

United States Court of Appeals for the Federal Circuit

02-1461, -1480

MEDICHEM, S.A.,

Plaintiff-Appellant,

v.

ROLABO, S.L,

Defendant-Cross Appellant.

Barry S. White, Frommer Lawrence & Haug LLP, of New York, New York, argued for plaintiff-appellant. With him on the brief were James K. Stronski, Tedd W. Van Buskirk, and John G. Taylor.

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Appealed from: United States District Court for the Southern District of New York

Judge Jed S. Rakoff

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MEDICHEM, S.A.,
Plaintiff-Appellant,

v.

ROLABO, S.L.,
Defendant-Cross Appellant.

DECIDED: December 23, 2003

Before CLEVINGER, GAJARSA, and DYK, Circuit Judges.

GAJARSA, Circuit Judge.

Medichem, S.A. (“Medichem”), appeals the decision of the United States District Court for the Southern District of New York following a bench trial that there was no interference-in-fact under 35 U.S.C. § 291 between the claimed inventions of U.S. Patent Nos. 6,084,100 (the “‘100 patent”) belonging to Medichem and 6,093,827 (the “‘827 patent”) belonging to Rolabo, S.L. (“Rolabo”). Medichem, S.A. v. Rolabo, S.L., No. 01-CV-3087 (S.D.N.Y. May 9, 2002) (“District Court Opinion”). Rolabo cross-appeals the district court’s conclusion that this was not an exceptional case under 35 U.S.C. § 285 and its denial of Rolabo’s request for attorney fees. Because we find the district court

erred in its application of the two-way test, we vacate its priority determination, reverse its conclusion that the '827 patent was neither anticipated nor obvious in light of the '100 patent, and remand for further proceedings consistent with this opinion. As further proceedings are necessary, any resolution of Rolabo's request for attorney fees under 35 U.S.C. § 285 is at this time premature.

I. BACKGROUND

A. The Patents

Medichem is a Barcelona-based manufacturer of pharmaceutical ingredients. The company is the assignee of the '100 patent, entitled "Process for the Preparation of Loratadine." Loratadine is an antihistamine that is the active pharmaceutical ingredient in the popular allergy medication Claritin[®]. Rolabo is also a manufacturer of pharmaceutical ingredients based in Barcelona, Spain, and is the assignee of the '827 patent, entitled "Process for the Preparation of 10,11-Dihydro-5H-dibenzo[a,d]cyclohept-5-enes and Derivatives Thereof," which, like the '100 patent, is a process for the preparation of Loratadine.

Claims 1 and 2 of the '100 patent claim read:

1. A process for the preparation of loratadine consisting of reacting, in an organic solvent and in the presence of a tertiary amine, 8-chloro-5,6-dihydrobenzo[5,6]cyclohepta [1,2-b]pyridin-11-one, of formula VII with a low-valent titanium species.
2. The process of claim 1, wherein the low-valent titanium species are generated by reduction of titanium tetrachloride with zinc dust.

'100 patent, col. 5, l. 59 to col. 6, l. 21. Claims 1 and 17 of the '827 patent read:

1. A process for preparing 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes comprising reacting a dibenzosuberone or an aza derivative thereof with an aliphatic ketone in the presence of low valent titanium wherein said low valent titanium is generated by zinc.
17. A process as claimed in claim 1 for preparing Loratadine.

'827 patent, col. 5, ll. 34-38, col. 8, ll. 3-4 (emphasis added). Both the '100 and the '827 patents involve chemical reactions generally known in the art as "McMurry" reactions, after Professor John McMurry, who described the intermolecular coupling between the different carbonyl groups in a compound using

low valent titanium in a 1989 publication.

B. Proceedings to Date

1. District Court Proceedings

Medichem filed a complaint under 35 U.S.C. § 291 against Rolabo in the United States District Court for the Southern District of New York on April 13, 2001. Section 291, entitled “Interfering Patents,” provides a cause of action to one patent owner against another patent owner where the inventions claimed by their respective patents interfere with one another. Addressing priority first, the district court found that the evidence submitted by Medichem supported an invention date in the fall of 1996 for the ‘100 patent. Since Rolabo did not allege an invention date prior to the fall of 1996, the district court awarded priority to Medichem.

The district court turned next to the issue of interference-in-fact between the ‘100 and ‘827 patents, and announced that it was applying the two-way test for identifying an interference provided in the Patent and Trademark Organization’s (“PTO”) regulation, 37 C.F.R. § 1.601(n). Under the two-way test, the district court first treated the ‘100 patent as prior art, identifying the key question as “whether the inclusion of tertiary amine in Medichem’s patent claims is material in a way that negates obviousness and makes the patents noninterfering.”^[1] Because of the presence of a tertiary amine throughout the ‘100 patent’s claims and examples, the district court found that a tertiary amine would appear to a reader of the ‘100 patent as a necessary component of Medichem’s process. Absent the tertiary amine, the district court explained, it would not be obvious that the same result could be achieved. Therefore, the absence of a tertiary amine requirement in the ‘827 patent “strongly suggest [ed]” that the two processes were materially different.

Continuing its analysis under the interference inquiry, the district court assessed whether one of ordinary skill in the art would find the elimination of a tertiary amine obvious or anticipated in light of the ‘100 patent and the prior art in 1996, the invention date of the ‘100 patent. The district court accepted each of the parties’ expert witnesses, five in all, as representative of the ordinary skill in the relevant art of synthetic organic chemistry. All witnesses were not, however, determined by the district

court to be equally credible in their testimony. Ultimately, the district court relied entirely on the testimony of Rolabo's third expert, Dr. Leckta.

Dr. Leckta confirmed the district court's belief that, while a person of skill in the art in 1996 would have understood the role of the tertiary amine in Medichem's process, the result if the tertiary amine were omitted would not have been obvious. The tertiary amine, Dr. Leckta noted, was significant in aiding Medichem's process for creating Loratadine, but also had drawbacks in the form of longer reaction times, lower yields, and additional workup time. Based on its conclusion that the removal of the tertiary amine would not be obvious to one of ordinary skill in the art in 1996, the district court found that one leg of the two-way test (i.e., treating the '100 patent as prior art) required by the PTO's test for interferences under section 1.601(n) was not satisfied and, as a result, there could be no interference-in-fact. The district court did not reach the second leg of the two-way test. Medichem timely appealed the district court's finding of no interference and Rolabo cross-appealed the district court's denial of attorney fees under § 285. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

2. Interim PTO Proceedings

On December 11, 2002, during the interim period between the district court's resolution of the case and the date on which Rolabo filed its brief in this court, the Board of Patent Appeals and Interferences ("Board") declared an interference-in-fact between claim 2 of the '100 patent and claim 17 of the '827 patent. Stampa v. Jackson, No. 105,069, 65 USPQ2d 1942, 2002 Pat. App. LEXIS 191 (Bd. Pat. App. & Int. Dec. 11, 2002). The Board's proceedings occurred under the parallel interference procedures of 35 U.S.C. § 135(a), which govern interferences between an application for a patent and another pending application or unexpired patent. These requirements were met in this instance because, on September 3, 2002, Stampa, one of the listed inventors on the '100 patent, had filed Reissue Application No. 10/234,659 (the "'659 Reissue") for the '100 patent. A reissue application qualifies as an application under § 135(a).

The Board began by concluding that a § 291 proceeding did not preclude the Director of the PTO from declaring an interference under § 135(a) due to the difference in statutory requirements. Stampa,

65 USPQ2d at ____, 2002 Pat. App. LEXIS 191 at *9-*18; see also Masco Corp. v. United States, 303 F.3d 1316, 1329 (Fed. Cir. 2002) (“Issue preclusion is appropriate only when . . . (1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) plaintiff had a full and fair opportunity to litigate the issue in the first action.”). The Board, like the district court, applied the two-way test described by 37 C.F.R. § 1.601(n) to identify the existence of an interference-in-fact between the reissue application and the ‘827 patent. Unlike the district court, however, the Board found that the term “comprising” in the transition of claim 1 of the ‘827 patent permitted the inclusion of additional elements, including tertiary amines. Because tertiary amines were not excluded from the ‘827 patent, claim 17 was anticipated by claim 2 of the ‘100 patent. Applying the second leg of the two-way test—treating the ‘827 patent as prior art [2]—the Board found that the use of tertiary amines to carry out McMurry reactions was well known in the art. Therefore, the Board concluded, the second leg of the two-way test was also satisfied, resulting in an interference-in-fact.

II. DISCUSSION

A. Standard of Review

This court has only indirectly addressed the standard used in reviewing a district court’s conclusions regarding interference under 35 U.S.C. § 291. See Advanced Transformer Co. v. Levinson, 837 F.2d 1081, 1083 (Fed. Cir. 1988) (upholding a district court determination of no interference where that conclusion was not “shown to be clearly erroneous”). By PTO regulation, however, the underlying questions to the interference-in-fact inquiry are those of anticipation and obviousness under 35 U.S.C. §§ 102-103. See 37 C.F.R. § 1.601(j) (“An interference-in-fact exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.” (emphasis added)); § 1.601(n) (“Invention ‘A’ is the same patentable invention as an invention ‘B’ when invention ‘A’ is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention ‘B’ assuming invention ‘B’ is prior art with respect to invention ‘A’.” (emphasis added)); see also Eli Lilly & Co. v. Bd. of Regents of the Univ. of Wash., 334 F.3d 1264, 1267-69 (Fed. Cir. 2003). Following from the two-way test, the

standards of review for an interference-in-fact should mirror the standards of review employed in anticipation and obviousness inquiries.

Both anticipation under § 102 and obviousness under § 103 are two-step inquiries. Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1339 (Fed. Cir. 2003); Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709, 714 (Fed. Cir. 1998). The first step in both analyses is a proper construction of the claims, which we review de novo. Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1996). The second step in the analyses requires a comparison of the properly construed claim to the prior art. Oakley, 316 F.3d at 1339. In the context of an interference under § 291, the two-way test defines the available prior art as including the allegedly interfering subject matter. See 37 C.F.R. § 1.601(n). Anticipation under § 102 is a question of fact that we review for clear error. Electro Med. Sys., S.A. v. Cooper Life Scis., 34 F.3d 1048, 1052 (Fed. Cir. 1994). Obviousness under § 103 is a legal conclusion based on underlying factual determinations. We review the legal conclusion de novo and the underlying factual determinations for clear error. Oakley, 316 F.3d at 1339.

B. Analysis

1. Claim Construction

Claim 1 of the '827 patent includes the transition term "comprising." Medichem argues that this term is open-ended and that, as a result, additional material elements or method steps may be included in the claimed process. According to Medichem, the absence of a tertiary amine in Rolabo's claims is therefore irrelevant. Rolabo's claim encompasses not only any improved processes for the manufacture of Loratadine that do not include tertiary amines, but also, because of the open-ended transition term, processes like Medichem's that do include tertiary amines. Consequently, Medichem asserts, the district court misconstrued the subject matter claimed by the '827 patent by reading the absence of a tertiary amine requirement as excluding tertiary amines from the Rolabo process. Had it wanted to, Medichem continues, Rolabo could have drafted its claim to exclude the presence of tertiary amines by using the transition phrase "consisting of" rather than "comprising." Rolabo does not dispute Medichem's argument regarding claim construction, and, in fact, admitted its correctness during the district court

proceedings.

We agree with Medichem in its urged construction. “The transition ‘comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.” Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368 (Fed. Cir. 2003) (citations omitted). In the course of its analysis, the district court apparently assumed that the absence of an affirmative claiming of tertiary amines excluded them from its scope. See District Court Opinion, slip op. at 9 (“[T]he test . . . is whether someone reasonably skilled in the art would find the elimination of a tertiary amine obvious or anticipated in light of the prior art at the relevant time.” (emphasis added)). The assumption that tertiary amines were excluded from the claims of the ‘827 patent is consistent throughout the district court’s opinion. As drafted, however, the process described in the ‘827 patent includes not only the steps listed in the claim, but also any additional steps that may be added. Invitrogen, 327 F.3d at 1368. The addition of a tertiary amine to the process described by the ‘827 patent is an indisputable possibility, as demonstrated by both the ‘100 patent itself and Rolabo’s concession at oral argument. Thus, while the process described by claims 1 and 17 of the ‘827 patent does not require the presence of a tertiary amine, it certainly cannot be read to exclude it.^[3]

2. Interference-in-Fact Analysis

“[I]n order to provoke an interference in district court under § 291, the interfering patents must have the same or substantially the same subject matter in similar form as that required by the PTO pursuant to 35 U.S.C. § 135.” Slip Track Sys., Inc. v. Metal-Lite, Inc., 304 F.3d 1256, 1263 (Fed. Cir. 2002). A district court “has no jurisdiction under § 291 unless interference is established.” Albert v. Kevelex Corp., 729 F.2d 757, 760-61 (Fed. Cir. 1984). Thus, the first step in any interference proceeding under § 291 is the evaluation of whether an interference-in-fact exists under the two-way test. Though PTO regulations do not bind a district court, a district court defines “the same or substantially the same subject matter” in the same manner as would the PTO under its own regulations—by using the two-way test.^[4] See Slip Track, 304 F.3d at 1263.

According to the regulations outlining interference proceedings in the PTO, “[a]n interference-

in-fact exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.” 37 C.F.R. § 1.601(j). The “same patentable invention” is defined by a separate subsection of the same regulation. *Id.* § 1.601(n). This is referred to as the “two-way test.” Eli Lilly, 334 F.3d at 1265. As has been explained by the Board of Patent Appeals & Interferences,

The claimed invention of Party A is presumed to be prior art vis-a-vis Party B and vice versa. The claimed invention of Party A must anticipate or render obvious the claimed invention of Party B and the claimed invention of Party B must anticipate or render obvious the claimed invention of Party A.

Winter v. Fujita, 53 USPQ2d 1234, 1243 (Bd. Pat. App. & Int. 1999); *see also* Eli Lilly, 334 F.3d at 1269 (endorsing an identical interpretation). As written, section 1.601(n) incorporates the standards for both anticipation under § 102 and obviousness under § 103 in determining the existence of an interference, permitting either circumstance to satisfy that leg of the two-way test.

Construed properly, claims 1 and 2 of the ‘100 patent plainly anticipate claims 1 and 17 of the ‘827 patent when the ‘100 patent is the assumed prior art under the two-way test. Rolabo appropriately conceded this point at oral argument. “It is . . . an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is ‘anticipated’ if one of them is in the prior art.” Titanium Metals Corp. v. Banner, 778 F.2d 775, 782 (Fed. Cir. 1985) (citations and emphasis omitted). The broader claims of the ‘827 patent permit, but do not require, a tertiary amine. The narrower claims of the ‘100 patent are restricted to processes including a tertiary amine. Since the ‘100 patent teaches a process that falls within the scope of the claims of the ‘827 patent, claims 1 and 2 of the ‘100 patent, when treated as prior art, anticipate claims 1 and 17 of the ‘827 patent. As a result, we reverse the district court’s findings that the first leg of the two-way test was not satisfied.

Medichem further argues that the district court found that the requirement of a tertiary amine in the claims of the ‘100 patent would have been obvious to one of ordinary skill in the art, assuming the ‘827 patent was prior art as required by the second leg of the two-way interference inquiry. We can affirm this finding, Medichem explains, not only because of the minor differences between the ‘100 and ‘827 patents, but also because the use of tertiary amines in McMurry reactions was well known since the

1970s, and was reported in a 1989 article by Professor McMurry himself. Given the finding of anticipation of claims 1 and 17 of the '827 patent under the first leg of the two-way test and the purported obviousness finding of the district court under the second leg, Medichem concludes that the two-way test is satisfied, resulting in an interference-in-fact. We disagree with Medichem's reading of the district court opinion.

The district court treated the '100 patent as prior art in the first leg of the two-way interference test. District Court Opinion, slip op. at 9 (“[I]t would not be obvious that one could achieve a similar result without adding a tertiary amine.” (emphasis added)). As best we can tell, the district court did not move beyond this first step of the inquiry. See id. at 13 (“What someone skilled in the art would not find obvious . . . was what would be the result if tertiary amine were eliminated from the process . . .”). Finding one leg of the two-way test not satisfied, the district court appropriately ended its inquiry—there can be no interference-in-fact without satisfaction of each leg of the two-way test. As we have reversed the district court's conclusion that the first leg was not satisfied, however, continued analysis under the second leg now becomes necessary.

Since the district court made no findings of fact regarding the second leg of the interference inquiry, it is impossible for this court in the first instance to undertake any review. As the '827 patent contains genus claims and the '100 patent contains species claims, an arrangement that assumes that the '827 patent is prior art does not necessarily anticipate or make obvious the narrower claims of the '100 patent. See Eli Lilly, 334 F.3d at 1270 (“[E]arlier disclosure of a genus does not necessarily prevent patenting a species member of the genus.”). The second leg of the two-way test is satisfied, however, if either condition is met. Anticipation is a question of fact. Oakley, 316 F.3d at 1339. Although obviousness is a question of law, it is based on underlying factual determinations. Id. Accordingly, we remand this portion of the interference inquiry to the district court to make factual determinations of anticipation and obviousness in the first instance.

3. Priority Determination

The district court determined that Medichem established the priority of the '100 patent at trial. It

did so, however, prior to engaging in the interference-in-fact analysis. This was an error. “[I]nterference between patents is a sine qua non of an action under § 291.” Albert, 729 F.2d at 760. Without first identifying an interference-in-fact under the two-way test, a court has no jurisdiction to make a priority determination between two patents under § 291. Id. at 760-61. This jurisdictional limitation on a court’s power has significant import where, as here, the district court ultimately finds no interference-in-fact. While the district court is free to reach the same conclusion on remand, it may do so only once proper jurisdiction—an interference-in-fact—has been established. We accordingly vacate the district court’s priority determination.

C. Effect of the Board Proceedings

As mentioned, in the period between the conclusion of the district court proceedings and the commencement of proceedings in this court, Medichem initiated reissue proceedings before the Board of Patent Appeals and Interferences. At the time of oral argument, the Board had declared an interference-in-fact and, following resolution of several pending motions from the parties, was set to begin proceedings on the issue of priority. See Stampa, 65 USPQ2d at ___, 2002 Pat. App. LEXIS 191 at *17. We point out that, on remand, a stay of proceedings in the district court pending the outcome of the parallel proceedings in the PTO remains an option within the district court’s discretion. See Slip Track Sys. v. Metal Lite, 159 F.3d 1337, 1341 (Fed. Cir. 1998).

Although proceedings in the PTO under § 135 and proceedings in a district court under § 291 are not identical, they are closely related. The Board has already declared an interference-in-fact. Stampa, 65 USPQ2d at ___, 2002 Pat. App. LEXIS 191 at *17. While the issues of interference before the Board may, as pointed out by the Board itself, differ from those in front of the district court, the Board’s resolution of the matter will certainly aid the district court in subsequent proceedings. See Fisher Controls Co. v. Control Components, Inc., 443 F. Supp. 581, 582 (S.D. Iowa 1977). The record generated by the Board, particularly in light of the Board’s expertise in the matter, may permit the district court to avoid a needless duplication of efforts. Furthermore, a priority determination that results in the cancellation of the interfering claims of the ‘100 patent would eliminate the need for further

proceedings in the district court altogether. The discretion to stay proceedings pending the outcome of the PTO proceedings remains available to the district court, and the district court should in no way view our remand as suggesting otherwise.

D. Attorney Fees

As there is no final resolution of the dispute in this case, there is no “prevailing party” as is required for an award of attorney fees under 35 U.S.C. § 285. As such, the district court’s decision not to award fees was premature and is accordingly vacated.

III. CONCLUSION

For the foregoing reasons, we reverse the district court’s finding that the first leg of the two-way test, treating the ‘100 patent as prior art, was not satisfied, vacate the district court’s priority determination and decision not to award attorney fees, and remand with an order to stay further proceedings pending the outcome of the interference proceedings involving the ‘659 Reissue.

REVERSED-IN-PART, VACATED-IN-PART, AND REMANDED

IV. COSTS

No costs.

[1] Pyridine, a required component in Medichem's process, is an example of a tertiary amine.

[2] As mentioned previously, this leg of the two-way test was not reached by the district court because it found that the first leg was not satisfied.

[3] This is consistent with the conclusion reached by the Board of Patent Appeals and Interferences. Stampa, 65 USPQ2d at ___, 2002 Pat. App. LEXIS 191 at *14-*15.

[4] We are aware that the PTO has issued a notice of proposed rulemaking, with proposed § 41.203(a) clarifying the interference-in-fact standard. See Rules of Practice Before the Board of Patent Appeals and Interferences, 68 Fed. Reg. 66,664, 66,664-65. Our opinion in this case should not be read to require any particular result or otherwise influence in any way the outcome of the PTO's rulemaking.