 1161, 1165 (Fed. Cir. 1994); Fireman's Fund, 909 F.2d at 499; see also 19 George C. Pratt, Moore's Federal Practice § 205.04[2], at 205-45 (3d ed. 1998); 15A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 3904, at 199-203 (2d ed. 1992).

If the grounds urged in support of the judgment have not been presented to and passed upon by the trial court, an appellate court may prefer not to address them in the first instance. See Fireman's Fund, 909 F.2d at 499 (citing Granfinanciera, S.A. v. Nordberg, 492 U.S. 33, 38-39 (1989)). If, however, the ground urged is one of law, and that issue has been fully vetted by the parties on appeal, an appellate court may choose to decide the issue even if not passed on by the trial court. See id.; Wright & Miller, supra, § 3904, at 199-203.

When a matter comes before an appellate court following a summary judgment, the appellate court is free to adopt a ground advanced by the appellee in seeking summary judgment but not adopted by the trial court. See Hester Indus., Inc. v. Stein, Inc., 142 F.3d 1472, 1480, 46 USPQ2d 1641, 1648-49 (Fed. Cir. 1998) (affirming summary judgment of invalidity on ground advanced by defendant in summary judgment motion but not adopted by district court); Boli v. United States, 831 F.2d 276, 278 (Fed. Cir. 1987) (affirming summary judgment on statutory grounds advanced by appellee before the trial court even though that court rested its decision on constitutional grounds). This appears to be the law of our sister circuits as well. See, e.g., Degan v. Ford Motor Co., 869 F.2d 889, 892 (5th Cir.

1989) ("[S]ummary judgment may be affirmed, regardless of the correctness of the district court's rulings, when we find in the record an adequate, independent basis for that result."); Schuster v. Martin, 861 F.2d 1369, 1371 (5th Cir.1988); Rueckert v. Internal Revenue Serv., 775 F.2d 208, 212 (7th Cir. 1985) ("An appellate court may affirm a grant of summary judgment if the judgment or order is correct, although the reasons given by the trial court are erroneous."); Davis v. United States, 589 F.2d 446, 448 n.3 (9th Cir. 1979) ("Even if we disagree with the district Judge's reasoning, we may nevertheless affirm his Disposition `on any ground squarely presented on the record.'" (quoting Grosz v. Andrus, 556 F.2d 972, 974 n.3 (9th Cir. 1977))).

Such an approach does not convert an argument advanced by one of the parties into an impermissible interlocutory appeal of the denial of a summary judgment. For our purposes, the judgment on review is a "final judgment;" otherwise, we would not have jurisdiction. Compare 28 U.S.C. § 1295(a)(1) (1994) with 28 U.S.C. § 1292 (1994). The cases cited by Glaxo are not to the contrary. [2] Those cases simply stand for the unremarkable proposition that a naked denial of a summary judgment is not immediately appealable. They do not address the much different issue found here, of whether an appellee may advance a ground presented to the district court, but not adopted, to support that court's judgment on appeal. Rejecting Glaxo's meritless procedural diversion, we consider each of TorPharm's alternative grounds for affirmance.

III.

TorPharm argues that we can affirm the summary judgment of non- infringement based on Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 30 USPQ2d 1285 (Fed. Cir. 1994). That case, like the present one, involved a patent claiming a chemical compound-a new crystalline form of cefadroxil. The patent claim at issue there also claimed the compound according to its spectral characteristics, although using a different method (x-ray versus IR). The patentee conceded that the accused compound did not literally infringe the asserted claim in its pre-ingested form. Nonetheless, the patentee argued that the accused compound converted into the patented compound during ingestion. See id. at 1420, 30 USPQ2d at 1287.

The problem for the patentee, however, was that it could not sample and test the accused compound once it was ingested. See id. at 1422, 30 USPQ2d at 1288. In order to overcome this problem, the patentee had its expert perform a surrogate test. In that test, the expert simulated the in vivo conditions of a patient's stomach. The expert then compared the x-ray diffraction pattern of the accused compound under those conditions with the x-ray diffraction pattern of a sample of the patentee's commercial embodiment of the patented compound. See id. at 1423, 30 USPQ2d at 1289. Using this methodology, the expert confirmed that the accused compound exhibited 22 of the 30 lines exhibited by the patentee's commercial embodiment. See id. at 1424, 30 USPQ2d at 1289. The district court found this proof adequate to establish literal infringement. The defendant appealed, and we reversed.

We concluded that the patentee's proof was inadequate in two principal ways. See id. at 1424, 30 USPQ2d at 1289-90. First, the trial court impermissibly permitted the patentee to compare the accused device to a commercial embodiment of the invention. See id. at 1423, 30 USPQ2d at 1289. Second, the patentee failed to prove that each and every one of the limitations of the claim were met. In particular, the claim defined the compound by reciting 37 lines of relative intensity; yet the patentee's proof demonstrated at most 22 of those lines. See id. at 1424, 30 USPQ2d at 1289-90.

TorPharm argues on appeal that Glaxo's proof of infringement suffers from the same deficiencies as the patentee's in Zenith. In particular, TorPharm argues that Glaxo's expert impermissibly compared the accused product to a commercial embodiment of the patented compound. In order to understand TorPharm's theory, a brief explanation of the methodology used by Glaxo's expert is in order. Glaxo's expert generated an IR spectrum for each of 13 different individual mixtures of Form 1 and Form 2 RHCl (ranging from 0% Form 2 to 3.97% Form 2). These IR spectra were then input into a spectral analysis software program, which generated a calibration model using a partial least squares (PLS) algorithm. The IR spectrum of the accused product was then input into the model, which indicated that 0.5% of Form 2 was present in the accused product. As part of the calibration process, Glaxo's expert confirmed that all 29 main peaks were present in the case of the Form 2 reference sample. Here is where TorPharm contends Glaxo ran afoul of Zenith.

According to TorPharm, Glaxo's methodology simply compares the IR spectrum of the accused product to that of the "pure Form 2" calibration sample in violation of the principle laid down in Zenith. Such an approach, argues TorPharm, is particularly inappropriate in this case because Glaxo's expert did not independently verify that the calibration sample supplied by Glaxo was in fact "pure." TorPharm contends that there is no way to verify whether the sample was in fact "pure" because Glaxo has never been able to determine polymorphic purity with less than 1% resolution.

We are not persuaded by TorPharm's argument. Glaxo's expert verified that the calibration samples included all 29 main peaks, and TorPharm does not contest this on appeal. The calibration model verified, to within 0.1% according to Glaxo's expert, that 0.5% of the accused product matched the IR spectrum of the calibration sample. It follows, and Glaxo's expert so stated, that this demonstrates that the accused product shows all 29 main peaks. Such an approach does not run afoul of Zenith. In Zenith, the patentee's expert failed to verify that the reference sample exhibited all 37 lines of the x-ray diffraction pattern. Thus, even assuming the comparison was correct, the patentee failed to prove that all of the express limitations of the claim were satisfied. See id. at 1424, 30 USPQ2d at 1289-90. That is not the case here. (To the extent that TorPharm challenges the accuracy of Glaxo's methodology, that raises a question of fact about which there is a genuine dispute.) Accordingly, summary judgment cannot be sustained on this ground.

IV.

TorPharm advances several claim constructions that, if resolved in its favor, would provide an

adequate and independent basis to affirm the summary judgment of non-infringement. Because these issues involve questions of law, see Markman v. Westview Instruments, Inc., 52 F3d. 967, 976, 34 USPQ2d 1321, 1329 (Fed. Cir. 1995) (in banc), aff'd, 116 S. Ct. 1384, 38 USPQ2d 1461 (1996), over which we exercise plenary review, see Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448,1451, 46 USPQ2d 1169, 1171 (Fed. Cir. 1998) (in banc), and that were adequately developed before the district court, we will consider them, see Fireman's Fund, 909 F.2d at 499.

Claim 1 of the `431 patent recites "Form 2 ranitidine hydrochloride characterized by an infra-red spectrum as a mull in mineral oil showing the following main peaks: [table listing 29 frequencies]." (emphasis added). TorPharm argues that when "showing" and "main" are properly interpreted, there is no infringement. TorPharm contends that the word "main" should be interpreted to mean "chief in size, extent, or importance; principal; leading," quoting a dictionary definition. According to TorPharm, this definition is not only supported by the plain language but is also supported by the prosecution history. TorPharm argues that because the peaks of the Form 2 component of the accused product are overwhelmed by the predominant peaks of the Form 1 component in the overall spectrum, the 29 peaks of Form 2, even if present, could not be "main peaks." The problem with TorPharm's argument is that it fails to recognize that "main" is a relative term. In order to be "chief in size," the peaks must be measured relative to something. We think it is clear from the intrinsic record, including the prosecution history, that all the word "main" requires is that the peaks be "chief in size" relative to the baseline of the pure Form 2 compound. TorPharm's definition would require us to define "main" relative to the overall compound, which is not the subject of the claim.

TorPharm also contends that the word "showing" requires the 29 main peaks to be visually identifiable, again citing a dictionary definition, which defines "show" as "to cause or allow to be seen." We disagree. The word "show" is broader than that. All that "show" requires is that Glaxo demonstrate with an acceptable degree of certainty, visually or by other appropriate means of data display, that the accused product contains the 29 main peaks. The district court so held, and we agree. When the facts are construed in a light most favorable to Glaxo, Glaxo's calibration model does "show" that the accused product contains the 29 main peaks. Accordingly, we cannot affirm the grant of summary judgment on either of these alternative grounds.

Conclusion

Because the district court committed errors of law and fact in granting summary judgment, that decision must be vacated. [3] While the appellees have advanced several alternative grounds for affirmance, none of those grounds provide the footing upon which we can support the judgment. Accordingly, the judgment of the district court is

VACATED AND REMANDED.

COSTS

Each party to bear its own costs.

1. TorPharm also filed a motion to shorten the 30- month statutory bar against the FDA's approval of TorPharm's ANDA, asserting that Glaxo's pattern of delay and refusal to cooperate warranted the reduction permitted in 21 U.S.C. § 355 (j)(4)(B)(iii) (1994). That matter is not before us on appeal.

2. See Switzerland Cheese Ass'n v. East Horne's Market, Inc., 385 U.S. 23, 25 (1966); Senza- Gel Corp. v. Seiffhar, 803 F.2d 661, 669, 231 USPQ 363, 369 (Fed. Cir. 1986); Glaros v. H.H. Robertson Co., 797 F.2d 1564, 1573, 230 USPQ 393, 399 (Fed. Cir. 1986). Glaxo also cites Fireman's Fund for the proposition that "where the summary judgment grounds have not been passed on (much less denied!) by the trial court, this Court prefers not to address them in the first instance." Reply Brief of Appellants at 8. Even though Fireman's Fund does state that general proposition, in that case this court actually considered appellee Fireman's Fund's alternative ground of affirmance, for reasons of judicial economy, even though "it [was] unclear whether Fireman's Fund even presented its [alternative] theory to the trial court." Fireman's Fund, 909 F.2d at 499.

3. Because of the manner in which the district court disposed of the case, the district court did not decide the question of whether 0.5% Form 2 RHCl in a mixture with Form 1 RHCl would infringe the '431 patent. In view of the errors that require us to vacate and remand the district court's judgment, we are not required to reach that issue on appeal. Thus, the question raised and left unanswered in Novopharm II regarding the threshold level of polymorphic purity claimed by the '431 patent, remains unanswered. See Novopharm II, 110 F.3d 1562, 1566 n.1, 42 USPQ2d 1257, 1260 n.1.