

**United States Court of Appeals
for the Federal Circuit**

CREATIVE COMPOUNDS, LLC,
Plaintiff-Appellant,

v.

STARMARK LABORATORIES,
Defendant-Appellee.

2010-1445

Appeal from the United States District Court for the Southern District of Florida in case no. 07-CV-22814, Judge Alan S. Gold.

Decided: June 24, 2011

MATTHEW A. ROSENBERG, Law Offices of Matthew Rosenberg, LLC, of St. Louis, Missouri, argued for plaintiff-appellant.

FREDERICK A. TECCE, McShea Tecce, P.C., of Philadelphia, Pennsylvania, argued for defendant-appellee.

Before RADER, *Chief Judge*, CLEVINGER and LINN, *Circuit Judges.*

LINN, *Circuit Judge*.

Creative Compounds, LLC (“Creative”) filed a complaint with the U.S. District Court for the Southern District of Florida against Starmark Laboratories (“Starmark”) seeking a declaratory judgment that Starmark’s patent, U.S. Patent No. 7,109,373 (the “’373 Patent”), is invalid and not infringed. Starmark, in its Answer, alleged infringement of the ’373 patent and sought a declaration that Creative’s patent, U.S. Patent No. 7,129,273 (the “’273 Patent”), is invalid. The district court granted Starmark’s motion for summary judgment on all counts and denied Creative’s motion to dismiss for lack of jurisdiction. Order, *Creative Compounds, LLC v. Starmark Labs., Inc.*, No. 07-cv-22814 (S.D. Fla. Sept. 17, 2009), ECF No. 107 (“*Summary Judgment Order*”). Creative appeals. For the reasons explained below, this court affirms the district court’s judgment as to the ’373 Patent, reverses the district court’s determination as to jurisdiction over the ’273 Patent, and vacates the district court’s decision as to the validity of the ’273 Patent.

I. BACKGROUND

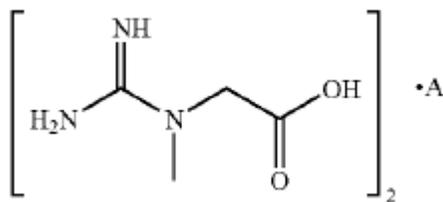
Both the ’373 and ’273 Patents relate to innovations in dietary supplements and food products. These patents relate to creatine formulations that increase the bioavailability of creatine. Creatine is an amino acid derivative naturally present in muscle tissue. ’373 patent col. 1, ll. 15-17. It serves as a central component of the metabolic system and provides energy for work and exercise performance. *Id.* col. 1, ll. 15-20. It assists in producing adenosine triphosphate (“ATP”) during short bursts of high intensity exercise. The depletion of creatine has been associated with the onset of fatigue. *Id.* col. 1, ll. 20-29.

Creatine is most commonly used by body builders looking for a steroid-free way of improving athletic performance. *Id.* col. 2, ll. 4-11. The prior art teaches oral creatine supplementation using creatine monohydrate. *Id.* col. 2, ll. 15-20. Creatine monohydrate is typically sold as a nutritional supplement in powder form. *Id.* Drawbacks of using creatine monohydrate include its low solubility in water and low bioavailability. *Id.* col. 2, ll. 40-65.

A. Starmark's '373 Patent

The application for the '373 Patent was filed on December 18, 2003, claiming priority to a provisional application filed on December 18, 2002. The '373 Patent discloses creatine salts comprising two molecules of creatine and one molecule of dicarboxylic acid. *Id.* col. 3, ll. 55-59. These embodiments purport to provide hydro-soluble creatine salts. *Id.* Claims 1-6 cover creatine salts, whereas claims 7-13 cover methods of making these creatine salts. Independent claim 1 recites:

1. A creatine salt having the formula



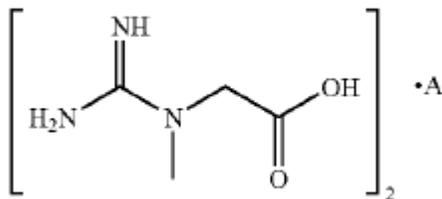
wherein A represents an anion of a dicarboxylic acid.

Dependent claim 3 recites:

3. The creatine salt of claim 1, wherein A is an anion of malic acid.

Independent claim 7, representative of the method claims, recites:

7. A process comprising reacting a molar excess of creatine monohydrate and a dicarboxylic acid or a tricarboxylic acid with heat to form a creatine salt having the formula:



The '373 Patent issued on September 19, 2006, to SAN Corporation ("SAN") listing SAN's CEO, Matthias Boldt ("Boldt"), as the sole inventor. In October 2006, Boldt formed Starmark, where he serves as CEO, president, and sole shareholder. All right, title, and interest in the '373 Patent was then assigned to Starmark.

B. Creative's '273 Patent

Creative filed the application for the '273 Patent on April 30, 2003. Unlike the '373 Patent, which claims a genus of possible creatine salts, Creative's '273 Patent is narrower and covers only dicreatine malate compounds. Claims 1-3 cover a dicreatine malate compound and claims 4-10 cover methods of administering a dicreatine malate compound.

Independent claim 1, representative of the compound claims, recites:

1. A dicreatine malate compound comprising approximately two creatine cations per one malic acid dianion.

Independent claim 4, representative of the method claims, recites:

4. A method of increasing the production of adenosine triphosphate in a human body comprising administering to a subject a dicreatine malate compound comprising approximately two creatine cations per one malic acid dianion.

The '273 Patent issued to Creative on October 31, 2006, about one month after the issuance of Starmark's '373 Patent. Creative's '273 Patent lists Derek Cornelius ("Cornelius") and Gary Haynes ("Haynes") as co-inventors.

C. Factual History

Starmark and Creative are competitors in the creatine market. Creative markets and sells a dicreatine malate compound under the trade name 2CM. Starmark retails its own dicreatine malate compound under its own mark.

In August 2009, after receiving a notice of allowance on the '373 Patent, Boldt, as SAN's CEO, mailed letters to purchasers of dicreatine malate compounds. These letters advised the industry that SAN's '373 Patent would soon issue.

Viewing these letters as threatening, Creative decided to mail letters of its own. Creative's letter advised the industry about a notice of allowance on its competing patent, the '273 Patent. Creative did not simply stop there. Rather, Creative included a letter from its patent counsel. This letter, in relevant part, stated:

It has also come to my attention that SAN Corporation has sent a number of threatening letters to the industry alleging that it also has received a

Notice of Allowance of its patent application entitled *Creatine Salts and Method of Making Same*, [the '373 Patent] Even if SAN is correct that a patent will issue from its application, the patent will not be enforceable because of [Creative's] prior inventions and work.

While Creative did not mail any of these letters to SAN, SAN learned of Creative's letters from its own customers. One such customer informed SAN of Creative's correspondence and refused to license SAN's patent after receiving the above-mentioned "letter from [Creative's] counsel . . . assert[ing] that [the '373 Patent] will not be enforceable because of Mr. Haynes prior invention." Similarly, a letter from another one of SAN's customers stated: "we do not believe [the '373 Patent] to be valid in light of [the '273 Patent] . . . moving forward [we] will no longer be using compounds covered by the ['373 Patent]."

D. Procedural History

In October 2007, Creative filed suit against Starmark in the United States District Court for the Southern District of Florida. Creative sought a declaratory judgment that the '373 Patent was invalid and not infringed. Starmark, in its Answer and Counterclaim, alleged infringement of the '373 Patent and sought a declaratory judgment that the '273 Patent was invalid. The parties stipulated to a claim construction for the '373 Patent.

Starmark filed a motion for summary judgment on all counts. Subsequently, Creative filed a motion to amend its affirmative defense of unclean hands and to dismiss Starmark's declaratory judgment action concerning the '273 Patent for lack of subject matter jurisdiction. The district court ultimately granted Starmark's motion for summary judgment on all counts and denied Creative's motions to amend and dismiss. *Summary Judgment*

Order. The parties stipulated to actual damages of \$112,500, subject to Creative's right to appeal. The district court, after a bench trial, found that Creative's infringement was not willful, that enhanced damages were unwarranted, and that a permanent injunction against Creative was warranted.

Creative timely appeals on multiple grounds. First, Creative challenges the district court's grant of summary judgment that the '373 Patent is not invalid. Second, Creative challenges the district court's grant of summary judgment that the '373 Patent is infringed. Third, Creative challenges the district court's denial of its motion to dismiss Starmark's declaratory judgment counterclaim on the '273 Patent for lack of subject matter jurisdiction. Finally, Creative challenges the district court's denial of Creative's motion to amend its Answer. This court has jurisdiction under 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standards of Review

"We review a district court's grant of summary judgment de novo." *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed. Cir. 1998).

"This court reviews a grant or denial of a motion to dismiss for lack of subject matter jurisdiction de novo." *Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358, 1361 (Fed. Cir. 2009). "The usual standard for reviewing a district court's findings of jurisdictional facts is the clearly erroneous standard." *Lawrence v. Dunbar*, 919 F.2d 1525, 1530 (11th Cir. 1990).

We review an order granting or denying leave to amend under the pertinent regional circuit law. See *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1124 (Fed. Cir. 2004). In the Elev-

enth Circuit, a denial of leave to amend is reviewed for abuse of discretion. *Carruthers v. BSA Adver., Inc.*, 357 F.3d 1213, 1217-18 (11th Cir. 2004).

B. Invalidity of the '373 Patent

The district court granted Starmark's motion for summary judgment that the '373 Patent was not invalid. In doing so, the district court determined that Creative both failed to raise a genuine issue of material fact and, in the absence of opinion or expert testimony, could not succeed as a matter of law in proving invalidity of Starmark's '373 Patent by clear and convincing evidence.

1. Burden of Proof

Before addressing the validity of the '373 Patent, Creative argues that the district court applied the wrong burden of proof for Creative to establish invalidity of Starmark's patent. Relying on *Environ Products, Inc. v. Furon Co.*, 215 F.3d 1261 (Fed. Cir. 2000) and *Slip Track Systems, Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256 (Fed. Cir. 2002), Creative argues "[t]he correct standard of proof of priority of invention, as between co-pending interfering patents, is the preponderance of the evidence, the junior party bearing the burden of pleading and proving priority." *Environ*, 215 F.3d at 1266. Because the '373 Patent and '273 Patent were co-pending and Creative alleges that there is no patentable distinction between claim 1 of the '273 Patent and claim 3 of the '373 Patent, Creative claims it was entitled to a preponderance of the evidence standard for proving invalidity of the '373 Patent.

Starmark responds that the district court applied the proper standard of clear and convincing evidence. According to Starmark, *Environ* and *Slip Track* are distinguishable from this case because both cases involved either an action predicated upon 35 U.S.C. § 291 or a judicial delineation of conflicting subject matter. *See Eli Lilly & Co.*

v. Aradigm Corp., 376 F.3d 1352, 1367 (Fed. Cir. 2004). In this case, Starmark asserts that the parties never stipulated to the common claimed subject matter, that Creative did not present evidence of common claimed subject matter, and that Creative did not plead a count under § 291. Creative “must surmount the clear and convincing burden of proof to demonstrate priority.” *Id.* Finally, Starmark notes that the district court stated that even if it erred in not applying the preponderance standard, “any error could not have ‘changed the result.’” Order at 4, *Creative Compounds, LLC v. Starmark Labs., Inc.*, No. 07-22814 (S.D. Fla. Aug. 31, 2010), ECF No. 187 (citing *Environ*, 215 F.3d at 1267).

This court agrees with Starmark. This court has long held that because “[u]nder 35 U.S.C. § 282, each claim of a patent shall be presumed valid[,] an accused infringer must prove invalidity by clear and convincing evidence.” *Tokai Corp. v. Easton Enters.*, 632 F.3d 1358, 1367 (Fed. Cir. 2011) (citing *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004)); see also *Microsoft Corp. v. i4i Ltd. P’Ship*, 564 U.S. ___, slip op. at 19 (June 9, 2011) (“For nearly 30 years, the Federal Circuit has interpreted § 282 as we do today.”).

Environ and *SlipTrack* are distinguishable on their facts and are limited to a narrow set of circumstances. *Environ* began as a multi-party infringement action in which Environ accused Advanced Polymer and Furon of infringing its patent. *Environ*, 215 F.3d at 1265. Both Advanced Polymer and Furon raised invalidity defenses based on prior invention. *Id.* Two issued patents and a pending application were all co-pending in the PTO at the same time. *Id.* The parties agreed that the same invention was common to the patents and application, “agreed on the description of the common subject matter that would serve as the basis for determining who was the original inventor,” and left it for the jury to determine

which party established priority of invention. *Id.* at 1262-64. Thus, *Environ* turned into a three-way priority contest between two issued patents and a patent application. *Id.* at 1264.

On appeal in *Environ*, Furon argued that the proper standard should have been the “preponderance of the evidence” standard, the same standard used in PTO interference proceedings and § 291 actions in district courts. *Id.* Indeed, this court noted that “had 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.” *Id.* at 1266.

This court determined that the formality of invoking § 291 should not affect the standard of proof for establishing priority of invention when the parties conceded that the patents did, in fact, interfere. Thus, this court stated, “[t]he 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 1266. The accompanying footnote explains that this holding “relates *solely* to that of priority of invention of *common claimed subject matter* in issued patents; this does not affect the standard of proof as to any other question that may be in dispute.” *Id.* at 1266 n.4 (emphases added). Thus, for the lower standard to apply, there must be common claimed subject matter and the junior party bears the burden of raising this issue.

In both interference proceedings and § 291 actions, common claimed subject matter must be identified. In an interference proceeding before the PTO, common claimed subject matter is identified at the outset in the form of a “count.” *See* 37 C.F.R. § 1.601(i) (“An interference may be

declared . . . when . . . any application . . . claims the same patentable invention.”). Similarly, in § 291 proceedings before a district court, “a single description of the interfering subject matter *is necessary for a determination of priority.*” See *SlipTrack*, 304 F.3d at 1264 (appeal from § 291 proceeding); *Albert v. Kevex Corp.*, 729 F.2d 757, 761 (Fed. Cir. 1984) (“[T]he court has no jurisdiction under § 291 unless interference is established.”).

In *Environ*, the parties had already stipulated to the single description of the interfering subject matter. 215 F.3d at 1266. This court concluded that the fact that the priority dispute arose as a defense to an infringement allegation, rather than in a § 291 action, was irrelevant. *Id.* The *Environ* court determined that the district court should have applied the preponderance of the evidence standard, but ultimately concluded that the court’s application of the clear and convincing standard, in that case, was harmless. *Id.* at 1266-67 (“This procedural flaw could not have changed the result”). *SlipTrack* is consistent. In *SlipTrack*, this court applied the preponderance standard where the action was brought under § 291, the parties did not dispute that the patents interfered, and this court had previously stated that “the PTO issued two patents for the same invention on the same day.” *SlipTrack*, 304 F.3d at 1264. Even if Creative is correct that *Eli Lilly’s* characterization of *Environ* was dicta, its reasoning was sound. Because the facts of this case squarely address the issue, we now hold that an accused infringer cannot obtain the benefit of the lower burden of proof that prevails in an interference proceeding simply by alleging, as a defense to infringement, that the asserted patent is invalid based upon a co-pending patent unless common claimed subject matter is first identified and an adjudication of priority is sought.

Here, unlike *Environ*, the parties did not identify or agree on common claimed subject matter. Further, here,

unlike in *SlipTrack*, Creative did not file an action under § 291. Finally, here, unlike in *Environ* or *SlipTrack*, the parties did not seek an adjudication of priority as to identified common subject matter. Absent those special circumstances, the preponderance standard of *Environ* does not apply. See *Eli Lilly*, 376 F.3d at 1367 (stating “*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.”). Creative faces the same presumption of validity faced by all accused infringers and must prove invalidity by clear and convincing evidence. The district court did not err in holding Creative to the clear and convincing standard. Having determined the proper standard, this court will now address the merits of Creative’s invalidity allegation.

2. Merits

Creative challenges the district court’s grant of Star-mark’s motion for summary judgment that the ’373 Patent was not invalid. According to Creative, a genuine issue of material fact exists as to whether the ’373 Patent is invalid under §§ 102(g), (f), and (e). Star-mark responds, and this court agrees, that there is an absence of evidence on at least one element in each of Creative’s three invalidity theories, and, as such, Creative’s conclusory attorney arguments fail to raise a genuine issue of material fact. See *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986) (“[T]he burden on the moving party may be discharged by ‘showing’—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party’s case.”). Although Creative did submit expert testimony, the district court excluded it for failure to comply with the court’s scheduling order and Creative did not appeal that issue. Each invalidity theory is discussed in turn.

i.

Creative contends that the '373 Patent is invalid under § 102(g)(2) because of Creative's prior invention. Creative alleges that Cornelius, named inventor on the '273 Patent, conceived the subject matter of the '373 Patent prior to Boldt, named inventor of the '373 Patent. For support, Creative points to an email order for "dicreatine malate" placed with Creative's Chinese supplier as evidence of prior conception. This email, which also speculates that the method of making dicreatine malate should be the same as the method of making creatine citrate, predates the filing date of the provisional application that led to the '373 Patent. Creative further alleges that Cornelius was diligent through his constructive reduction to practice, when he and co-inventor Haynes filed the application leading to the '273 Patent.

To establish prior invention, Creative was required to prove prior conception. "Conception is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is therefore to be applied in practice." *Singh v. Brake*, 317 F.3d 1334, 1340 (Fed. Cir. 2003). An idea is sufficiently definite for conception "when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue." *Burroughs Wellcome Co. v. Barr Labs.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). "Conception requires (1) the idea of the structure of the chemical compound, and (2) possession of an operative method of making it." *Oka v. Youssefyeh*, 849 F.2d 581, 583 (Fed. Cir. 1988). "When, as is often the case, a method of making a compound with conventional techniques is a matter of routine knowledge among those skilled in the art, a compound has been deemed to have been conceived when it was described, and the question of whether the conceiver was in possession of a method of making it is simply not raised." *Id.*

Here, Creative relied on the 2001 email order for “dicreatine malate” and simply concluded that this sufficiently demonstrated conception of that compound. In this email, Cornelius speculates that the method of making dicreatine malate “should” be like that of making creatine citrate. The district court concluded, and this court agrees, that this email is insufficient to establish prior conception of the subject matter of the ’373 Patent. Creative failed to submit testimony explaining the significance of this email and whether this reference would constitute conception of subject matter within the scope of even a single claim in the ’373 Patent. Moreover, the email fails to reveal knowledge of a process for making dicreatine malate and, to the contrary, merely speculates that the process “should” be like that for creatine citrate. The email far from establishes that Cornelius actually possessed an operative method of making dicreatine malate. In the absence of expert testimony, Creative has failed to show how this email raises a genuine issue of material fact that a method of making dicreatine malate would have been a matter of routine knowledge among those skilled in the art. Creative’s evidentiary shortcomings are not overcome by its reliance on attorney argument. “It is well established that conclusory statements of counsel or a witness that a patent is invalid do not raise a genuine issue of material fact.” *Biotec Biologische Naturverpackungen GmbH v. Biocorp, Inc.*, 249 F.3d 1341, 1353 (Fed. Cir. 2001).

Even if Creative raised a genuine issue of material fact as to conception, which it did not, Creative’s bald assertion that Cornelius was “diligent” during the intervening eighteen months between conception and Creative’s first reduction to practice fails to raise a genuine issue of material fact as to diligence—a required element of Creative’s § 102(g) defense. Merely asserting diligence is not enough; a party must “account for the entire period during which diligence is required.” *Gould v. Schawlow*,

363 F.2d 908, 919 (CCPA 1966). Accordingly, the district court correctly determined that, as to Creative's § 102(g)(2) defense, there were no genuine issues of material fact and that Starmark was entitled to judgment as a matter of law.

ii.

Creative next alleges that the '373 Patent is invalid under § 102(f) because Starmark derived the invention from Cornelius. In order to establish derivation, Creative was required to "prove both prior conception of the invention by another and communication of that conception to the patentee." *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1334 (Fed. Cir. 2003). As stated above, Creative failed to raise a genuine issue of material fact concerning Cornelius's prior conception. Furthermore, as the district court found, Creative failed to present any record evidence supporting any communication or that the alleged communicator actually knew of the claimed subject matter. Creative's only evidence on this issue was the uncorroborated deposition testimony of Cornelius himself. "[T]he case law is unequivocal that an inventor's testimony respecting the facts surrounding a claim of derivation or priority of invention cannot, standing alone, rise to the level of clear and convincing proof." *Price v. Symsek*, 988 F.2d 1187, 1194 (Fed. Cir. 1993). "Such evidence is insufficient as a matter of law to establish invalidity of the patent." *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1370 (Fed. Cir. 1990). Thus, in the absence of any other factual bases for Creative's § 102(f) derivation defense, there were no genuine issues of material fact and Starmark was entitled to judgment as a matter of law.

iii.

Creative also alleges that the '373 Patent is invalid under § 102(e) in light of U.S. Patent App. Pub. No.

2004/0077902, a reference previously considered by the PTO and overcome by the applicant. Again, Creative failed to provide any testimony from one skilled in the art identifying each claim element and explaining how each claim element is disclosed in the prior art reference. *See Schumer*, 308 F.3d at 1315. “It is not the trial judge’s burden to search through lengthy technologic documents for possible evidence.” *Id.* at 1353. Conclusory statements simply mentioning the alleged prior art patent, relying on the same prior art considered by the PTO, and alleging invalidity fail to raise a genuine issue of material fact. *See id.* at 1354 (finding that merely mentioning an allegedly invalidating, yet otherwise unexplained, prior art reference is insufficient to survive a summary judgment of no invalidity); *see also Tokai*, 632 F.3d at 1367 (“[A]lthough the standard of proof does not depart from that of clear and convincing evidence, a party challenging validity shoulders an enhanced burden if the invalidity argument relies on the same prior art considered during examination by the [PTO]”).

Creative failed to raise a single genuine issue of material fact as to even one of its three asserted invalidity theories. Thus, the district court properly granted Starmark’s motion for summary judgment finding the ’373 Patent not invalid. *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1320 (Fed. Cir. 2010) (“When a party has failed to introduce evidence sufficient to establish the existence of an essential element of that party’s case in accordance with the applicable standard of proof, summary judgment is properly granted against that party.”).

C. Infringement of the ’373 Patent

The district court granted Starmark’s motion for summary judgment that Creative’s 2CM product infringed claims 1-3 and 7-10 of Starmark’s ’373 Patent. In moving for summary judgment of infringement, Starmark

relied upon an expert report furnished by Dr. Perlmutter. As to the method claims, claims 7-10, Dr. Perlmutter noted that “Creative has not produced information regarding its manufacturing process.” Nonetheless, Dr. Perlmutter concluded that Creative’s 2CM product was “most likely synthesized” according to claim 7, “consistent with having been manufactured” according to claim 8, and manufactured according to claims 9 and 10.

Creative concedes infringement of the compound claims and only contests infringement of the method claims, claims 7-10. Creative argues that Dr. Perlmutter’s report was entirely devoid of analysis or testing and discusses no evidence of how Creative’s product infringes the method claims. Creative asserts that “[i]t is nonsensical for Starmark to say that the 2CM product has every element of the method claims.” Appellant Br. 28. Creative also takes a “head-in-the-sand” approach to avoid infringement liability, arguing that “Creative merely imports the 2CM product that is manufactured by another party located in China. Creative does not manufacture 2CM or even have any information on the precise manufacturing process used by its supplier.” *Id.* Creative faults the district court for impermissibly shifting the burden to Creative to prove noninfringement. *Summary Judgment Order* at 32 (stating that Creative “has offered no argument as to why or how the process employed to create the product does not infringe the ’373 Patent.”).

Starmark responds that Creative failed to submit expert testimony rebutting Dr. Perlmutter’s conclusions and failed to offer any theory of noninfringement. Starmark contends that Dr. Perlmutter’s expert report satisfied Starmark’s burden, as movant, and therefore the burden shifted to Creative to present specific evidence indicating a genuine issue for trial. *See Air Turbine Tech., Inc. v. Atlas Copco AB*, 410 F.3d 701, 708 (Fed. Cir. 2008). Because Creative failed to point to record evidence con-

cerning the method of making 2CM, Starmark asserts it was entitled to judgment as a matter of law.

“The patentee bears the burden of proving infringement by a preponderance of the evidence.” *SRI Int’l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1123 (Fed. Cir. 1985). If the patentee fails to meet that burden, the patentee loses regardless of whether the accused comes forward with any evidence to the contrary. *See Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008). While the burden typically rests with the patentee to prove infringement, the law makes exceptions. In actions alleging infringement of a process claim under § 271(g), there is a rebuttable presumption that the imported product was made from the patented process if the court finds: “(1) that a substantial likelihood exists that the product was made by the patented process, and (2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine.” 35 U.S.C. § 295. If both conditions are met, “the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.” *Id.* Because the accused infringer is in a far better position to determine the actual manufacturing process than the patentee, fairness dictates that the accused, likely the only party able to obtain this information, reveal this process or face the presumption of infringement. Jeffrey I.D. Lewis & Art C. Cody, *Unscrambling the Egg: Pre-Suit Infringement Investigations of Process and Method Patents*, 84 J. Pat. & Trademark Off. Soc’y 5, 22-23 (2002).

In this case, the district court found that Dr. Perlmutter “opined that the process most likely used to manufacture 2CM is the method claimed in claims 7 through 10 of the [373 Patent].” *Summary Judgment Order* at 32. Furthermore, Starmark sought discovery on the manufac-

turing process by which 2CM was made and “Creative failed to produce documentation regarding the process.” *Id.* Thus, under § 295, the burden of establishing that the product was not made by claims 7-10 was properly on Creative. Because Creative “offered no argument as to why or how the process employed to create the product does not infringe the ’373 Patent,” *id.*, the district court properly granted Starmark’s motion for summary judgment of infringement.

D. Subject Matter Jurisdiction Over the ’273 Patent

The district court denied Creative’s motion to dismiss Starmark’s declaratory judgment counterclaim of invalidity of the ’273 Patent for lack of subject matter jurisdiction. The district court analyzed several letters sent by Creative to the industry. *See Lawrence v. Dunbar*, 919 F.2d 1525, 1529 (11th Cir. 1990) (holding that, in addressing a factual attack to jurisdiction, the court may consider evidence outside the pleadings and is “free to weigh the evidence and satisfy itself as to the existence of its power to hear the case”). These letters contained a separate letter from Creative’s patent counsel opining that the ’373 Patent was invalid in light of the ’273 Patent and Haynes’s prior work. The district court concluded that “the dispute regarding . . . the competing ’273 and ’373 patents runs with the patents. As the ’373 Patent is now held by Starmark, the dispute is between Creative and Starmark.” *Summary Judgment Order* at 9. As further factual support for this finding, the district court also analyzed those letters addressed to Boldt from SAN’s customers in response to Creative’s letters. The district court found these customer letters similarly “reference the validity and enforceability of the ’373 Patent and do not limit the customers’ understanding of the dispute to SAN.” *Id.* at 10.

Creative argues that the district court erred in finding subject matter jurisdiction over Starmark's counterclaim. According to Creative, "the only grounds on which Starmark could establish declaratory judgment jurisdiction is if it was in objective apprehension that Creative would sue it (not its customers) for infringement of the '273 Patent." Appellant Br. 35. Because Creative had never accused Starmark of infringing the '273 Patent, it argues that there is no case or controversy between Creative and Starmark concerning the '273 Patent. Creative contends that the dispute between the '373 and '273 patents is insufficient to create a case or controversy because "if Creative cannot prove that the '373 Patent is invalid, the mere existence of the '273 Patent will not affect the '373 Patent." *Id.* at 34.

Starmark responds that a charge of infringement is just one factor in which an actual case or controversy may arise and that Creative failed to show clear error in the district court's finding that the dispute concerning the competing '273 and '373 Patents was in itself enough to show a case or controversy. Starmark contends that the opinion letters sent by Creative to the industry declaring that Starmark's '373 Patent was invalid in light of Creative's '273 Patent, along with Haynes's prior work, evidenced a "substantial controversy" between parties with "adverse legal interests" sufficient to satisfy the test set forth in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

Subject matter jurisdiction in declaratory judgment actions exists when "the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* at 127. A court's decision must "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opin-

ion advising what the law would be upon a hypothetical state of facts.” *Id.* “The purpose of the Declaratory Judgment Act . . . in patent cases is to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights.” *Micron Tech. Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008) (citations omitted).

The concept of adverse legal interests requires that there be a dispute as to a legal right, such as an underlying legal cause of action that the declaratory defendant could have brought or threatened to bring, if not for the fact that the declaratory plaintiff had preempted it. *Arris Grp., Inc. v. British Telecomm. PLC*, 639 F.3d 1368, 1374-75 (Fed. Cir. 2011); *Microchip Tech. Inc. v. Chamberlain Group, Inc.*, 441 F.3d 936, 943 (Fed. Cir. 2006). “Without an underlying legal cause of action, any adverse economic interest that the declaratory plaintiff may have against the declaratory defendant is not a legally cognizable interest sufficient to confer declaratory judgment jurisdiction.” *Microchip*, 441 F.3d at 943. Starmark contends that Creative could have brought two causes of action: (1) an infringement action alleging infringement of the ’273 Patent, or (2) an action under § 291 alleging an interference between the ’373 and ’273 Patents. These contentions are addressed in turn.

Here, Creative never accused Starmark of infringing its ’273 Patent. While Creative did send letters to purchasers of dicreatine malate alleging that dicreatine malate would infringe claims of the ’273 Patent, none of these letters were sent to Starmark. To the extent Starmark contends those letters were sent to its customers, this contention rings hollow when the letters were sent to SAN’s customers in August 2006 and Starmark was not formed until October 2006. In the absence of an indemnity agreement between Starmark and one of these “customers,” Starmark has, at most, only an economic interest

in clarifying its customers' rights under Creative's patents. "Such an economic interest alone, however, cannot form the basis of an 'actual controversy' under the Declaratory Judgment Act." *Microchip Tech.*, 441 F.3d at 943; *see also Arris*, 639 F.3d at 1374 n.4. Thus, the district court lacked declaratory judgment jurisdiction over the '273 Patent. *See Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008) ("*MedImmune* does not change our long-standing rule that the existence of a patent is not sufficient to establish declaratory judgment jurisdiction.>").

Counsel for Creative noted at oral argument that "[t]he whole time, the parties had been discussing . . . with each other, that we have these competing patents." Oral Argument at 7:55, available at <http://www.cafc.uscourts.gov/oral-argument-recordings/2010-1445/all>. Starmark alleges this fight over competing patents arguably demonstrates an underlying cause of action under 35 U.S.C. § 291. Starmark is correct that a cause of action under § 291 does not require an infringement allegation. 35 U.S.C. § 291; *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.*, 973 F.2d 911, 914 (Fed. Cir. 1992) (stating "by its very language, a cause of action under section 291 does not require that 'the owner of the interfering patent' accuse 'the owner of another' of infringement.>"). And a district court could adjudicate the validity of either interfering patent in a § 291 action. *Albert*, 729 F.2d at 760. A district court lacks jurisdiction under § 291, however, unless an interference is established. *Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 934 (Fed. Cir. 2003) (citing *Albert*, 729 F.2d at 760-61). Here, neither party filed an action under § 291, neither party established the existence of an interference, nor, as discussed above, did either party seek an adjudication at trial as to any identified common claimed subject matter.

Importantly, Starmark itself does not contend that the claims of the patents do, in fact, interfere. *Cf. Kimberly-Clark*, 914 F.2d at 914 (finding jurisdiction over § 291 action where parties concede that patents interfere). Indeed, Starmark's purported theory of invalidity for the '273 Patent relies on the disclosure contained in the specification of the '373 Patent, rather than the claims of the '373 Patent. As Creative stated, "the mere existence of the '273 Patent will not affect the '373 Patent." Appellant Br. 34. Thus, the district court's jurisdictional predicate to a potential § 291 claim involving the '373 and '273 Patents had not been established. *Albert*, 729 F.2d at 761 ("Until it is determined that there are patents which do, in fact, interfere, § 291 simply does not apply. Nor is § 291 comparable to the declaratory judgment statute.").

In the absence of a substantial controversy between the parties concerning an adverse legal interest, the district court lacked declaratory judgment jurisdiction of the '273 Patent. Accordingly, the district court's determination of jurisdiction is reversed, and its grant of summary judgment of invalidity of the '273 Patent is vacated.

E. Motion for Leave to Amend

Creative argues that the district court abused its discretion in denying its motion for leave to amend its Answer. In the Eleventh Circuit, "it is not an abuse of discretion for a district court to deny a motion for leave to amend following the close of discovery, past the deadline for amendments, and past the deadline for filing dispositive motions." *Carruthers v. BSA Adver., Inc.*, 357 F.3d 1213, 1217-18 (11th Cir. 2004). Here, as the district court noted, Creative "sought leave to amend on May 15, 2009, nine months after the date for such amendments, as set forth in the Scheduling Order; six months after the close of fact and expert discovery; almost three months after summary judgment motions were due and have been

filed; and two months before trial.” Order at 3, *Creative Compounds, LLC v. Starmark Labs., Inc.*, No. 07-22814 (S.D. Fla. June 23, 2009), ECF No. 97. We see no basis on which to conclude that the district court abused its discretion in denying Creative’s “tardy and unduly prejudicial” motion to amend. *Id.*

III. CONCLUSION

Based on the foregoing, this court concludes that the district court did not err in granting Starmark’s motion for summary judgment that the ’373 Patent is not invalid and is infringed and, therefore, affirms that determination. Because the district court lacked declaratory judgment jurisdiction over the ’273 Patent, this court reverses the district court’s determination of declaratory judgment jurisdiction and vacates its invalidity determination as to the ’273 patent. Finally, because the district court did not abuse its discretion in denying Creative’s motion for leave to amend, that portion of the district court’s decision is affirmed.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND VACATED-IN-PART

COSTS

Each party shall bear its own costs.