United States Court of Appeals for the Federal Circuit

04-1310

MEDPOINTE HEALTHCARE INC.,

Plaintiff-Appellee,

v.

HI-TECH PHARMACAL CO., INC.,

Defendant-Appellant.

DECIDED: November 17, 2004

Before MAYER, Chief Judge, SCHALL, and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge PROST. Dissenting opinion filed by Chief Judge MAYER.

PROST, Circuit Judge.

Hi-Tech Pharmacal Co. ("Hi-Tech") appeals a preliminary injunction granted by the United States District Court for the District of New Jersey to plaintiff Medpointe Healthcare Inc. ("Medpointe") in regard to the sale and manufacture of a pharmaceutical composition protected by United States Patent No. 6,417,206 ("the '206 patent"). Because Medpointe has not shown Hi-Tech's invalidity defense based on obviousness is without substantial merit, we vacate the preliminary injunction.

BACKGROUND

MedPointe brought suit against Hi-Tech for allegedly infringing the '206 patent. The '206 patent claims therapeutic compositions of a pharmaceutical drug containing three active ingredients: (1) carbetapentane tannate, (2) pyrilamine tannate, and (3) phenylephrine tannate.[1] Hi-Tech is a generic drug company that manufactures the same claimed composition. It does not dispute that its generic version of the drug infringes the '206 patent, but asserts in its defense that the patent is invalid for obviousness under 35 U.S.C. § 103. In this appeal, Hi-Tech argues that the district court erred in concluding that it had not raised a substantial question of validity of the '206 patent. Hi-Tech contends that a pharmaceutical composition, named "Candettes,"[2] either alone or in combination with other prior art, such as Medpointe's Tussi-12 product,[3] renders the claims of the '206 patent obvious. The Candettes product, which has been available to the public since 1938, contains the same three types of active molecules claimed by the '206 patent, but has associated with each type of active molecule a different salt counterion than that claimed by the '206 patent. According to

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[1] The sole independent claim in the patent reads as follows:

> 1. A therapeutic composition for the symptomatic relief of cough associated with adverse respiratory tract conditions in warm-blooded animals in need of such treatment said composition comprising pharmaceutically effective amounts of active ingredients, wherein said active ingredients consist of carbetapentane tannate, pyrilamine tannate and phenylephrine tannate.

[2] Candettes contains carbetapentane citrate, phenylephrine hydrochloride, and pyrilamine maleate.

[3] Tussi-12 contains carbetapentane tannate, phenylephrine tannate, and chlorpheneramine tannate.

Hi-Tech, it would have been obvious to substitute tannate for the counterions in Candettes. Alternatively, Hi-Tech contends that it would have been obvious to modify the prior art, by substituting, for example, pyrilamine tannate for chlorpheniramine tannate in Medpointe's Tussi-12 product. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Standard of review

"[T]his court reviews a district court's decision granting, denying, or modifying an injunction, in a patent case . . . applying Federal Circuit law." Int'l Rectifier Corp. v. Samsung Elecs. Co., 361 F.3d 1355, 1359 (Fed. Cir. 2004); see also Lab. Corp. of Am. Holdings v. Chiron Corp., ___ F.3d. ___, 2004 WL 2186670, at *5 (Fed. Cir. Sept. 30, 2004) (recognizing the Federal Circuit's precedent of reviewing the grant or denial of an injunction directed to substantive issues in patent cases under Federal Circuit law). We review the grant or denial of a preliminary injunction by a district court for abuse of discretion. Novo Nordisk of N. Am., Inc. v. Genentech, Inc., 77 F.3d 1364, 1367 (Fed. Cir. 1996). "An abuse of discretion may be established by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings." Amazon.com, Inc. v. BarnesandNoble.com, Inc., 239 F.3d 1343, 1359 (Fed. Cir. 2001) (quoting Novo Nordisk, 77 F.3d at 1367).

Medpointe is entitled to a preliminary injunction only if it can carry its burden of showing: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the

injunction's favorable impact on the public interest. Id. at 1350. Although in some circumstances these factors taken individually may not be dispositive because the district court's decision to grant or deny a preliminary injunction rests on an overall process of balancing, a preliminary injunction cannot be granted if the movant is unable to show a reasonable likelihood of success on the merits. Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd., 357 F.3d 1319, 1325 (Fed. Cir. 2004). To succeed at demonstrating the likelihood of success, Medpointe must present a "clear case" supporting the validity of the patent in suit, thus showing that Hi-Tech's invalidity defense lacks substantial merit. Amazon.com, 239 F.3d at 1359. Hi-Tech may defeat the motion for a preliminary injunction by showing that the patent is "vulnerable" to attack based on validity. Id.

II. Analysis

A.

Hi-Tech relies on Candettes, which was not before the Patent and Trademark Office ("PTO"), as the primary reference that allegedly renders the claims of the '206 patent obvious. Hi-Tech contends that Candettes provides the requisite teaching that it would be desirable to combine salts of carbetapentane, pyrilamine, and phenylephrine, and that reference, either alone or in combination with Tussi-12, renders obvious the tannate composition defined by claim 1 of the '206 patent. Hi-Tech complains that the district court erroneously determined that ammonium chloride, which Candettes lists as one of its ingredients, is an active ingredient that must be removed, among other things, to transform Candettes into the composition defined by the claims of the '206 patent. Further, Hi-Tech argues that the court effectively ignored Candettes in addressing the

incentive to combine prior art. In addition, the district court allegedly made a legal error by erroneously requiring an explicit teaching to combine the three active ingredients claimed by the '206 patent, thereby effectively requiring anticipation by the prior art to raise a substantial question of invalidity based on obviousness, and mischaracterizing Hi-Tech's arguments as "obvious to try." Further, Hi-Tech argues that the district court erred in regard to a number of factual findings that allegedly should not have weighed in favor of finding the '206 patent nonobvious, including (1) the difficulty of working with tannates as a disincentive to combine prior art products, (2) the patented invention's commercial success, (3) the copying by Hi-Tech after MedPointe released its product, and (4) the failure of others to formulate or market an anticipatory pharmaceutical composition before the '206 patent. As to the other preliminary injunction factors, Hi-Tech asserts that the district court erred in finding that MedPointe would be irreparably harmed without an injunction.

B.

The parties' principal dispute revolves around the district court's scrutiny of Candettes. For the reasons that follow, we find that the district court clearly erred in concluding that ammonium chloride must be removed to place Candettes within the scope of the claims of the '206 patent. In addition, we find that the district court clearly erred in its assessment of evidence concerning a teaching or motivation to modify Candettes by replacing the counterion associated with each active ingredient with a tannate. Lastly, the district court erred in its weighing of the evidence of secondary considerations against the evidence of incentive to modify Candette. These errors

mandate that we vacate the district court's preliminary injunction. We discuss the errors in greater detail below.

1.

Although claim 1 uses open-ended, i.e., "comprising," language to permit pharmaceutically acceptable inactive ingredients to be a part of the claimed therapeutic composition, it limits the range of active ingredients to only carbetapentane tannate, pyrilamine tannate and phenylephrine tannate. Because the district court held that the ammonium chloride must be removed as part of the transformation to place Candettes within the scope of the composition defined by claim 1, the court evidently assumed that ammonium chloride is an active ingredient. Neither the district court nor Medpointe, however, cite any record evidence to support the assumption or to rebut Hi-Tech's expert, who testified that ammonium chloride is an inactive ingredient. Medpointe contends that Hi-Tech's testimony should be disregarded because its expert did not testify "how one of ordinary skill would interpret the Candettes reference." Alternatively, Medpointe argues that we should infer that ammonium chloride is active merely because it is listed in a specific quantity on the specification sheet for the Candettes product.

After careful review of the record evidence proffered by Medpointe in its briefs and at oral argument, we discern no reasonable basis for the court's implicit factual finding that ammonium chloride is an active ingredient that must therefore be removed to transform Candettes into the composition claimed by the '206 patent. In view of the

uncontroverted testimony from Hi-Tech's expert that ammonium chloride is inactive, the court's factual determination to the contrary is unsupported and thus clearly erroneous.

2.

Operating under the false premise that a suggestion or motivation must be found to remove the ammonium chloride for Candettes to read on the claims of the '206 patent, the district court determined that it was "far more likely for a practitioner to have discerned a suggestion or motive in the prior art to add an anti-tussive to Ryna-12 or the '597 composition" than to modify Candettes.[4] Notwithstanding the erroneous factual finding in regard to ammonium chloride that underlies the court's preliminary injunction, Medpointe maintains that the injunction may still stand. Medpointe asserts that any incentive to undertake the exchange of salts to make the tannate version of Candettes would have been counteracted by the knowledge that tannate salts are difficult to work with and present significant formulation problems at high levels.

The district court, in agreement with Medpointe, found "it is difficult for practitioners of ordinary skill to work with tannates," and "a practitioner would thus not have been inclined to experiment with them barring external reason for doing so." The district court appeared, however, to unduly discount other evidence in the record, which weighs in favor of finding that there was indeed incentive to modify Candettes to attain the composition claimed by the '206 patent. In particular, the court found that tannates were "well-known to ordinarily skilled practitioners" and that such practitioners would know tannate salts are useful as a way to provide longer-lasting dosages of

[4] Ryna-12 and the '597 composition (United States Patent No. 6,287,597) contain both phenylephrine tannate and pyrilamine tannate.

pharmaceuticals to a person. Further, the record shows that the three active ingredients found in Candettes were each previously converted with success from a non-tannate to a tannate salt, demonstrating that the barriers imposed by working with tannates were in fact not insurmountable or so great as to deter those skilled in the art from undertaking the conversion. Moreover, the evidence shows that each of the active ingredients found in Candettes was successfully used in the tannate form, often in combination with the tannate versions of one of the other active ingredients present in Candettes. Medpointe submits no evidence to suggest that any person skilled in the art expected the tannate version of the three active ingredients in Candettes would not work together. Perhaps most importantly, the inventors of the '206 patent admitted in the Background of Invention section of their patent that at the time of invention it was at least somewhat accepted that "[a]ntitussives, antihistamines, and decongestants in the form of their tannate salts are very desirable because such salts are generally stable and may be combined in such form without any untoward side effects." '206 patent, col. 1, l. 63 – col. 2, l. 2 (emphasis added). The statement from the '206 patent appears to acknowledge the presence of an existing motivation to undertake the salt conversion that the district court evidently deemed missing from the record evidence. Thus, the court clearly abused its discretion when it failed to give weight to the significance of this professed motivation in its scrutiny of Candettes.

3.

As for evidence of secondary considerations, we find them insufficient to show that the defendant's invalidity defense based on Candettes is without substantial merit. Evidence of secondary considerations, such as failure of others, unexpected results,

long felt but unresolved need, commercial success, and copying, is often probative in the obviousness analysis. Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1274 (Fed. Cir. 2004). Here, the district court did not find evidence of failure of others or unexpected results. Moreover, the court opined that "[i]t was unclear whether the '206 patent fulfills any 'long felt need.'" Although the district court found that Medpointe had demonstrated the commercial success of its claimed composition (marketed as Tussi-12D), the purported commercial success is somewhat tenuous given that Medpointe's product has so far only broken even in the amount of money made, with the product's long-term profitability yet to be established. The weak evidence of commercial success and copying by competitors is inadequate to demonstrate nonobviousness of the claimed invention in view of the substantial question of validity raised by Candettes and the strong desirability professed by the '206 patent to use antitussives, antihistamines, and decongestants in their tannate form.

CONCLUSION

We conclude that the district court erred in failing to recognize that Candettes raises a substantial question of invalidity.[5] Because Medpointe has not shown Hi-Tech's obviousness defense lacks substantial merit, Medpointe has failed to carry its

[5] Our decision today on the validity issue in no way resolves the ultimate question of invalidity. It remains to be determined in what way any shortcomings in Hi-Tech's initial preliminary validity challenge will be developed with further fact finding. We hold at this juncture only that Hi-Tech has cast enough doubt on the validity of the '206 patent to avoid a preliminary injunction.

burden of showing it will likely prevail on the merits at the final hearing. Accordingly, we must conclude that a necessary prerequisite for entry of a preliminary injunction is absent. We therefore vacate the preliminary injunction.[6]

[6] Because we find that Medpointe has failed to show it will likely prevail on the merits, as required, to warrant issuance of the preliminary injunction, we find it unnecessary to address the alleged errors by the district court in regard to the irreparable harm finding.

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MAYER, Chief Judge, dissenting.

Based on the evidence and keeping in mind the proper role of an appellate court, I would affirm the district court's decision to maintain the status quo pending a resolution of Medpointe's allegation of infringement. There are three major flaws in this court's opinion. First, the court overturns the district court's finding that ammonium chloride is an active ingredient in the Candettes formulation. The court bases this determination on a single statement by Hi-Tech's expert witness James O'Donnell: "Ammonium Chloride, however, is an inactive ingredient." The court apparently believes that this evidence is particularly weighty because Medpointe failed to rebut it with expert testimony. O'Donnell's testimony, however, is conclusory and unsupported. Further, the district court also considered the Candettes reference, which itself provides compelling evidence that ammonium chloride is an active ingredient. The reference

lists only four ingredients: carbetapentane citrate, pyrilamine maleate, phenylephrine hydrochloride and ammonium chloride. The precise amount of ammonium chloride is specified in a manner similar to that of the other three ingredients. And, the Candettes reference conspicuously fails to list any of the inactive ingredients that are required for a preparation of this type. If ammonium chloride is an inactive ingredient, why does the Candettes reference list it but fail to list any others? The district court, which has special expertise in making credibility determinations, was entitled to disregard O'Donnell's testimony, especially in light of the Candettes reference. See Rohm and Haas Co. v. Brotech Corp., 127 F.3d 1089, 1092 (Fed. Cir. 1997) ("Nothing in the rules or in our jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness."); see also Libas, Ltd. v. United States, 193 F.3d 1361, 1366 (Fed. Cir. 1999) ("It would make little sense to say that a trial court in its fact-finding role should accord much if any weight to expert testimony, the reliability of which is not established."). Consequently, this court's decision that ammonium chloride is an inactive ingredient required the reversal of a credibility determination in addition to a reweighing of the evidence. Such a foray into the virtually exclusive province of the district court has been regularly and consistently criticized by both the Supreme Court and this court. See, e.g., Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 122 n.18 (1969) ("Rule 52(a) admonishes due regard for the trial court's opportunity to assess the credibility of witnesses."); Applied Med. Res. Corp. v. United States Surgical Corp., 147 F.3d 1374,1379 (Fed Cir. 1998).

The court then disputes the district court's determination that tannates are difficult to work with. In so doing, it takes issue with the district court's failure to properly

weigh the evidence. This court apparently feels that because tannates are both "well-known to ordinarily skilled practitioners" and long-lasting, ante, at 7, the district court could not have found that tannates are difficult to work with. The district court, however, was also presented with evidence in the testimony of Dr. D'Addio that the volume of tannates in the '206 formulation exceeded any other previous preparation and that such a high concentration presented increased difficulty. Presented with this testimony, which the district court obviously credited, it is hard to see how this court was "left with the definite and firm conviction that a mistake has been committed." United States v. United States Gypsum Co., 333 U.S. 364, 395 (1948).

Finally, this court found that the "commercial success [of Tussi-12D] is somewhat tenuous given that Medpointe's product has so far only broken even," and that the evidence of copying is weak. Ante, at 9. I have been unable to find any case that suggests that a product was commercially unsuccessful because it had only broken even at the time of inquiry. Tussi-12D has been on the market since 2002, barely enough time to have recouped the investment in R&D that was necessary for its development. At the time the district court's opinion was written, Medpointe had already sold in excess of $14 million worth of Tussi-12D. Further, no fewer than four companies are poised to flood the market with generic formulations of the '206 patent. Based on this evidence, it is hard to imagine that Tussi-12D has not been greeted favorably by consumers. Because I cannot join in the court's de novo review of the district court's findings of fact, I respectfully dissent.