United States Court of Appeals for the Federal Circuit

05-1179, -1248

MEDICHEM, S.A.,

Plaintiff-Appellee,

v.

ROLABO, S.L.,

Defendant-Appellant.

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

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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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Defendant-Appellant.

DECIDED: February 3, 2006

Before SCHALL, GAJARSA, DYK, Circuit Judges.

GAJARSA, Circuit Judge.

This is the second round of a protracted litigation to establish priority of invention between Stampa et al.'s U.S. Patent No. 6,084,100 ("the '100 patent"), assigned to Medichem, S.A. ("Medichem"), and Jackson's U.S. Patent No. 6,093,827 ("the '827 patent"), assigned to Rolabo, S.L. ("Rolabo"). In the first round appealed to this court, we remanded to the district court, requiring it to establish an interference-in-fact under 35 U.S.C. § 291 before determining priority. Medichem, S.A. v. Rolabo, S.L., 353 F.3d 928 (Fed. Cir. 2003) ("Medichem II"). Rolabo now appeals from the judgment on remand, in which the United States District Court for the Southern District of New York found the existence of an interference-in-fact and awarded priority of invention to Medichem. See Medichem, S.A. v. Rolabo, S.L., Memorandum Order, No. 01 Civ.

3087, 2004 WL 2674632 (S.D.N.Y Nov. 22, 2004) ("Medichem III"). For the reasons discussed below, we affirm the judgment of the district court on the proper establishment of the interfering subject matter and on the finding of the existence of an interference-in-fact. We reverse, however, the district court's award of priority to Medichem, based on the insufficiency of the evidence that Medichem introduced at trial to corroborate the testimony of its inventors regarding reduction to practice of the invention.

BACKGROUND

A. The Patents

Medichem and Rolabo are both pharmaceutical manufacturers based in Barcelona, Spain. Rolabo's '827 patent and Medichem's '100 patent both claim a process for making loratadine from two precursor chemicals via a chemical reaction known as the McMurry reaction. Loratadine is the active ingredient in the allergy medication Claritin®. McMurry reactions involve the coupling of two starting materials in the presence of low-valent titanium. In general, McMurry reactions can lead to two types of products, diols and alkenes; loratadine, the desired end product of this reaction, is an alkene. McMurry reactions can be optimized for alkene production by adjusting various reaction parameters, such as the temperature and length of the reaction in this case, and also by adding additional reactants. The only significant

difference between the processes claimed by Medichem[1] and Rolabo[2] is that Medichem's process requires the reaction to be carried out in the presence of a type of chemical known as a tertiary amine.[3] In contrast, the Rolabo process permits by not excluding, but does not require, the presence of a tertiary amine. Conceptually, therefore, the Medichem invention, which requires a tertiary amine, is a species within the genus of the Rolabo invention.

B. Proceedings to Date

Medichem brought an action under 35 U.S.C. § 291, alleging an interference-in-fact between the '100 and '827 patents, claiming priority of invention, and seeking invalidation of Rolabo's patent under 35 U.S.C. § 102(g). Transcript of Verdict at 653-67, Medichem, S.A. v. Rolabo, S.L., No. 01 Civ. 03087, 2002 U.S. Dist. LEXIS 27086 (S.D.N.Y May 8, 2002) ("Medichem I"). Because Rolabo was the party with the earlier effective filing date, Medichem sought to establish priority by proving an actual reduction

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[1] Claims 1 and 2 of Medichem's '100 patent 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- dihyrobenzo[5,6]cyclohepta[1,2-b]pyridin-11-one, of formula VII with a low-valent titanium species. (emphasis added).
>
> 2. The process of claim 1, wherein the low-valent titanium species are generated by reduction of titanium tetrachloride with zinc dust.

[2] Claims 1 and 17 of Rolabo's '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.

[3] A tertiary amine is a compound in which nitrogen is bonded three times to carbon. A commonly used tertiary amine is pyridine.

to practice that was even earlier.[4] After a bench trial, the district court found that there was no interference-in-fact between the claimed inventions, but it nonetheless awarded priority to Medichem. Id.

On appeal, this court vacated the priority holding, opining that because the existence of an interference-in-fact is a jurisdictional requirement under 35 U.S.C. § 291, it was therefore a precondition to the district court's consideration of the priority issue. Medichem II, 353 F.3d at 935-36. We explained that the first step in an interference analysis is for the court to determine whether an interference exists under 35 U.S.C. § 291 by asking whether the "patents . . . 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." Id. at 934 (internal quotations omitted). In order to make this determination, we use the "two-way" test which states that two patents interfere only if (1) invention *A* either anticipates or renders obvious invention *B*, where Party *A*'s claimed invention is presumed to be prior art vis-à-vis Party *B* and (2) vice versa. Id. (citing Eli Lilly & Co. v. Bd. of Regents of the Univ. of Wash., 334 F.3d 1264, 1268 (Fed. Cir. 2003)).

In Medichem II, we held that Medichem's claims to the "species" would clearly anticipate Rolabo's genus claim if the Medichem patent were assumed to be prior art. Id. at 934-35. Thus, we held that the first prong of the two-way test was clearly satisfied. Id. at 935. However, we remanded to the district court for a determination of whether the second prong was also satisfied—namely, whether Rolabo's genus claim, if prior art, would either anticipate or render obvious Medichem's species claim. Id. at

[4] Rolabo's effective filing date is February 26, 1997 and Medichem's is May 30, 1997.

935. We explained that "[a]s 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." Id.

On remand, the district court held that "assuming arguendo [pursuant to the two-way test] the priority of the '827 patent, claims 1 and 17 of the '827 patent clearly anticipate and render obvious the adding of a tertiary amine, as in the '100 patent." Medichem III, 2004 WL 2674632 at *7. Although the court went on to explain its holding on obviousness grounds, it was silent about the reasons underlying its apparent determination that Rolabo's genus claims would also anticipate Medichem's species claim. Instead, it improperly recharacterized our remand instructions as "reduc[ing] to the question of whether it would be 'obvious' to add tertiary amine to a McMurry reaction to make loratadine."[5] Id. (emphasis added).

The court then correctly stated that:

> Determining obviousness requires consideration of two factors: 1) whether the prior art would have suggested to one of ordinary skill in the art that he should carry out the claimed process; and 2) whether the prior art would have also revealed that in carrying out the process, one of ordinary skill would have a reasonable expectation of success.

Id. The district court proceeded to articulate factual bases for its obviousness holding, which included (1) an article that pointed to the use of amines to improve yields in coupling reactions, (2) testimony by Rolabo's expert about additional such prior art, and

[5] In so doing, the court appears not to have separately considered the question of whether the '827 patent, if taken as prior art, would anticipate the '100 patent.

(3) evidence that such prior art had actually motivated Medichem's inventor's to try adding tertiary amine to the reaction mixture. Medichem III, 2004 WL 2674632 at *7-8.

Having found the two-way test's second prong to be satisfied on both anticipation and obviousness grounds, the district court concluded that the Medichem and Rolabo patents interfered, a finding that gave it jurisdiction over the priority dispute pursuant to 35 U.S.C. § 291. It awarded priority to Medichem, after finding that the invention claimed in the '100 patent was reduced to practice prior to the constructive reduction to practice date of Rolabo's invention. See id. at *10-11 (referring to Medichem I and stating that the court "reinstates and reaffirms its former priority ruling").

In finding reduction to practice, the court neither explicitly discussed the legal requirement that reduction to practice be corroborated by independent evidence, nor made a factual finding of corroboration. However, it dismissed Rolabo's argument that Medichem's inventors were not credible as a result of having fraudulently backdated documents that it had offered to show reduction to practice in 1995. The court thus affirmed its finding in Medichem I that Medichem had provided adequate proof of reduction to practice in 1996. The court did so notwithstanding its previous observation that "the willingness of Medichem to fraudulently backdate [evidence of reduction to practice in 1995], coupled with Medichem's less than punctilious recordkeeping practices . . . does convince the Court that it cannot place the same reliance on plaintiff's testimony and documents as it might otherwise have." Transcript of Verdict at 658, Medichem I. However, the court apparently adhered to its view that Medichem's fraudulent backdating was "chiefly a belated attempt to deal with their noncompliance with [certain] regulatory requirements." Id. The Medichem III court therefore reaffirmed

its award of priority to Medichem, and Rolabo appealed on February 9, 2005. This court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

As an aside, we wish to note that in parallel with the district court proceedings under 35 U.S.C. § 291, the Board of Patent Appeals and Interferences ("Board") has been considering essentially the same interference and priority issues pursuant to 35 U.S.C. § 135. See Stampa v. Jackson, 65 U.S.P.Q.2d 1942 (B.P.A.I. 2002) (involving an interference between Medichem's then-pending reissue application and both Rolabo's patent and a pending continuation application thereof, giving rise to Patent Interference Nos. 105,069 and 105,212). The Board held that the district court's holding in Medichem I did not bar the Board proceedings on grounds of issue preclusion. See id. at 1945-47.

Shortly after the district court's remand decision in Medichem III, the Board resolved the interference in favor of Rolabo, reaching a conclusion opposite to that of the district court. See Stampa v. Jackson, Inter. Nos. 105,069 & 105,212, 2005 WL 596770 (B.P.A.I. January 25, 2005). Central to its decision was Medichem's failure to corroborate its account of an alleged actual reduction to practice with evidence independent of its inventors' testimony. Id. at *19-20. The Board noted that "[a]ll of the evidence regarding an experiment on May 7, 1996 which is said to have obtained loratadine via a process of the count and conducted by [non-inventor] Lola Casas and said to be recorded [in her notebook] is based on the testimony of [Medichem inventors]." Id. at *15. Significantly, Medichem did not produce any testimony from Casas, a failure that the Board perceived as sufficient to permit the inference that Casas' testimony would have been adverse to Medichem. Id. at *20. However, the

Board declined to apply such an adverse inference on the grounds that "[Medichem's] case is so weak, we find it unnecessary to draw an inference one way or the other."[6] Id. While appellant does not argue that the Board decision has a binding effect on this court, Board decisions nevertheless represent the views of a panel of specialists in the area of patent law. Medichem has appealed the Board's decision to this court. See Stampa v. Jackson, appeal docketed, Nos. 06-1004 & -1029 (Fed. Cir. Oct. 6, 2004 & Oct. 24, 2004).

DISCUSSION

There are three issues in this case—namely, whether the district court (1) erred in finding the existence of an interference-in-fact; (2) committed reversible error in failing to formally define a count corresponding to the interfering subject matter; and (3) erred in awarding priority of invention to Medichem based on the oral testimony of Medichem co-inventors, testimony that Rolabo claims was not corroborated by independent evidence, and thus should not have been credited in the final determination of whether reduction to practice was established before the critical date.

A. Existence of an Interference-in-Fact

For the reasons explained below, we agree that under the second prong of the two-way test for obviousness, Rolabo's genus claim renders obvious the Medichem species claim. We therefore affirm the lower court's finding of an interference-in-fact

[6] A final judgment on the merits was issued the same day. See Stampa v. Jackson, Inter. Nos. 105,069 & 105,212, 2005 WL 596771 (B.P.A.I. January 25, 2005). The Board later denied Medichem's request for rehearing, stating inter alia that "[t]he importance of Lola Casas' testimony is manifest. She is the principal, if not the only, corroborating witness on the issue of whether an actual reduction to practice took place." See Stampa v. Jackson, Inter. Nos. 105,069 & 105,212, 2005 WL 1541082 (B.P.A.I. June 27, 2005).

without needing to review the district court's unsupported factual finding that the second prong of the two-way test was independently satisfied on anticipation grounds.

1. Standard of Review

In reviewing a district court's finding of an interference-in-fact pursuant to the two-way test, this court reviews, where necessary, both the subsidiary findings of anticipation and/or obviousness as they relate to the application of the test. See Medichem II, 353 F.3d at 932 (articulating the standard of review for findings of an interference-in-fact under 35 U.S.C. § 291). Here, because we agree with the district court's subsidiary finding of obviousness, which is sufficient to support its finding of an interference-in-fact, it is not necessary for us to review the court's finding of anticipation.

Obviousness under 35 U.S.C. § 103 is a legal conclusion that is reviewed de novo; however, it is based in turn on underlying factual determinations which are reviewed for clear error. Id. Under the clear error standard, a reversal is permitted "only when this court is left with a 'definite and firm conviction' that the district court was in error." Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1275 (Fed. Cir. 2004) (quoting Amhil Enters. Ltd. v. Wawa, Inc., 81 F.3d 1554, 1562 (Fed. Cir. 1996)).

2. Obviousness

The ultimate determination of whether an invention would have been obvious under 35 U.S.C. § 103(a) is a legal conclusion based on the factual Graham findings, e.g., "(1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; and (3) the differences between the claimed invention and the prior art." Velander v. Garner, 348 F.3d 1359, 1363 (Fed. Cir. 2003) (citing Graham v. John Deere Co., 383 U.S. 1, 17 (1966)).

This court has held that if all the elements of an invention are found in a combination of prior art references:

> a proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.

Id.

The first requirement, the motivation to combine references, serves to prevent hindsight bias. See McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351 (Fed. Cir. 2001) ("To prevent hindsight invalidation of patent claims, the law requires some 'teaching, suggestion or reason' to combine cited references.") (quoting Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573 (Fed. Cir. 1997)). In making obviousness determinations, the test is "whether the subject matter of the claimed inventions would have been obvious to one skilled in the art at the time the inventions were made, *not* what would be obvious to a judge after reading the patents in suit and hearing the testimony." Panduit Corp. v. Dennison Mfg. Co., 774 F.2d 1082, 1092 (Fed. Cir. 1985). Whether such a motivation has been demonstrated is a question of fact. See Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1348 (Fed. Cir. 2000). Evidence of a motivation to combine prior art references "may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved." Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1125 (Fed. Cir. 2000).

When a piece of prior art "suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant"

the piece of prior art is said to "teach away" from the claimed invention. In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994). As with other subsidiary obviousness inquiries, "[w]hat a reference teaches and whether it teaches toward or away from the claimed invention are questions of fact." Winner, 202 F.3d at 1349 (internal quotations omitted). However, obviousness must be determined in light of all the facts, and there is no rule that a single reference that teaches away will mandate a finding of nonobviousness. Likewise, a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine. See id. at 1349 n.8 ("The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another."). Where the prior art contains "apparently conflicting" teachings (i.e., where some references teach the combination and others teach away from it) each reference must be considered "for its power to suggest solutions to an artisan of ordinary skill. . . . consider[ing] the degree to which one reference might accurately discredit another." In re Young, 927 F.2d 588, 591 (Fed. Cir. 1991).

As stated above, an obviousness determination requires not only the existence of a motivation to combine elements from different prior art references, but also that a skilled artisan would have perceived a reasonable expectation of success in making the invention via that combination. While the definition of "reasonable expectation" is somewhat vague, our case law makes clear that it does not require a certainty of success. See In re O'Farrell, 853 F.2d 894, 903-04 (Fed. Cir. 1988) ("Obviousness

does not require absolute predictability of success. . . . [A]ll that is required is a reasonable expectation of success.").

However, to have a reasonable expectation of success, one must be motivated to do more than merely to "vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." Id. at 903. Similarly, prior art fails to provide the requisite "reasonable expectation" of success where it teaches merely to pursue a "general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." Id.

The district court's finding of a reasonable expectation of success is a question of fact, which we review for clear error. See Ruiz, 357 F.3d at 1275 (explaining that the obviousness determination rests on "various factual findings that this court reviews for clear error following a bench trial"); Brown & Williamson, 229 F.3d at 1129 (reviewing the district court's finding of reasonable expectation of success under the clear error standard); see also Velander v. Garner, 348 F.3d 1359, 1376 (Fed. Cir. 2003) (reviewing the Board of Patent Appeals and Interferences' finding of a reasonable expectation of success under a "substantial evidence" standard).

3. Analysis

Rolabo argues that the district court erred in finding that the Medichem invention (which uses a tertiary amine) would have been obvious over the broader Rolabo invention (which does not require it). Specifically, it appears to argue both that the prior

art contained no motivation to combine references so as to have encouraged one reasonably skilled in the art to have added a tertiary amine to a McMurry reaction and that an artisan, even if motivated to add a tertiary amine to Rolabo's process, would have had no reasonable expectation of succeeding in making loratadine via a McMurry reaction in the presence of a tertiary amine.

In support of its arguments, Rolabo cites the trial testimony of an expert witness who explained that a seminal review article in the field showed that a tertiary amine could have "a positive effect, a negative effect, and in some cases, both a positive and negative effect" on the McMurry reaction. Rolabo goes on to cite prior art references that disclose negative effects and essentially argues that the existence of prior art references that teach away from the invention clearly negates the motivation to combine and that the district court's finding of motivation was clearly erroneous. We disagree.

Granted, it is clear that the prior art disclosed not only potential advantages of using a tertiary amine in a McMurry reaction but also potential disadvantages. On the one hand, some pieces of prior art taught that low concentrations of a tertiary amine could sometimes be used to improve the yield of reactions or to avoid the formation of undesirable rearranged products. On the other hand, other references reported that tertiary amines could sometimes promote the formation of undesirable diol side-products and that when they were used as the reaction solvent (i.e., when tertiary amines are present at their highest possible concentrations), they could stop the reaction completely.

We also note the ambivalence of Medichem co-inventor Dr. Onrubia toward the introduction of a tertiary amine to the reaction mixture. On the one hand, she testified

that she had added a tertiary amine "[b]ecause the literature said that it might be possible to use tertiary amines in the reaction, that it wouldn't interfere, that it wasn't incompatible, and it's habitual in these circumstances to try various options until you get the reaction to work." On the other hand, when asked, "Is this purely hit or miss or is there some logical cause . . . for believing that tertiary amine would add something?" she responded: "Frankly, as an organic chemist I have no reason to say that there were grounds for expecting anything from the addition of tertiary amine."

As we have explained above, the fact that some teachings in the prior art conflict with others does not render the findings of the district court clearly erroneous per se. Rather, the prior art must be considered as a whole for what it teaches. We understand the prior art, viewed as a whole, to teach that the addition of a tertiary amine sometimes works to improve the yield of McMurry reactions, especially when a tertiary amine is used in relatively low concentrations. In light of this, we cannot say that the district court clearly erred in finding that the prior art would have provided the skilled artisan with a motivation to combine references so as to use pyridine in the McMurry reaction. We wish to emphasize that this is not a case where the prior art's lack of definiteness or certainty about the result of using a tertiary amine in a specific reaction system renders the inventive subject matter "obvious to try" but not obvious. While we have made clear that "'obvious to try' is not the standard under § 103[,] . . . the meaning of this maxim is sometimes lost." In re O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988). In O'Farrell, we opined that:

> [This] admonition . . . has been directed mainly at two kinds of error[, namely where] . . . what would have been "obvious to try" would have been . . . to vary all parameters or try each of numerous possible choices

> . . . where the prior art gave . . . no direction as to which of many possible choices is likely to be successful[or] . . . to explore . . . a promising field of experimentation, where the prior art gave only general guidance . . . .

Id. (citations omitted). In the instant case there are not numerous parameters to vary. Rather, the principal parameter is the concentration of tertiary amine that should be used, and the prior art teaches that if the tertiary amine were to have any positive effect at all, it would be when it was present at low concentrations. Likewise, this is not a case where the prior art gives merely general guidance. In contrast, the guidance is quite clear—namely, that McMurry reactions of this kind can sometimes be optimized by adding low levels of a tertiary amine.

For the aforementioned reasons, we find no clear error in the district court's determination that skilled artisans in possession of the Rolabo patent and the prior art would have not only been motivated to add a tertiary amine but that they would have possessed a reasonable expectation that they would succeed in optimizing the reaction. Reviewing de novo the trial court's application of these factual findings to reach the legal conclusion of obviousness, we likewise find no error. Accordingly, we agree with the district court's determination that the addition of a tertiary amine to a McMurry reaction would have been obvious in view of the Rolabo patent and the prior art. Because this obviousness finding satisfies the second prong of the two-way test for an interference-in-fact, we affirm the district court's determination that an interference-in-fact existed.

As a final matter, we note that we find no merit in Rolabo's contention that we should exclude from the subject matter of the interference that portion of its invention that is directed to running reactions where titanium is present in specific concentration

ranges (claims 10 and 11 of the '827 patent). Claim 10 requires a relative titanium concentration of 1.5:1 to 4:1, and claim 11 requires a ratio of 2:1 to 3:1. The district court relied on the testimony of Medichem's expert witness, Dr. Finney, in holding that all of the various claims of the '827 patent were "essentially identical to one another and substantially the same as claim 2 of Medichem's patent." See Medichem III, 2004 WL 2674632 at *4. Rolabo argues that Finney's expert testimony was "conclusory" and therefore insufficient to establish an interference. However, it is clear from the record that Finney's testimony was far from conclusory. In fact, Finney provided a solid factual basis for his opinion, stating that

> "[c]laim 10 says that you should have between, a ratio of one and a half to 4 to 1 titanium to dibenzosuberone. Claim 11 states the range should be 2 to 1 to 3 to 1. These are both perfectly normal ranges. And in fact, the patent examples in the '827 [Rolabo's] patent specify I think about a 2.2 to 1 ratio. . . ."

Indeed, other evidence of record also supports the conclusion that these are normal ranges. The Banerji reference discloses ratios of 2:1 and 1:1, Ishida discloses ratios of 1.5:1, 2.5:1 and 5:1, and Lenoir discloses a ratio of about 1:1.

In short, it is clear that Rolabo's claims 10 and 11 are directed to titanium ratios that are entirely within the range of the prior art, and this fact is dispositive. This court has held that "[s]electing a narrow range from within a somewhat broader range disclosed in a prior art reference is no less obvious than identifying a range that simply overlaps a disclosed range." In re Peterson, 315 F.3d 1325, 1330 (Fed. Cir. 2003). Moreover, when "the claimed ranges are completely encompassed by the prior art, the conclusion is even more compelling than in cases of mere overlap." Id. We have explained that the "normal desire of scientists or artisans to improve upon what is

already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." Id. Therefore, because Rolabo's claims 10 and 11 are directed to ratios that are entirely within the prior art, the district court properly held those claims to be part of the interfering subject matter pursuant to the two-way test.

B. Identification of Interfering Subject Matter

Having affirmed the district court's determination that an interference-in-fact exists, and that it properly includes those claims directed to specific titanium ratios, this court turns to address Rolabo's procedural argument that the district court erred when it failed to comply with the Board's practice of articulating a precise count of the interference prior to making priority determinations.

This court has not yet addressed "whether district courts handling interfering patent suits under § 291 must define this interfering subject matter in a way similar to a count." Slip Track Sys., Inc. v. Metal-Lite, Inc., 304 F.3d 1256, 1264 (Fed. Cir. 2002). Nevertheless, we have made clear that at least "a single description of the interfering subject matter is necessary for a determination of priority." Id.

That said, Slip Track does not require a court to refer explicitly to the interfering subject matter as a "count," and we believe that in this case the district court was clear about the identity of the interfering subject matter, stating in its opinion "all the various claims of the '827 patent are essentially identical to one another and substantially the same as claim 2 of Medichem's patent." Medichem III, 2004 WL 2674632 at *4. Moreover, to the extent that the district court may not have been clear about whether the tertiary amine limitation was part of the interfering subject matter, we can resolve

this issue on appeal. See Slip Track, 304 F.3d at 1264-65 (holding that where "the parties . . . dispute only whether one limitation is part of the interfering subject matter, and determination of this issue is dependent upon issues of law alone, we will resolve this issue on appeal.") Accordingly, we hold that the interfering subject matter in this case does not include the limitation of the tertiary amine, and corresponds to claim 17 of Rolabo's '827 patent. See id. 1265 ("Since the claims of the '760 patent do not include a wallboard . . . the wallboard cannot be an element of the interfering subject matter in this case, even though it is a limitation in the claims of the '203 patent.").[7]

C. Priority of Invention

Finally, we review the district court's award of priority of invention to Medichem. Because the Medichem '100 patent issued from an application that had a later effective filing date than did Rolabo's '827 patent application, see supra note 4, Medichem bears the burden of establishing priority by a preponderance of the evidence. See Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1365 (Fed. Cir. 2004) ("[U]nder 35 U.S.C. § 291, a party that does not have the earliest effective filing date needs only to demonstrate by a preponderance of the evidence that it was the first to invent if the two patents or applications at issue were co-pending before the PTO . . . ."). Medichem bears no

[7] We note that in parallel interference proceedings, pursuant to 35 U.S.C. § 135, the Board reached a similar definition of the count. See Stampa v. Jackson, 65 U.S.P.Q.2d 1942, 1948 (B.P.A.I. 2002) (defining the count as Jackson's (Rolabo's) claim 17).

heightened burden, because neither patent enjoys a statutory presumption of validity. See id. ("[T]he presumption of validity is nonexistent and the preponderance of the evidence burden is appropriate even if both of the patents have issued by the time a section 291 interference proceeding is initiated in a district court.").

We have held that "priority of invention goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive of the invention and that it exercised reasonable diligence in later reducing that invention to practice." Cooper v. Goldfarb, 154 F.3d 1321, 1327 (Fed. Cir. 1998). Here, because neither party relied on a date of conception, priority is properly awarded to the party that was the first to reduce its invention to practice, either actually or constructively. Rolabo relies on its date of constructive reduction to practice, namely its February 26, 1997 effective filing date. Medichem, on the other hand, alleges that it achieved an actual reduction to practice in the spring of 1996, a date which if proven would antecede Rolabo's filing date, and thereby entitle it to priority. See supra note 4 (effective filing dates).

In order to establish an actual reduction to practice, Medichem must establish three things: "(1) construct[ion of] an embodiment or perform[ance of] a process that met all the limitations of the interference count; [ ] (2) . . . determin[ation] that the invention would work for its intended purpose," Cooper, 154 F.3d at 1327; and (3) the existence of sufficient evidence to corroborate inventor testimony regarding these events, see id. at 1330 ("In order to establish an actual reduction to practice, an inventor's testimony must be corroborated by independent evidence."). The key issue

on appeal is the last one, namely whether Medichem provided adequate corroboration of the inventors' testimony regarding the alleged actual reduction to practice.

For purposes of conceptual clarity, as well as clarity of language, it should be noted that no similar condition of "corroboration" is imposed on an inventor's notebook, or indeed on any documentary or physical evidence, as a condition for its serving as evidence of reduction to practice. See, e.g., Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1577-78 (Fed. Cir. 1996) (explaining that "[t]his court does not require corroboration where a party seeks to prove conception through the use of physical exhibits [because t]he trier of fact can conclude for itself what documents show, aided by testimony as to what the exhibit would mean to one skilled in the art"); Price v. Symsek, 988 F.2d 1187, 1195 (Fed. Cir. 1993) ("Only the inventor's testimony requires corroboration before it can be considered."). Of course, the credibility (and therefore the corroborative value) of an inventor's notebook may vary. Nevertheless, a notebook, unlike the oral testimony of an inventor, may be weighed, for whatever it is worth, in the final determination of reduction to practice. However, in a case involving reduction to practice, an unwitnessed notebook is insufficient on its own to support a claim of reduction to practice. See Reese v. Hurst, 661 F.2d 1222, 1232 (CCPA 1981) ("The inventors' notebooks are accorded no more weight than the inventors' testimony in this instance, since they were not witnessed or signed and were unseen by any witness until after this interference was declared."); Hahn v. Wong, 892 F.2d 1028, 1033 (Fed. Cir. 1989) (stating that "affiants' statements that by a certain date they had 'read and understood' specified pages of Stephen Hahn's laboratory notebooks did not corroborate a reduction to practice . . . because they established only that those pages

existed on a certain date . . . [and] did not independently corroborate the statements made on those pages); Singh v. Brake, 222 F.3d 1362, 1370 (Fed. Cir. 2000) (stating that Hahn v. Wong did not nullify the value of laboratory notebooks in corroborating conception because "the standard of proof required to corroborate a reduction to practice [is] more stringent . . . than that required to corroborate a conception.").[8] Once properly admitted into evidence, documentary and physical evidence is assigned probative value and collectively weighed to determine whether reduction to practice has been achieved. This is what is meant by the maxim that documentary and physical evidence do not require "corroboration."

1. Corroboration

Credibility concerns undergird the corroboration requirement, the purpose of which is to prevent fraud. See Chen v. Bouchard, 347 F.3d 1299, 1309 (Fed. Cir. 2003) ("[T]he purpose of corroboration . . . is to prevent fraud, by providing independent confirmation of the inventor's testimony.") (internal quotations omitted). As such, the corroboration requirement provides an additional safeguard against courts being deceived by inventors who may be tempted to mischaracterize the events of the past through their testimony. See Mahurkar, 79 F.3d at 1577 ("While perhaps prophylactic in application given the unique abilities of trial court judges and juries to assess credibility, the rule provides a bright line for both district courts and the PTO to follow in addressing the difficult issues related to invention dates.").

[8] Cf. Stern v. Trs. of Columbia Univ., No. 05-1291, slip op. at 5 (Fed. Cir. Jan. 17, 2006) ("[R]egardless of the contents of the notebooks, unwitnessed laboratory notebooks on their own are insufficient to support his claim [of conception, and therefore] of co-inventorship.").

Sufficiency of corroboration is determined by using a "rule of reason" analysis, under which all pertinent evidence is examined when determining the credibility of an inventor's testimony. See Price v. Symsek, 988 F.2d 1187, 1195 (Fed. Cir. 1993) ("'A rule of reason' analysis is applied to determine whether the inventor's prior conception testimony has been corroborated."); Berges v. Gottstein, 618 F.2d 771, 776 (CCPA 1980) ("In the final analysis, each corroboration case must be decided on its own facts with a view to deciding whether the evidence as a whole is persuasive.").

The requirement of independent knowledge remains key to the corroboration inquiry. See Reese v. Hurst, 661 F.2d 1222, 1225 (CCPA 1981) ("[A]doption of the 'rule of reason' has not altered the requirement that evidence of corroboration must not depend solely on the inventor himself."). "Independent corroboration may consist of testimony of a witness, other than the inventor, to the actual reduction to practice or it may consist of evidence of surrounding facts and circumstances independent of information received from the inventor." Id. One consequence of the independence requirement is that testimony of one co-inventor cannot be used to help corroborate the testimony of another. See, e.g., Lacks Indus. v. McKechnie Vehicle Components USA, Inc., 322 F.3d 1335, 1350 (Fed. Cir. 2003) (opining that the Special Master rightly refused to accept cross-corroboration of oral testimony as being adequate).

Despite the importance of the independence requirement, however, "[t]he law does not impose an impossible standard of 'independence' on corroborative evidence by requiring that every point of a reduction to practice be corroborated by evidence having a source totally independent of the inventor. . . ." Cooper v. Goldfarb, 154 F.3d at 1330 (internal quotations omitted). Similarly, "it is not necessary to produce an actual

over-the-shoulder observer. Rather, sufficient circumstantial evidence of an independent nature can satisfy the corroboration requirement." Id.

When an inventor claims a process for making a chemical compound rather than the compound itself, it is the successful reduction to practice of the process that must be corroborated, and not merely the successful production of the compound per se. Thus, spectral evidence that might be sufficient per se to corroborate a claim directed to the product will generally not be sufficient to corroborate a claim directed to the process, in the absence of some evidence to corroborate that the product was produced via that process.

2. Standard of Review

Whether or not corroboration exists is a question of fact, the district court's determination of which we review for clear error. This is true because "issues of conception and reduction to practice are questions of law predicated on subsidiary factual findings," Eaton v. Evans, 204 F.3d 1094, 1097 (Fed. Cir. 2000), and corroboration is properly viewed as a subsidiary factual finding. See Singh v. Brake, 222 F.3d at 1368 (implying that corroboration is a question of fact by holding that "substantial evidence supports the Board's finding that this [notebook] entry alone was insufficient to corroborate Singh's testimony . . . .")(emphasis added).

Before reviewing the determination of the court below, we note that it is true that corroboration is fundamentally about "credibility," see supra Discussion, Part C.1, and that in reviewing factual findings under the clear error standard, this court "gives great deference to the district court's decisions regarding credibility of witnesses." See Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1378-79 (Fed. Cir. 2000)

(internal quotations omitted). Indeed, such deference is appropriately accorded to assessments of witness credibility because "only the trial judge can be aware of the variations in demeanor and tone of voice that bear so heavily on the listener's understanding of and belief in what is said." Anderson v. Bessemer City, 470 U.S. 564, 575 (1985).

Nonetheless, such deference is often of little consequence in a corroboration inquiry because the raison d'etre of the corroboration requirement is our refusal to base priority determinations on a court's uncorroborated assessments of a testifying inventor's credibility. Even the most credible inventor testimony is a fortiori required to be corroborated by independent evidence, which may consist of documentary evidence as well as the testimony of non-inventors. To the extent that a district court's finding of corroboration rests on its assessment of the credibility of non-inventor testimony, we apply the deferential standard of review stated in Ecolochem. To the extent that it rests, as it does here, on the district court's assessment of documentary, as opposed to testimonial evidence, we still apply clear error review; however, clear error is less difficult to establish.

3. Analysis

The parties in this case dispute whether or not there was adequate corroboration of the inventors' testimony that Medichem had actually reduced to practice the process of the claimed invention before Rolabo's effective filing date. Medichem put forward two

principal types of corroborating evidence: documentary evidence generated by inventors and that generated by non-inventors.[9]

In the first category, it produced a documented request for the analysis of a sample, purported to have been produced via the claimed synthetic route, which was sent by one co-inventor to another. Also in this category were the NMR spectral data obtained by the co-inventor pursuant to that request. These spectra were consistent with loratadine, and the accuracy of that chemical identification is not being challenged. Finally, this category includes the original laboratory notebook of co-inventor Dr. Rodriguez. In the second category, documentary evidence by non-inventors, there is the original laboratory notebook of former Medichem employee, and non-inventor, Lola Casas.

This court now turns to consider the corroborative value of the three principal pieces of potentially corroborative evidence: the NMR spectra, the notebooks of Medichem's inventors, and the notebook of non-inventor Casas. We note at the outset that the problem with the dated NMR data is that at most they corroborate that the inventors were in possession of the chemical loratadine as of that date; they do not, in themselves, adequately corroborate the claimed process, as they do not establish whether the sample that was analyzed was actually produced by that process. If this case dealt with a claim to a composition of matter, rather than to a process, the NMR evidence might very well take on a different relevance in this regard. As far as the corroborative value of the inventors' notebooks is concerned, they were not witnessed,

[9] This patent bore a number of co-inventors, many of whom testified at trial. As we have noted above, the testimony of one inventor cannot be corroborated by the testimony of co-inventors.

and they do not provide an "independent" source of authority on the issue of reduction to practice. Hence, they have minimum corroborative value.

It is clear to this court, therefore, that Medichem's claim of corroboration stands or falls with the modicum of additional corroborative value that can properly be assigned to non-inventor Casas' notebook.[10] However, Casas did not testify regarding the notebook or the genuineness of its contents. In addition, although Casas' notebook was dated, it was neither signed nor witnessed, and inventor Rodriguez testified that she and Casas had made entries in each others' notebooks. Rodriguez characterized these occasions as not out of the ordinary. As a result, the district court was clearly reliant on the inventor to help to identify the author of specific entries made in Casas' notebook, because in a reduction to practice inquiry, only those passages of the unsigned, unwitnessed notebooks authored by non-inventor Casas could possess significant corroborative value. In addition, without testimony from Casas, the court lacked any non-inventor testimony regarding the genuineness of the notebook's contents.

We also note that Medichem admitted fraudulently backdating certain documents relating to a purported 1995 reduction to practice. Even though the backdating of the 1995 documents was unrelated to the critical pages in Casas' notebook, which purport

[10] When an inventor attempts to offer into evidence the notebook of a non-inventor as evidence of corroboration, evidentiary issues might be implicated. For example, the notebook is likely to be hearsay, and if so, there may be an issue as to whether or not it falls within an exception to the hearsay rule, such as the business record exception. Indeed, in Chen v. Bouchard, this court affirmed the decision of the Board of Patent Appeals and Interferences to exclude as inadmissible hearsay a non-inventor's notebooks, which had been offered to corroborate reduction to practice where, as in the instant case, the non-inventor did not testify. 347 F.3d 1299, 1308 (Fed. Cir. 2003).

to establish a reduction to practice in 1996, the district court found that the credibility of the Medichem inventors was accordingly diminished.

Where a laboratory notebook authored by a non-inventor is offered into evidence pursuant to authentication by an inventor, where the author of the notebook has not testified at trial or otherwise attested to its authenticity, and where the notebook has not been signed or witnessed and has not been maintained in reasonable accordance with good laboratory practices sufficient to reasonably ensure its genuineness under the circumstances, then the corroborative value of the notebook is minimal. Given the facts of this case, Casas' notebook should therefore not be accorded much corroborative value. In view of the minimal corroborative value of the inventors' notebooks and the limited value of the NMR spectrum, we conclude that the evidence, evaluated as a whole under the rule of reason, is insufficient as a matter of law to corroborate Medichem's reduction to practice.

The district court did not specifically address corroboration in its obviousness inquiry, a fact that might, in some circumstances, hamper our ability to conduct clear error review. Here, however, the facts of the case admit of only one conclusion as a matter of law, and we therefore decide the case without remanding to the district court for an explanation of why it implicitly found corroboration to be present. We hold that corroboration is absent and that the district court therefore erred in reaching its legal conclusion that Medichem had reduced its invention to practice in the spring of 1996. Accordingly, we reverse the district court's award of priority to Medichem.

AFFIRMED-IN-PART, REVERSED-IN-PART

No costs.