United States Court of Appeals for the Federal Circuit

03-1336, -1337

ELI LILLY AND COMPANY,

Plaintiff-Appellant,

v.

ARADIGM CORPORATION,

Defendant-Cross Appellant.

Donald E. Knebel, Barnes & Thornburg, of Indianapolis, Indiana, argued for plaintiff-appellant. With him on the brief were Todd G. Vare and Erin Roth Bohannon.

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Appealed from: United States District Court for the Southern District of Indiana

Judge Richard L. Young

United States Court of Appeals for the Federal Circuit

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v.

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DECIDED: July 20, 2004

Before LOURIE, CLEVENGER, and GAJARSA, Circuit Judges.

Opinion for the court filed by Circuit Judge CLEVENGER. Concurring opinion filed by Circuit Judge LOURIE.

CLEVENGER, Circuit Judge.

Eli Lilly and Company ("Lilly") sued Aradigm Corporation ("Aradigm") seeking, inter alia, to have two of its scientists recognized as joint inventors on Aradigm's U.S. Patent No. 5,888,477 ("the '477 patent"). Based on a jury verdict, the United States District Court for the Southern District of Indiana entered final judgment in favor of Lilly insofar as it ordered the Patent and Trademark Office to

add one of Lilly's scientists, Dr. DiMarchi, as an inventor. Eli Lilly & Co. v. Aradigm Corp., No. IP 98-828-C-Y/F (S.D. Ind. Mar. 5, 2003). On the inventorship issue, Aradigm cross appeals and we reverse.

In the same district court proceedings, Lilly also sought to recover damages based on contract and unjust enrichment causes of action. The district court entered final judgment in favor of Aradigm on the unjust enrichment claim and in favor of Lilly on the contract claim, but it awarded only nominal contract damages to Lilly. Id. Lilly appeals the district court's judgment on these state law claims, and we affirm.

I

Lilly is a pharmaceutical company. In May 1996, U.S. Patent No. 5,514,646 ("the '646 patent") issued to Lilly. It claims among other inventions the insulin analog "lispro" (now commercially marketed by Lilly as Humalog®), and it lists Dr. DiMarchi as an inventor. Traditionally, regular, or natural, insulin is administered by subcutaneous injection, i.e., via a needle that deposits the insulin under the skin, to help diabetics regulate their blood glucose levels. When regular insulin molecules are in aqueous solution in the syringe, they self-associate into a stable hexamer, or six-molecule cluster. It is believed that the approximately thirty-minute delay between the insulin's injection and the onset of its therapeutic effect can be traced to the time required for the hexamer delivered under the skin to disassociate into unclustered monomers and to diffuse away from the injection site and into the blood stream.

Lispro is a modified version of regular insulin. Like all proteins, insulin is a molecule made up of linear sequences of amino acids strung together in chains. Lispro is comprised of chains of amino acids identical to those in regular insulin except that two amino acids at one point in one of the chains are reversed in order. According to the '646 patent, this slight structural alteration makes lispro "less prone to . . . self-association" than regular insulin and endows lispro with "a comparatively more rapid onset of activity," while at the same time enabling lispro to "retain[] the biological activity of [regular] insulin." '646 patent, col. 1, ll. 17-20. In other words, "[a]lthough [lispro] exists in solution as a

hexamer, it very rapidly disassociates into a virtually entirely monomeric form following subcutaneous administration . . . [permitting it to be] absorbed quantitatively faster than [regular] insulin after subcutaneous administration." '477 patent, col. 12, ll. 14-19.

Aradigm's business focuses on drug delivery through the inhalation of aerosols. In January 1997, a number of Aradigm scientists filed a patent application that, in March 1999, issued as the '477 patent. Titled "Use of Monomeric Insulin as a Means for Improving the Bioavailability of Inhaled Insulin," Aradigm's '477 patent claims methods of aerosolized administration of lispro, among other monomeric insulin analogs, in which the lispro "quickly enters the circulatory system after being inhaled into the lung." Id. at col. 3, ll. 9-10. One difficulty with administering regular insulin in aerosolized form is believed to be that inhaled insulin "is sequestered in the lung to a significant degree" and therefore does not rapidly or predictably enter the bloodstream where insulin must be located to have its therapeutic effect. Id. at col. 13, l. 8. When filing the '477 patent, Aradigm believed that inhalation of lispro instead of regular insulin would reduce the tendency of insulin to remain in the lungs because, "as with subcutaneous delivery, the disassociation of insulin from hexameric to monomeric form is an important first step prior to the absorption of insulin into the blood stream," and because lispro dissociates more rapidly than regular insulin does. Id. at col. 13, ll. 15-18.

As relevant to this appeal, the '477 patent contains the following method claims:

> 5. A method of improving the bioavailability of insulin delivered via the lung, comprising:
> aerosolizing a formulation of an insulin analog which analog rapidly disassociates into monomeric form;
> inhaling the aerosolized formulation of the insulin analog into the lungs in a manner which allows the particles of the insulin analog to deposit on the lung tissue.
>
> 6. The method of claim 5, wherein the inhaled insulin analog is insulin lispro which rapidly disassociates in a monomeric form producing a relative bioavailablity greater than twice that seen after the inhalation of a similar amount of recombinant human insulin.
>
> 15. A method of reproducibly effecting a serum glucose level, comprising:
> aerosolizing a formulation comprising monomeric insulin;
> administering the aerosolized formulation.
>
> 17. The method of claim 15, wherein the monomeric insulin is insulin lispro.

Id. at col. 49, l. 65 to col. 50, l. 10; col. 50, ll. 38-42, 48-49.

II

All of Lilly's allegations reduce to a single alleged wrong: that Aradigm improperly appropriated information about the advantages of pulmonary delivery of lispro from Lilly and incorrectly claimed the invention in the '477 patent as exclusively its own. In 1995 and 1996, Lilly and Aradigm held four meetings to discuss a possible collaboration that would take advantage of Lilly's expertise in insulin compounds and Aradigm's expertise in aerosolized drug delivery. Several scientists from Lilly were involved in the four meetings with Aradigm scientists: In June and November of 1995, Dr. Harrison from Lilly attended; in June 1996, Dr. Roeder from Lilly attended; and in July 1996, Drs. DiMarchi and Wolff from Lilly, among others, attended. Lilly insists that its scientists conveyed to Aradigm during these meetings the specific advantages to be expected from using lispro instead of regular insulin in an aerosol delivery device.

In the district court, Lilly brought a claim under 35 U.S.C. § 256 to address the alleged omission of Drs. Harrison and DiMarchi from the list of inventors on the '477 patent,[1] arguing to the jury that both were joint inventors of the inventions in dependent claims 6 and 17. The verdict form instructed the jury to answer whether or not Lilly had proved by clear and convincing evidence that either Dr. Harrison or Dr. DiMarchi had contributed to either of the two following inventions: "inhaling an aerosolized formulation of insulin lispro into the lungs, which produces a relative bioavailability greater than twice that seen after the inhalation of a similar amount of [regular] insulin," or "a method for aerosolizing a formulation of insulin lispro and administering that aerosolized formulation." The former states the invention of claim 6, and the latter states the invention of claim 17. The jury found that Dr. DiMarchi only—not Dr. Harrison—was a co-inventor of the former invention claimed in claim 6, but that neither Lilly scientist was a co-inventor of the latter invention of a method for aerosolizing and administering lispro claimed in claim 17.

In its cross-appeal, which we address first, Aradigm argues that the jury verdict finding Dr. DiMarchi to be a co-inventor of claim 6 cannot stand. Aradigm argues that the district court's

instructions to the jury on the inventorship issue were legally erroneous, and that, even if the instructions were not erroneous, Lilly did not introduce substantial evidence to demonstrate by clear and convincing evidence that Dr. DiMarchi was a co-inventor of the invention in claim 6. We hold that the instructions were not erroneous, but that the record does not contain substantial evidence to support the jury's finding that Dr. DiMarchi was a co-inventor given Lilly's clear and convincing burden of proof on the issue. Lilly argues that, if we reverse the jury verdict due to insufficient evidence, a new trial is required because Lilly should only have been required to satisfy a preponderance of the evidence burden of proof to demonstrate co-inventorship.[2] We reject this argument.[3]

Lilly also tried two contract claims and an unjust enrichment claim to the jury. These claims resulted in only two dollars of nominal damages against Aradigm. In its post-judgment briefing, Lilly did not argue that the jury's findings on these claims were incorrect. Instead, Lilly argued that the jury's findings demonstrated that Lilly was entitled to an injunction prohibiting Aradigm from continuing to file and prosecute patent applications containing information in which Lilly retains contractual or equitable rights. The district court denied Lilly's requests for injunctive relief, and Lilly appeals this denial to us. We affirm.

We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

III

Section 256 creates a cause of action in the district courts for correction of non-joinder of an inventor on a patent provided the non-joinder error occurred without deceptive intent. See 35 U.S.C. § 256 (2000) (permitting correction of inventorship "[w]henever . . . through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part"); MCV, Inc. v. King-Seeley Thermos Co., 870 F.2d 1568, 1571 (Fed. Cir. 1988) (holding that deceptive intent in failing to join an inventor would not permit correction of inventorship under section 256 and could invalidate the patent).[4]

In a section 256 proceeding, "[t]he inventors as named in an issued patent are presumed to be

correct." Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980 (Fed. Cir. 1997). The general rule is that a party alleging misjoinder or non-joinder of inventors must meet the heavy burden of proving its case by clear and convincing evidence, see id. (citing Garret Corp. v. United States, 422 F.2d 874, 880 (Ct. Cl. 1970)),[5] and must provide evidence to corroborate the alleged joint inventor's conception, see Ethicon, Inc. v. United States Surgical Corp., 135 F.3d 1456, 1461 (Fed. Cir. 1998) (holding that "an alleged co-inventor must supply evidence to corroborate his testimony" of conception).

Section 116 of Title 35 is the statutory locus of joint inventorship doctrine. It provides that a person not listed on a patent need not demonstrate that he made a contribution equal in importance to the contribution made by the listed inventors to claim his right to joint inventor status. See 35 U.S.C. § 116 (2000) ("Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent."). In fact, section 116 "sets no explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor." Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997). However, a long line of decisions in this court holds that a person is a joint inventor only if he contributes to the conception of the claimed invention. See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1352 (Fed. Cir. 1998); Fina Oil, 123 F.3d at 1473 ("The case law thus indicates that to be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention."); Sewall v. Walters, 21 F.3d 411, 415 (Fed. Cir. 1994); see also Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1227-28 (Fed. Cir. 1994) ("Conception is the touchstone of inventorship, the completion of the mental part of invention."). The line between actual contributions to conception and the remaining, more prosaic contributions to the inventive process that do not render the contributor a co-inventor is sometimes a difficult one to draw. Contributions to realizing an invention may not amount to a contribution to conception if they merely explain what was "then state of the art," Hess, 106 F.3d at 981, if they are too far removed from the real-world realization of an invention, see, e.g., Garret Corp., 422 F.2d at 881 ("One who merely suggests an idea of a result to be accomplished, rather than means of

accomplishing it, is not a joint inventor."), or if they are focused solely on such realization, see, e.g., Ethicon, 135 F.3d at 1460 ("[O]ne does not qualify as a joint inventor by merely assisting the actual inventor after conception of the claimed invention.").

It is however uncontroversial that the alleged joint inventor seeking to be listed on a patent must demonstrate that his labors were conjoined with the efforts of the named inventors. Joint inventorship under section 116 can only arise when collaboration or concerted effort occurs—that is, when the inventors have some open line of communication during or in temporal proximity to their inventive efforts:

> What is clear is that the statutory word "jointly" is not mere surplusage. For persons to be joint inventors under Section 116, there must be some element of joint behavior, such as collaboration or working under common direction, one inventor seeing a relevant report and building upon it or hearing another's suggestion at a meeting. . . .
>
> [J]oint inventorship under Section 116 requires at least some quantum of collaboration or connection.

Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., 973 F.2d 911, 917 (Fed. Cir. 1992).

A

First, we review Aradigm's suggestion that the jury instructions are erroneous. We apply the law of the regional circuit in which the district court sits, here the Seventh Circuit, to this issue. "The standard of review for jury instructions is prejudicial legal error." Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1201 (Fed. Cir. 2002); see also Hasham v. Cal. State Bd. of Equalization, 200 F.3d 1035, 1051 (7th Cir. 2000) ("[T]he first question to be answered is whether the instructions misstate or insufficiently state the law. If they do, [the next] question [is] whether the flawed instruction 'confused or misled the jury causing prejudice to a litigant.'" (quoting Doe v. Burnham, 6 F.3d 476, 479 (7th Cir. 1993) (citation omitted))). "In reviewing the correctness of jury instructions, the United States Court of Appeals for the Seventh Circuit 'look[s] to the instructions as a whole, in a common sense manner, avoiding fastidiousness, inquiring whether the correct message was conveyed to the jury reasonably well.'" C&F Packing Co. v. IBP, Inc., 224 F.3d 1296, 1303 (Fed Cir. 2000) (quoting Wilk v. Am. Med.

Ass'n, 719 F.2d 207, 218 (7th Cir. 1983)). "A party seeking to alter a judgment based on erroneous jury instructions must establish that (1) it made a proper and timely objection to the jury instructions, (2) those instructions were legally erroneous, (3) the errors had prejudicial effect, and (4) it requested alternative instructions that would have remedied the error." Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1281 (Fed. Cir. 2000) (citations omitted). If the challenging party prevails, then it is entitled to a new trial. Ecolab Inc. v. Paraclipse, Inc., 285 F.3d 1362, 1373 (Fed. Cir. 2002). "Whether a jury instruction is legally erroneous is a question of law," and thus is reviewed without deference to a trial court. Id.

Aradigm initially argues that the district court erred by not construing claim 6 before sending the inventorship issue to the jury. It is true that the legal scope of a claim must be known before the contributions of an alleged co-inventor can be compared to that claim to determine whether the correct inventors were named. See Trovan, Ltd. v. Sokymat SA, Irori, 299 F.3d 1292, 1302 (Fed. Cir. 2002) ("[A]n inventorship analysis, like an infringement or invalidity analysis, begins as a first step with a construction of each asserted claim to determine the subject matter encompassed thereby. The second step is then to compare the alleged contributions of each asserted co-inventor with the subject matter of the properly construed claim to then determine whether the correct inventors were named." (citation omitted)). Aradigm, however, never requested that the district court construe any terms in claim 6 and never offered a construction of claim 6. Only after the presentation of all of the evidence to the jury did Aradigm even suggest that claim construction might be helpful to determine the proper scope of the claimed invention. We hold that Aradigm has waived its right to request a construction of claim 6 and that Aradigm has thereby implicitly conceded that the meanings of the terms in claim 6 are clear and not in need of construction. See United States Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997) (holding that claim construction is required only "when the meaning or scope of technical terms and words of art is unclear and in dispute and requires resolution to determine" the issue before the court).

Likely realizing the difficulties of requesting a claim construction at such an advanced stage of the proceedings, Aradigm next falls back to argue that the jury instructions on inventorship of claim 6

are error because the description in the instructions of the invention to which Dr. DiMarchi was alleged to have contributed prejudicially paraphrased the actual language of claim 6. The jury was presented with descriptions of the invention of claim 6 in two places. First, in final instruction number 20, the jury was told that: "The 'inventions' at issue in this case include: . . . that aerosolized lispro produces a relative bioavailability greater than twice that seen after the inhalation of a similar amount of [regular] human insulin." Second, as earlier described, the jury's verdict form described the invention in claim 6 as "inhaling an aerosolized formulation of insulin lispro into the lungs, which produces a relative bioavailability greater than twice that seen after the inhalation of a similar amount of [regular] insulin." At trial, Aradigm objected to the paraphrasing in jury instruction 20 and the special verdict question, noting that "the jury should be directed to the specific claims to which Lilly claims to have made a contribution rather than these characterizations of the claims," that "a characterization of the claims will confuse the jury," and "that a characterization of the claims simply by pulling words out of them is not a complete description of what is claimed."

We hold that Aradigm cannot demonstrate error in the paraphrasing that merits a new trial for two reasons. First, Aradigm's objection was not sufficiently specific to preserve its prejudicial paraphrasing argument on appeal. It is black letter law that objections must state "distinctly the matter objected to and the grounds of the objection." Fed. R. Civ. P. 51 (2002); see also Avern Trust v. Clarke, 415 F.2d 1238, 1241 (7th Cir. 1969) ("Rule 51 of the Federal Rules of Civil Procedure precludes the assignment of error when no specific objection to an instruction is made."). As the Supreme Court has stated, the purpose of this rule is to ensure that objections point out to a district court its alleged error so that the district court has the first opportunity to correct the error. See Palmer v. Hoffman, 318 U.S. 109, 119 (1943) ("In fairness to the trial court and to the parties, objections to a charge must be sufficiently specific to bring into focus the precise nature of the alleged error."). Aradigm alleged that the jury would be confused by the paraphrase, but Aradigm's objection neither communicated to the district court why the paraphrase was prejudicial nor "br[ought] into focus the precise nature of the alleged error." Id. Aradigm never indicated what aspect of the claim the paraphrase left out. Generically alleging that the wording of a jury instruction is confusing, without suggesting the logical

error the jury might make, does not give the district court the information that it requires to see the alleged error of its ways and to have a meaningful first opportunity to consider changing course.

Second, addressing Aradigm's argument on the merits, we conclude that the jury instructions were not erroneous as a whole. Read in conjunction with independent claim 5, dependent claim 6 claims a method comprising the two steps of "aerosolizing" lispro and "inhaling the aerosolized formulation of [lispro] . . . into the lungs" in a manner in which the lispro "rapidly disassociates in a monomeric form producing a relative bioavailability greater than twice that seen after the inhalation of a similar amount of [regular] insulin." '477 patent, col. 50, ll. 1, 3-4, 7-9. Although it does not recite the aerosolizing of lispro as a distinct first step, the description of the invention on the verdict form does contain the requirement that the invention include "inhaling an aerosolized formulation" of lispro, necessarily encompassing the step of aerosolizing. Thus we see little difference—and certainly not a prejudicial difference—between the language of the claim and the language of the verdict form. In fact, on appeal, Aradigm does not allege error in the statement of the invention on the verdict form.

The statement of the invention in instruction 20, however, recites only one limitation on the method of aerosolizing lispro claimed in claim 6: that aerosolized lispro satisfy the double-bioavailability limitation. We conclude that this is not error prejudicial to Aradigm. The Seventh Circuit "'look[s] to the instructions as a whole, in a common sense manner, avoiding fastidiousness, inquiring whether the correct message was conveyed to the jury reasonably well.'" C&F Packing, 224 F.3d at 1303 (quoting Wilk, 719 F.2d at 218). In light of the verdict form, any alleged error in instruction 20 did not prevent the jury from reasonably discerning the correct message. Additionally, the law of inventorship does not hinge co-inventor status on whether a person contributed to the conception of all the limitations in any one claim of the patent. Rather, the law requires only that a co-inventor make a contribution to the conception of the subject matter of a claim. See 35 U.S.C. § 116 ("Inventors may apply for a patent jointly even though . . . each did not make a contribution to the subject matter of every claim of the patent."); Ethicon, 135 F.3d at 1461-63 (granting co-inventorship status provided the person "contributed to the invention defined by" a claim or "if [the person's] contribution found its way into the defined invention" in a claim). If Dr. DiMarchi had in fact conceived

of the double-bioavailability limitation on the method of inhaling lispro and communicated this conception to Aradigm, then Dr. DiMarchi would on the record before us be a co-inventor of claim 6 as the invention in claim 6 is nothing more than using lispro in the aerosolizing/inhaling method of claim 5 in a manner that meets the double-bioavailability limitation.

Finally, Aradigm argues that the district court's paraphrase of claim 6 permitted the jury to find that Dr. DiMarchi was a co-inventor when Dr. DiMarchi contributed only "a mere realization about the chemical properties of lispro" that were in the public domain. A contribution of information in the prior art cannot give rise to joint inventorship because it is not a contribution to conception. See Hess, 106 F.3d at 981. Aradigm's argument, however, presumes that the limitation of aerosolized lispro "producing a relative bioavailability greater than twice that seen after the inhalation of a similar amount of recombinant human insulin" in claim 6 merely recites a fact of nature. Aradigm argues that the double bioavailability of aerosolized lispro vis-á-vis aerosolized natural insulin is inherent in all uses of aerosolized lispro, and that the double-bioavailability language is therefore not a limitation on the scope of claim 6 at all. Regardless of their veracity, we refuse to accept these presumptions as proven fact for the first time at this point in the proceedings. Furthermore, Aradigm's argument is not an argument that the district court improperly paraphrased claim 6 in the jury instructions, but is rather an argument that claim 6 requires construction because it does not convey its scope through the plain and clear meaning of its language. If a litigant seeks to raise such an argument, it must press the district court to engage in claim construction early in the proceedings. As previously discussed, Aradigm failed to make such a timely request.

B

Next, we turn to Aradigm's argument that there is insufficient evidence in the record to support the jury verdict, that is, to satisfy Lilly's burden to demonstrate by clear and convincing evidence that Dr. DiMarchi was a joint inventor of claim 6 of the '477 patent.

Inventorship is a mixed question of law and fact: The overall inventorship determination is a question of law, but it is premised on underlying questions of fact. See Univ. of Colo. Found., Inc. v.

Am. Cyanamid Co., 342 F.3d 1298, 1304 (Fed. Cir. 2003); Ethicon, 135 F.3d at 1460. When we review the denial of a post-verdict motion for judgment as a matter of law on a mixed question of law and fact given to a jury without a special verdict form detailing the underlying questions of fact, we must sustain the jury's conclusion unless the jury was not presented with substantial evidence to support any set of implicit findings sufficient under the law to arrive at its conclusion. See Applied Med. Res. Corp. v. United States Surgical Corp., 147 F.3d 1374, 1376 (Fed. Cir. 1998) (stating that for the appellant to prevail it must demonstrate that "the facts were not sufficient to support the conclusions necessarily drawn by the jury on the way to its verdict").

"Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Consol. Edison Co. v. NLRB, 305 U.S. 197, 229 (1938). Substantial evidence is not a fixed quantum of evidence: What is or is not substantial may only be determined with respect to the burden of proof that the litigant bore in the trial court. "For example, in reviewing whether the evidence supports a finding of fact . . . the decision might be affirmed if the standard of proof below were 'weight of evidence' and might be reversed on the same record if the standard of proof were 'clear and convincing' evidence." SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n, 718 F.2d 365, 383 (Fed. Cir. 1983) (Nies, J., additional comments); see also, e.g., Juicy Whip, Inc. v. Orange Bang, Inc., 292 F.3d 728, 738 (Fed. Cir. 2002) (reviewing a jury verdict for "substantial evidence satisfying [defendant's] clear and convincing burden of proof" on an invalidity defense).

Dr. DiMarchi's claim to co-inventorship depends on the subject matter communicated during the 1995 and 1996 meetings between Aradigm and Lilly, and Lilly cannot demonstrate by clear and convincing evidence that Dr. DiMarchi communicated to Aradigm's scientists that aerosolized lispro might be used to produce "a relative bioavailability greater than twice that seen after the inhalation of a similar amount of human insulin." Dr. DiMarchi did not state that he communicated this conception to Aradigm's scientists. He only testified that he remembered talking about insulin at a meeting in July of 1996, and that he never talks about insulin without discussing lispro and its properties:

Q: Did you ever have occasion to discuss with Aradigm directly your views on the

> characteristics of the lispro molecule and how it would be effective in an aerosolized delivery system?
> A: [I]f you mention human natural insulin, I'm thinking lispro. So if someone comes to me under a confidentiality agreement and starts to discuss insulin delivery by the pulmonary route, it is just inconceivable that I'm not going to think about lispro and begin to talk about its virtues. (Trial Tr. 343.)
>
> Q: Do you remember discussing lispro during that meeting?
> A: I remember discussing insulin, and, as I have shared with you [insulin and lispro] are one – they are synonymous. We talk about insulin, we are going to talk about lispro. (Trial Tr. 344.)

Dr. Wolff, another Lilly scientist testified that at this meeting "there was a question from Aradigm as to whether there were . . . other molecules that Lilly might be interested in pursuing besides regular insulin, and then Richard DiMarchi said that lispro would be one that would be a candidate." (Trial Tr. 805.) Lilly also argues that an email written by Ms. Hakes, a product development manager for Lilly, demonstrates that Dr. DiMarchi communicated his conception of the relevant invention. The email, however, only summarized a "follow-up" on the July meeting, not the July meeting itself, in which Ms. Hakes stated "that different molecules [other than natural insulin] may offer better treatment of diabetes than natural insulin and that lispro was just one such example." None of this testimony directly states that Dr. DiMarchi communicated to Aradigm that the bioavailability of aerosolized insulin could be increased twofold by using lispro rather than natural insulin. Evidence that Dr. DiMarchi merely suggested that Aradigm try lispro in its aerosol delivery devices is insufficient to support the jury's verdict on claim 6 by clear and convincing evidence.

The testimony of Lilly's Dr. Roeder, who met with Aradigm scientists in June of 1996, is no more helpful to Lilly. At most, Dr. Roeder's testimony shows that he too viewed lispro as a candidate for aerosolization, but damning to Lilly, Dr. Roeder explicitly testified that he did not mention that aerosolized lispro should be used to produce a relative bioavailability greater than twice that seen after inhalation of human insulin.

Without any direct evidence of communication of conception, Lilly relies largely on circumstantial evidence. Lilly argues that there is no evidence in the record that Aradigm was considering using lispro in an aerosol device prior to the July 1996 meeting, that emails and notes

demonstrate Aradigm's post-meeting interest, and that the January 1997 application for the '477 patent proves Aradigm's firm grasp of the concept shortly thereafter. Lilly argues that the jury's inference that Dr. DiMarchi communicated the idea at the July 1996 meeting of aerosolizing lispro rather than insulin to increase bioavailability twofold is therefore a permissible inference. We disagree. While circumstantial evidence may in some cases be sufficient to surmount the clear and convincing evidence burden of proof, we conclude that the circumstantial evidence presented here is insufficient and that the jury's verdict cannot stand.

C

Assuming we were to find, as we have, that there is insufficient evidence in the record to support the jury's finding of clear and convincing evidence to demonstrate Dr. DiMarchi's inventive contribution to claim 6, Lilly, too, argues that the jury instructions contain prejudicial error. Lilly argues that it need only demonstrate that Dr. DiMarchi contributed to the conception of claim 6 by a preponderance of the evidence. Under this less demanding trial court burden of proof, Lilly proposes that the circumstantial evidence in the record is sufficient to support a jury verdict in its favor and that we must therefore remand for a new trial. See Price v. Symsek, 988 F.2d 1187, 1194 (Fed. Cir. 1993) ("[T]he erroneous burden of proof utilized by the [the tribunal below] worked against [appellant's] interest, i.e., it was more difficult to overcome than the proper burden of proof. Such a situation cannot ordinarily be classified as 'harmless.'"). We reject Lilly's argument that a preponderance of the evidence burden is the correct burden in this case.

Lilly does not contend that, as a general rule, the clear and convincing evidence burden of proof announced in Hess, see 106 F.3d at 980, is incorrect. Rather, Lilly argues that its non-joinder inventorship claim falls into an exception to the Hess rule to which the preponderance of the evidence burden of proof applies. As a legal proposition, Lilly proposes that the Hess rule does not apply "when there are two co-pending patent applications claiming the same subject matter" in front of the Patent and Trademark Office ("PTO"), one of which issues as the patent allegedly omitting the inventor, and the other of which was filed by the allegedly omitted inventor. As a factual proposition, Lilly points to a

patent application that it filed prior to the issuance of Aradigm's '477 patent and alleges that its application claims the same subject matter as the claims of the '477 patent at issue in this inventorship dispute.

Doctrinally, Lilly's argument borrows from the burden of proof used in interference proceedings in which multiple parties claim that they deserve exclusive rights to an invention because they were the first to invent it. See 37 C.F.R. § 1.601(i) (2003) ("An interference is a proceeding . . . to determine any question of patentability and priority of invention between two or more parties claiming the same patentable invention." (emphasis omitted)). To succeed in an interference proceeding, regardless of whether it is conducted in the PTO or a district court under 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. See Slip Track Sys., Inc. v. Metal-Lite, Inc., 304 F.3d 1256, 1262 (Fed. Cir. 2002). The general presumption of patent validity does not pertain to patent applications before they issue, so there is no presumption that the inventors on a patent application are correct when two claims in co-pending patent applications assert inherently conflicting rights to the same invention. See Apotex USA, Inc. v. Merck & Co., Inc., 254 F.3d 1031, 1037 n.1 (Fed. Cir. 2001). Provided the applications were co-pending, the timing of the interference proceeding is immaterial: the 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. "However, the presumption [of validity] may effectively be implicated in the case of a priority contest between an issued patent and an application that was filed after the issuance of the patent. In such a situation, the junior party must establish priority of invention by clear and convincing evidence." Id.

To make its burden of proof argument, Lilly does not ask us to make an unprecedented analogical leap directly from a priority claim in an interference proceeding to a joint inventorship claim under section 256. Lilly argues that our decision in Environ Products, Inc. v. Furon Co., 215 F.3d 1261 (Fed. Cir. 2000), has already taken that step, or at least that it strongly counsels us to take that step now. We disagree on both counts. We conclude that Environ Products has not established a preponderance of

the evidence burden of proof in section 256 joint inventorship disputes when the person allegedly omitted from an issued patent had a co-pending patent application claiming the same subject matter as the issued patent. Furthermore, we decline to extend the holding of Environ Products to create such a rule.

Our Environ Products opinion addressed a complicated, multi-party infringement action. Environ accused Advanced Polymer and Furon of infringing its patent. Both Advanced Polymer and Furon raised invalidity defenses based on prior invention. Advanced Polymer relied on a pending patent application to establish priority, and Furon based its defense on its issued patent. In addition, Furon raised a defense of invalidity alleging incorrect inventorship on Environ's patent and filed a separate infringement action against Environ that was consolidated with Enivron's infringement action against Furon. Thus, at the end of the day, Environ Products involved a three-way priority contest between two issued patents and a patent application—all of which were pending before the PTO at the same time. The parties stipulated that Environ's patent, Furon's patent, and Advanced Polymer's application all claimed the same subject matter, and they "agreed on the description of the common subject matter that would serve as the basis for determining who was the original inventor." Id. at 1263.

The district court put the inventorship issue to a jury in the form of a special verdict form. Because Environ's patent had the earliest filing date, id. at 1262, the special verdict form required Advanced Polymer and Furon to provide clear and convincing evidence of priority of invention to prevail but only required Environ to provide preponderant evidence of priority to prevail, id. at 1264. The jury found Environ to be the original inventor of the common subject matter. Id. at 1262.

On appeal, the Federal Circuit held that all parties in the priority contest should only have had to prove their claim to original inventorship by a preponderance of the evidence. The court held that the priority contest was essentially the functional equivalent of the priority phase of an interference proceeding involving patents whose applications had been co-pending before the PTO:

> The challenge to inventorship was raised as an invalidity defense to Environ's charge of infringement . . . . On this basis the district court accorded [Environ's] patent the statutory presumption of validity . . . which requires that invalidity be established by clear

and convincing evidence. . . .

The case at bar differs from those in which the presumption of validity accorded a higher burden of proof to the challenged patent, however, in that the three competing claimants all had patent applications that were co-pending. . . . [H]ad these applications been the subject of an interference proceeding in the PTO or a § 291 proceeding in the district court, the burden of proof of prior invention would be with the junior applicants, but the standard of proof would be the preponderance of the evidence. The formality of invoking § 291 does not affect the standard of proof of priority of invention between co-pending interfering patents, whether the issue arises as a defense in an infringement suit or in an action designated as under § 291. The correct standard of proof of priority of invention, as between co-pending interfering patents, is the preponderance of the evidence, the junior patentee bearing the burden of pleading and proving priority.

Id. at 1265-66.

Environ Products does not bind us here: It did not involve a section 256 claim for non-joinder, and it expressly limited its holding to priority contests. See id. at 1266 n.4 (noting that the holding "relates solely to that of priority of invention of common claimed subject matter in issued patents" and that it "does not affect the standard of proof as to any other question that may be in dispute").

Nor should Environ Products be extended on policy grounds to apply in actions seeking to establish joint inventorship. There are differences between using a co-pending application to prove prior invention and using it to prove joint invention, and these differences counsel against permitting a co-pending application to reduce the burden of proof in an action seeking to correct non-joinder of an inventor. As discussed above, a claim to joint inventorship requires proof of "some element of joint behavior, such as collaboration or working under common direction, one inventor seeing a relevant report and building upon it or hearing another's suggestion at a meeting." Kimberly-Clark, 973 F.2d at 917. The existence of co-pending applications does throw into question the presumption of validity for the first-filed patent insofar as the presumption involves an issue of timing or priority, namely that the patentee was the first to invent. Apotex, 254 F.3d at 1037 n.1. The existence of co-pending applications, however, does not undermine to the same degree the presumption that each of the groups of inventors listed on the patent applications acted independently. The clear and convincing burden of proof is applied to joint inventorship disputes because of a "strong temptation for persons who consulted with the inventor and provided him with materials and advice, to reconstruct, so as to further their own position, the extent of their contribution to the conception of the invention." Hess, 106 F.3d at 980.

Proof of contribution to conception cannot rely entirely on the timing of conception: The burden of demonstrating the required "element of joint behavior," Kimberly-Clark, 973 F.2d at 917, should remain unaffected by an alleged joint inventor's co-pending patent application.

Furthermore, a party seeking to correct non-joinder is not required to risk any rights to any invention of its own, and it should not receive the benefit of a lower standard of proof without the accompanying risk. In an interference proceeding, or in a priority contest that is its functional equivalent as in Environ Products, the junior party places its own patent claims on the line and may lose its rights to those claims if it does not successfully demonstrate priority. In a section 256 action alleging non-joinder, however, the plaintiff does not have to put its patent assets at risk.

Lilly's argument that Environ Products should have controlled in the district court proceedings below is also tenuous because in Environ Products all the parties contesting priority agreed that their patents claimed the same subject matter. The first step of an interference proceeding is to determine whether two patents can and do claim the same subject matter; priority can be adjudicated only after the common subject matter has been identified. See 37 C.F.R. § 1.601(i) ("An interference may be declared . . . when . . . the applications contain claims for the same patentable invention."); see also Fujikawa v. Wattanasin, 93 F.3d 1559, 1569-71 (Fed. Cir. 1996) (affirming the PTO's denial of a motion to declare an interference or to consider priority concerning a particular invention because one of the patent applications at issue did not describe, and therefore could not claim, the invention).

Thus, even in a case seeking to determine priority rather than joint inventorship, there can be no functional equivalent of the priority phase of an interference proceeding as there was in Environ Products unless the parties agree to bypass judicial delineation of the conflicting subject matter. If no such agreement exists, a junior party with an issued patent that was co-pending at the PTO must either bring a formal claim under section 291 to determine if there is conflicting subject matter prior to the priority determination, or it must surmount the clear and convincing burden of proof to demonstrate priority. Lilly and Aradigm never agreed to the fact that Lilly's patent application claimed some of the same subject matter as is claimed in the '477 patent, let alone to the definition of the invention claimed

by both. We cannot, therefore, treat Lilly's inventorship claim as the functional equivalent of the priority determination in an interference proceeding.[6]

There was another forum in which Lilly could have tried a priority claim with a preponderance of the evidence burden of proof. Lilly knew of the '477 patent while its application was pending. Lilly could have sought to provoke an interference proceeding in the PTO based on the '477 patent—either by relying on the existing claim language in its application or by copying the claims of the '477 patent provided those claims were supported by the specification—but it chose not to do so. As Lilly elected not to provoke an interference proceeding in the PTO, it hardly seems unfair to Lilly to deny it the advantages that it would have enjoyed in such a PTO proceeding.

Environ Products prevents form from triumphing over substance in priority contests embedded in infringement proceedings, provided that the parties have stipulated to a definition of the interfering subject matter. The preponderance of the evidence burden of proof that Environ Products establishes, however, is not applicable to Lilly's joint inventorship claim under section 256 because that claim involves neither priority per se nor subject matter that has been determined to be interfering.

IV

Finally, we turn to that part of Lilly's appeal addressing the district court's state-law judgments. Lilly's first argument addresses the district court judgment entered on a contract claim. In 1996, Lilly and Aradigm entered into an Insulin Supply Agreement. Under this agreement, Lilly supplied regular insulin for Aradigm's use in studies investigating the pulmonary delivery of regular insulin. In return, Aradigm agreed, inter alia, that "[a]ll information provided to Aradigm . . . by Lilly will be kept in confidence for at least ten (10) years after execution of this Agreement, unless Lilly gives [Aradigm] written permission to disclose it sooner," that "[d]ata emanating from the . . . studies . . . will not be released by Aradigm . . . without Lilly's review and comment," and that "Lilly will be furnished with a copy of any proposed publication or presentation for review and comment thirty (30) days prior to such presentation or submission for publication." In 1997, Lilly and Aradigm also entered into a Lispro Supply Agreement with similar terms restricting Aradigm's use of lispro-related information.

At trial, Lilly argued that Aradigm breached both of these agreements by filing patent applications, including the '477 patent application, containing information encompassed within the supply agreements without obtaining Lilly's permission and without granting Lilly the opportunity to review the applications. The jury agreed, finding Aradigm in breach of both agreements. The jury awarded nominal damages—the only damages sought by Lilly. In its post-judgment briefing, Lilly requested an injunction prohibiting Aradigm from continuing to breach the supply agreements and, in particular, from filing further patent applications containing information encompassed within the supply agreements without complying with the terms of the contracts. The district court denied Lilly's post-judgment request for injunctive relief on the contract claim, see Eli Lilly & Co. v. Aradigm Corp., No. IP 98-828-C-Y/F, slip op. at 5-6 (S.D. Ind. Mar. 5, 2003) ("Entry on Post-Judgment Motions"), and Lilly appeals this denial to us.

The district court emphasized that Lilly had not requested injunctive relief as a remedy for its contract claim at any point prior to the entry of the judgment. Id., slip op. at 3 ("[A]s of the time of the jury verdict, Lilly had not requested any equitable relief from the court, which, if requested and granted, could have been reflected in the Original Judgment."). Lilly's complaint requested other forms of injunctive relief based on other causes of action, but it did not request equitable relief based on the contract claim. The district court therefore permissibly treated Lilly's post-judgment request for injunctive relief as a motion to amend the judgment under Federal Rule of Civil Procedure 59(e). Under Seventh Circuit law, a district court "may grant a Rule 59(e) motion to alter or amend the judgment if the movant presents newly discovered evidence that was not available at the time of trial or if the movant points to evidence in the record that clearly establishes a manifest error of law or fact." In re Prince, 85 F.3d 314, 324 (7th Cir. 1996). We review an order denying a motion to amend a judgment for abuse of discretion, id., and we conclude that the district court did not abuse its discretion in denying Lilly's belated request for a new form of relief based on breach of contract when Lilly could have made a timely request.

Lilly's second argument addresses the district court judgment entered on an unjust enrichment claim. On the special verdict form presenting the elements of this claim, the jury made two actual

findings in favor or Lilly—that "Lilly provided valuable services or benefits to Aradigm," presumably in the form of information about insulin or lispro, and that "the services or benefits provided were at the express or implied request of Aradigm." However, the jury also made a factual finding against Lilly that "the services or benefits were [not] provided under circumstances such that it is only fair that Lilly be compensated." Based on these factual findings, the district court entered judgment in favor of Aradigm on the unjust enrichment claim. In Lilly's post-judgment briefing, Lilly argued that the district court's judgment is erroneous because the jury's factual findings in Lilly's favor should ineluctably lead to a verdict in Lilly's favor on the unjust enrichment claim. As a corollary, Lilly argues that the jury's finding against Lilly on the fairness of compensation is merely a finding of no compensable monetary damages. Lilly presses this argument because if the judgment was in its favor Lilly believes it would be entitled to the same injunctive relief it sought under the contract claim—namely an injunction prohibiting Aradigm from further use of Dr. DiMarchi's contribution to the '477 patent and from further prosecuting patents based on the lispro study data. The district court denied Lilly's request, concluding that the findings in Lilly's favor were insufficient to support an unjust enrichment claim under Indiana law. Entry on Post-Judgment Motions, slip op. at 1-4.

As in Lilly's contract claim, under Seventh Circuit law, a district court "may grant a Rule 59(e) motion to alter or amend the judgment if the movant presents newly discovered evidence that was not available at the time of trial or if the movant points to evidence in the record that clearly establishes a manifest error of law or fact," and we review an order denying a motion to amend a judgment for abuse of discretion. In re Prince, 85 F.3d at 324. We affirm the district court's denial of Lilly's motion because the district court's interpretation of Indiana law under which a claim of unjust enrichment can be made out only "under circumstances in which equity demands compensation to prevent unjust enrichment," Briggs v. Clinton County Bank & Trust Co., 452 N.E.2d 989, 1004 (Ind. Ct. App. 1983) (internal quotation marks omitted), is neither manifest error nor an abuse of discretion.

V

In conclusion, we affirm the district court's denial of Lilly's requests for post-judgment relief on

the state law claims, but we reverse the district court's denial of Aradigm's motion for judgment as a matter of law on the section 256 joint inventorship claim. There is not sufficient evidence in the record to support the jury's conclusion that Lilly demonstrated by clear and convincing evidence that Dr. DiMarchi collaborated with Aradigm's scientists in a manner that could render him a joint inventor of claim 6 in the '477 patent.

COSTS

No costs.

AFFIRMED-IN-PART AND REVERSED-IN-PART

United States Court of Appeals for the Federal Circuit

03-1336,-1337

ELI LILLY AND COMPANY,

Plaintiff-Appellant,

v.

ARADIGM CORPORATION,

Defendant-Cross Appellant.

LOURIE, Circuit Judge, concurring.

I concur in the result reached by the majority and in its opinion, except for the analysis in Section III.C relating to the burden of proof and its purported basis for distinguishing the Environ case. The majority imposes a "clear and convincing" test for Lilly to show joint inventorship, asserting that a joint inventorship question is different from the priority dispute dealt with in Environ. I disagree; there is of course a difference, but one that should not affect the burden of proof.

First, it is important to note, as the majority does, that a preponderance of the evidence burden of proof applies when the contesting patents are, or were, copending in the Patent and Trademark Office. That is the holding of Environ. The two parties here had copending applications at one time, and thus the Environ burden should apply absent a meaningful distinction. The majority decides that Environ is distinguishable because it deals with priority whereas this case involves joint invention. However, in my view, that is not a meaningful distinction.

While joint inventorship is indeed a different issue from priority, I fail to see how the issues require a different standard. In each case, one party is trying to establish that his activities with respect to the invention claimed in another party's patent occurred at a time and/or in a relationship with that other party either to antedate the other party's effective date of invention or to establish a joint inventor relationship. An identical invention (or at least lack of separate patentability) and either a timeliness or jointness fact need to be shown. Thus, a preponderance of the evidence burden of proof should apply to both. Because of the copendency of the applications, the concern that a second applicant may simply have copied an invention already patented by another does not arise. But we do not need to decide that issue.

The majority holds, and I agree, that Lilly failed to provide substantial evidence to the jury that Dr. DiMarchi conveyed to Aradigm scientists that lispro should be administered by aerosol to achieve a doubling of bioavailability. That being the case, we need not decide that a joint inventorship situation

requires a different, and more severe, burden of proof than a priority situation. Lilly loses simply because it cannot show communication of the same invention as Aradigm claimed. For that reason, I would not make what I believe is a false distinction between Hess and Environ in order to decide an issue that is readily resolvable on a ground already dealt with by the panel. That decision is not necessary to the resolution of this case.

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[1] A person who alleges that he is a co-inventor of the invention claimed in an issued patent who was not listed as an inventor on the patent may bring a cause of action to correct inventorship in a district court under 35 U.S.C. § 256. See MCV, Inc. v. King-Seeley Thermos Co., 870 F.2d 1568, 1570 (Fed. Cir. 1988) (holding that "section 256 . . . explicitly authorizes judicial resolution of co-inventorship contests over issued patents"). At the time Lilly filed its complaint, the '477 patent had not yet issued. Lilly filed its complaint on June 19, 1998, and the '477 patent did not issue until March 30, 1999. Because section 256 creates a cause of action in the district courts only to modify inventorship on issued patents, Lilly initially styled its count seeking a declaratory judgment establishing Lilly's scientists as inventors on Aradigm's patent applications as an action under 35 U.S.C. § 116. The text of section 116, however, only grants the Director of the Patent and Trademark Office the authority to take certain actions and plainly does not create a cause of action in the district courts to modify inventorship on pending patent applications. At the time it filed its complaint, Lilly did not have a cause of action to challenge inventorship on the '477 patent application, and Lilly never moved to amend the complaint.

However, in its ruling on Aradigm's motion for summary judgment on March 31, 2000, after the issue date of the '477 patent, the district court held in a footnote that Lilly's claim seeking to correct an inventor's name could at that time be sustained under section 256. Because neither party objected, we conclude that the district court effected a constructive amendment of the complaint, supplementing the pleadings with a count properly based on section 256.

[2] In its briefs, Lilly styled its burden-of-proof argument as a direct appeal. However, a party lacks standing to appeal a judgment if that judgment grants the party all of the relief requested. See California v. Rooney, 483 U.S. 307, 311 (1987) ("The [lower court's] use of analysis that may have been adverse to the [appellant's] long-term interests does not allow the [appellant] to claim status as a losing party for purposes of this Court's review."); Mueller v. Reich, 54 F.3d 438, 441 (7th Cir. 1995), vacated on other grounds by 519 U.S. 1144 (1997), ("[A] party is not permitted to appeal or cross-appeal unless it wants the judgment of the lower court modified in some way."). Lilly conceded at oral argument that it had no standing to appeal directly on the inventorship issue because it received all of the relief it requested under section 256. The district court correctly held that Dr. DiMarchi's status as a co-inventor of the invention in claim 6 entitled Lilly, as the assignee of Dr. DiMarchi's interest, to the rights of a co-owner of the entire '477 patent. Eli Lilly & Co. v. Aradigm Corp., No. IP 98-828-C-Y/F, slip op. at 5-6 (S.D. Ind. Mar. 5, 2003) (relying on Ethicon, Inc. v. United States Surgical Corp., 135 F.3d 1456, 1465 (Fed. Cir. 1998) ("[I]n the context of joint inventorship, each co-inventor presumptively

owns a pro rata undivided interest in the entire patent, no matter what their respective contributions.")). We therefore reach Lilly's burden-of-proof argument on inventorship only because we conclude, as Aradigm maintains in its cross-appeal, that there is insufficient evidence to support the jury verdict under the more demanding clear and convincing burden of proof.

[3] Lilly does not seek to defend its co-inventorship judgment by contesting the adverse aspects of the jury's fact finding concerning Dr. DiMarchi's lack of a contribution to the invention in claim 17 or Dr. Harrison's lack of a contribution to the invention in either claim. We therefore do not review those aspects of the verdict.

[4] Despite the allegations of misappropriation of proprietary information, neither party has alleged deceptive intent.

[5] As noted above, Lilly argues that, on the facts of this case, the correct burden of proof is the more lenient preponderance of the evidence burden. We address and dismiss that contention below in Section III.C.

[6] Lilly argues that, although the existence of the same subject matter in its application and the '477 patent was not stipulated to by the parties, the examiner's remarks during the course of prosecuting Lilly's patent application prove the existence of mutually claimed subject matter. In a final office action, the examiner rejected all of the claims in Lilly's patent application because they were anticipated by, under section 102(e), or in the alternative obvious over, under section 103(a), the '477 patent. (From the record on appeal, this office action appears to be the last one, as it ends with the statement that "[a]pplicants apparently intend to abandon this application in favor of a related pending application.") To explain the rejection, the examiner further stated that "[t]he instant method claims and the claims of '477 are drawn to essentially the same subject matte[r]." We cannot, however, take this as a determination binding on Aradigm that there is common subject matter. The examiner also explained that the anticipation rejection was based on the disclosure in the specification of the '477 patent, so claims 6 and 17 of the '477 patent—the only ones at issue here—need not have claimed the same subject matter as the claims of Lilly's application for Lilly's application to have been anticipated. Furthermore, the examiner's rejection was not appealed to or reviewed by the Board of Patent Appeals and Interferences.