

United States Court of Appeals for the Federal Circuit

2007-1524

PRASCO, LLC,

Plaintiff-Appellant,

v.

MEDICIS PHARMACEUTICAL CORPORATION and
IMAGINATIVE RESEARCH ASSOCIATES, INC.,

Defendants-Appellees.

William A. Rakoczy, Rakoczy Molino Mazzochi Siwik LLP, of Chicago, Illinois, argued for plaintiff-appellant. With him on the brief were Deanne M. Mazzochi and Amy D. Brody.

Matthew D. Powers, Weil, Gotshal & Manges LLP, of Redwood Shores, California, argued for defendants-appellees. On the brief were Barry J. Coyne, Reed Smith LLP, of Pittsburgh, Pennsylvania, and William J. McNichol, Jr., of Philadelphia, Pennsylvania. Of counsel were Elizabeth S. Weiswasser and Jennifer H. Wu, Weil, Gotshal & Manges LLP, of New York, New York.

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

Judge Michael R. Barrett

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MEDICIS PHARMACEUTICAL CORPORATION and
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Defendants-Appellees.

Appeal from the United States District Court for the Southern District of Ohio in case no. 06-CV-313, Judge Michael R. Barrett.

DECIDED: August 15, 2008

Before GAJARSA, Circuit Judge, CLEVENGER, Senior Circuit Judge, MOORE, Circuit Judge.

GAJARSA, Circuit Judge.

This is a patent case concerning the scope of our jurisdiction over declaratory judgment actions. Plaintiff-appellant Prasco, LLC (“Prasco”) brought a declaratory judgment action against defendants-appellees Medicis Pharmaceutical Corp. and Imaginative Research Associates, Inc. (collectively “the defendants”), seeking a declaration that one of its products did not infringe various patents owned by the defendants. The district court dismissed the action for lack of jurisdiction, concluding that Prasco’s complaint failed to establish a case or controversy under Article III of the

Constitution. Prasco LLC v. Medicis Pharm. Corp., No. 1:06cv313, slip op. (S.D. Ohio Mar. 27, 2007) (Prasco I); Prasco LLC v. Medicis Pharm. Corp., No. 1:06cv313, slip op. (S.D. Ohio July 3, 2007) (Prasco II). Because the district court was correct that under the standard affirmed in MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007), this action does not present an Article III case or controversy, we affirm.

I.

As this case was dismissed on the pleadings, for the purposes of this appeal, we must take the facts in the complaint as true. Medicis markets a benzoyl peroxide cleansing product TRIAZ®, which is marked as being covered by four patents, U.S. Patent Nos. 5,648,389 (the “389 patent”); 5,254,334 (the “334 patent”); 5,409,706 (the “706 patent”); and 5,632,996 (the “996 patent”). Prasco makes a generic benzoyl peroxide cleansing product OSCION™, which it alleges will directly compete with Medicis’ TRIAZ® product. The ’389 patent is owned by Medicis; the ’334, ’706, and ’996 patents are owned by Imaginative Research Associates and licensed to Medicis.

On May 26, 2006, Prasco filed the current action, requesting a declaratory judgment that OSCION™ did not infringe the ’389, ’334, ’706, and ’996 patents.¹ At the time that Prasco filed its declaratory judgment action, it had not yet begun marketing OSCION™, but had devoted substantial efforts to development and marketing plans.

Prasco does not dispute that the defendants did not know about the existence of OSCION™ until the complaint was served. Rather, in its initial complaint, Prasco based its alleged Article III jurisdiction on two facts unrelated to the existence of OSCION™: (1) Medicis’ marking of TRIAZ® products with the numbers of the four patents-in-suit to

¹ The complaint does not challenge the validity of the four patents.

satisfy the public notice requirements of 35 U.S.C. § 287 and (2) an infringement suit brought by Medicis against Prasco and another generic company in October 2005, concerning a different cleanser product, covered by an unrelated patent.²

Defendants moved to dismiss the initial complaint on the grounds that a lack of case or controversy precluded subject matter jurisdiction. After the suit and the motion to dismiss were filed, Prasco sent a sample of OSCION™ and an ingredient list to Medicis and Imaginative Research Associates and requested a covenant not to sue under the four patents. The defendants did not sign the covenant not to sue and responded with a single sentence letter advising that they “do not plan to withdraw [their] motion to dismiss the complaint.” Prasco subsequently filed a second complaint, styled an “Amended Complaint” that included this post-filing conduct and the fact that it had begun to market OSCION™. Defendants renewed their motion to dismiss.

Shortly after the Supreme Court issued its decision in MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007), the district court granted the motion to dismiss the Amended Complaint. Prasco I, slip op. at 10. MedImmune reaffirmed that the proper test for subject matter jurisdiction in declaratory judgment actions is “whether 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.” MedImmune, 127 S. Ct. at 771. At the time of the district court’s initial decision, this court had yet to issue a decision interpreting MedImmune, and notwithstanding the MedImmune Court’s statement that the Federal Circuit’s “reasonable apprehension of suit” test for determining subject

² Imaginative Research Associates was not involved in the prior suit.

matter jurisdiction in declaratory judgment actions contradicted earlier Supreme Court precedent, id. at 774 n.11, the district court applied the Federal Circuit's reasonable apprehension of suit test and found that Prasco had not alleged a case or controversy. Prasco I, slip op. at 10. In a footnote, however, the court noted that even if MedImmune had overruled the reasonable apprehension of suit test, it would still conclude that there was no case or controversy because there was "no definite and concrete dispute that touches the legal relations of these parties." Prasco I, slip op. at 11 n.4.

Following this court's decision in Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp., 482 F.3d 1330 (Fed. Cir. 2007), which concluded that MedImmune had effectively overruled the reasonable apprehension of suit test, id. at 1339, the district court reconsidered its ruling pursuant to a Rule 59(e) motion, but declined to amend its decision. Prasco II, slip op. at 8. The court concluded that under all the circumstances there was not an Article III case or controversy. Id. Prasco appeals the final judgment of dismissal. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II.

The only issue on appeal is whether the facts alleged in this case establish that there is a justiciable case or controversy within the meaning of the Declaratory Judgment Act and Article III of the Constitution. We review issues of jurisdiction de novo. Novartis, 482 F.3d at 1335.

A.

The Declaratory Judgment Act provides:

In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the

rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201. The Declaratory Judgment Act is not an independent basis for subject matter jurisdiction. Skelly Oil Co. v. Phillips Petroleum Co., 339 U.S. 667, 671-72 (1950). Rather, it provides a remedy available only if the court has jurisdiction from some other source. Cat Tech LLC v. TubeMaster, Inc., 528 F.3d 871, 879 (Fed. Cir. 2008) (citing Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240 (1937)). Such jurisdiction is limited by Article III of the Constitution, which restricts federal judicial power to the adjudication of “Cases” or “Controversies.” U.S. Const. art. III, § 2; Cat Tech LLC, 528 F.3d at 879. The Declaratory Judgment Act’s requirement of “a case of actual controversy” simply affirms this Constitutional requirement, having long been interpreted as referring to any case and controversy that is justiciable under Article III. See Aetna Life Ins., 300 U.S. at 239-40 (explaining that the phrase “cases of actual controversy” refers “to controversies which are such in the constitutional sense”); see also MedImmune, 127 S. Ct. at 771. Thus, as long as the suit meets the case or controversy requirement of Article III, a district court may have jurisdiction over a declaratory judgment action. Novartis, 482 F.3d at 1340.³

For there to be a case or controversy under Article III, the dispute must be “definite and concrete, touching the legal relations of parties having adverse legal interests,” “real and substantial,” and “admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be

³ Of course, meeting the requirements of Article III is necessary but not sufficient for district court jurisdiction. All other jurisdictional requirements, including a statutory basis for subject matter jurisdiction and personal jurisdiction over the defendant, must also be met. Subject matter jurisdiction over actions for a declaratory judgment of patent non-infringement comes from 28 U.S.C. § 1338.

upon a hypothetical state of facts.” MedImmune, 127 S. Ct. at 771 (quoting Aetna Life, 300 U.S. at 240-41). As the Supreme Court has recently reiterated, however, there is no bright-line rule for determining whether an action satisfies the case or controversy requirement. Id. To the contrary, “[t]he difference between an abstract question and a ‘controversy’ contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy.” Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941). Instead of a bright-line rule, “the analysis must be calibrated to the particular facts of each case,” Cat Tech LLC, 528 F.3d at 879, with the basic standard being whether “the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment,” MedImmune, 127 S. Ct. at 771 (quoting Md. Cas. Co., 312 U.S. at 273); see also Caraco Pharms. Labs. Ltd. v. Forest Labs., 527 F.3d 1278, 1290 (Fed. Cir. 2008). While this standard can be analyzed directly, the Supreme Court has also developed various more specific but overlapping doctrines rooted in the same Article III inquiry, which must be met for a controversy to be justiciable, including standing, ripeness, and a lack of mootness. See Caraco, 527 F.3d at 1291 (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992) (standing); Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967) (ripeness); and U.S. Parole Comm’n v. Geraghty, 445 U.S. 388, 397 (1980) (mootness)). As satisfying these doctrines represents the absolute constitutional minimum for a justiciable controversy, they can be a helpful guide in applying the all-the-circumstances test. Id.

Prior to MedImmune, this circuit had generally required that a declaratory judgment plaintiff in a patent dispute demonstrate (1) conduct by the patentee that created a “reasonable apprehension” of suit on the part of the declaratory judgment plaintiff and (2) present activity by the declaratory judgment plaintiff that could constitute infringement or “meaningful preparation” to conduct potentially infringing activity. See, e.g., Glaxo Inc. v. Novopharm Ltd., 110 F.3d 1562, 1571 (Fed. Cir. 1997). However, in MedImmune, the Supreme Court found that requiring a reasonable apprehension of suit conflicted with the Court’s precedent. MedImmune, 127 S. Ct. at 774 n.11. While the Supreme Court rejected the reasonable apprehension of suit test as the sole test for jurisdiction, it did not completely do away with the relevance of a reasonable apprehension of suit. Rather, following MedImmune, proving a reasonable apprehension of suit is one of multiple ways that a declaratory judgment plaintiff can satisfy the more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy. Caraco, 527 F.3d. at 1291.⁴

B.

As an initial matter, the parties dispute whether the allegations in Prasco’s Amended Complaint that concern actions taken after the filing of the initial complaint can be used to establish subject matter jurisdiction. Because the Amended Complaint included allegations regarding events that happened after the first complaint, technically it is a supplemental complaint, not an “amended complaint.” See Fed. R. Civ. P. 15(d)

⁴ The second prong of the old test, whether there has been potentially infringing activity or meaningful preparation to conduct potentially infringing activity, “remains an important element in the totality of circumstances which must be considered in determining whether a declaratory judgment is appropriate.” Cat Tech LLC, 528 F.3d at 880. This element is not in contention here, however, as according to the complaint, Prasco is currently making and selling OSCION™.

(allowing a party to “serve a supplemental pleading setting forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented”); 6A Wright & Miller, Federal Practice and Procedure § 1504, at 184 (“Parties and courts occasionally confuse supplemental pleadings with amended pleadings and mislabeling is common. However, these misnomers are not of any significance and do not prevent the court from considering a motion to amend or supplement under the proper portion of Rule 15.”).

Rule 15(d) expressly allows for supplemental complaints to “cure” defects in the initial complaint. Fed. R. Civ. P. 15(d) (“Permission [to serve a supplemental pleading] may be granted even though the original pleading is defective in its statement of a claim for relief or defense.”). The Supreme Court has confirmed that supplemental pleadings can be used to cure subject matter jurisdiction deficiencies. See Mathews v. Diaz, 426 U.S. 67, 75 (1976) (explaining that there was “little difficulty” in a party’s failure to file an application that was a “nonwaivable condition of jurisdiction” until after he was joined in the action because “[a] supplemental complaint in the District Court would have eliminated this jurisdictional issue”); see also 6A Wright & Miller, Federal Practice and Procedure § 1505, at 191 (explaining that, prior to the 1963 amendment to Rule 15(d), some courts had not allowed curing of defects through supplemental complaints, but that the addition of the second sentence to 15(d) in 1963 removed “any uncertainty on the point”).

Thus, while “[l]ater events may not create jurisdiction where none existed at the time of filing,” the proper focus in determining jurisdiction are “the facts existing at the time the complaint under consideration was filed.” GAF Bldg. Materials Corp. v. Elk

Corp., 90 F.3d 479, 483 (Fed. Cir. 1996) (emphasis added) (quoting Arrowhead Indus. Water, Inc. v. Ecolochem Inc., 846 F.2d 731, 734 n.2 (Fed. Cir. 1988)); see also Rockwell Int'l Corp. v. United States, 127 S. Ct. 1397, 1409 (2007) (“[W]hen a plaintiff files a complaint in federal court and then voluntarily amends the complaint, courts look to the amended complaint to determine jurisdiction.”); Connectu LLC v. Zuckerberg, 522 F.3d 82 (1st Cir. 2008). As the district court accepted Prasco’s Amended Complaint, it is the Amended Complaint that is currently under consideration, and it is the facts alleged in this complaint that form the basis for our review.⁵

C.

Considering the totality of the circumstances, Prasco has not alleged a controversy of sufficient “immediacy and reality” to create a justiciable controversy. This “immediacy and reality” inquiry can be viewed through the lens of standing. To satisfy standing, the plaintiff must allege (1) an injury-in-fact, i.e., a harm that is “‘concrete’ and actual or imminent, not ‘conjectural’ or ‘hypothetical,’” (2) that is “fairly traceable” to the defendant’s conduct, and (3) redressable by a favorable decision. Caraco, 527 F.3d at 1291 (quoting Steel Co. v. Citizens for a Better Env’t, 523 U.S. 83, 102-03 (1998)); see

⁵ The district court seemed to assume that Prasco had the right to file its Amended Complaint “as a matter of course” under Federal Rule of Civil Procedure 15(a). Prasco I, slip op. at 5-6. This is incorrect. It is Rule 15(d), not Rule 15(a), that governs supplemental complaints, even if the complaint is mislabeled as an amended complaint. Under Rule 15(d) the district court had discretion to decide whether or not to allow Prasco’s supplemental complaint so long as it did so “upon reasonable notice and upon such terms as are just.” Defendants conceded at oral argument that it was within the district court’s discretion to accept Prasco’s Amended Complaint, and they have never argued that the district court’s arguable failure to acknowledge its own discretion was an abuse of discretion. Accordingly, any challenge to the district court’s decision to accept the Amended Complaint is waived. Moreover, as we conclude that there is no subject matter jurisdiction even when the additional facts alleged in the Amended Complaint are considered, any such error would be harmless.

also DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 342 (2006). Absent an injury-in-fact fairly traceable to the patentee, there can be no immediate and real controversy.⁶

As Prasco acknowledges, MedImmune does not change our long-standing rule that the existence of a patent is not sufficient to establish declaratory judgment jurisdiction. See Capo, Inc. v. Dioptics Med. Prods. Inc., 387 F.3d 1352, 1355 (Fed. Cir. 2004) (“More is needed than knowledge of . . . an adversely held patent.”). The mere existence of a potentially adverse patent does not cause an injury nor create an imminent risk of an injury; absent action by the patentee, “a potential competitor . . . is legally free to market its product in the face of an adversely-held patent.”⁷ Novartis, 482 F.3d at 1345.

Prasco argues that a case and controversy has nevertheless been created because Medicis has caused Prasco to suffer an actual harm—namely, “paralyzing uncertainty” from fear that Medicis will bring an infringement suit against it. Appellant’s Br. 23. As Prasco admitted at oral argument, however, any uncertainty has not been paralyzing. To the contrary, notwithstanding this lawsuit, Prasco has launched its

⁶ This justiciability problem can also be viewed through one of the prongs of the ripeness doctrine, whether the complained-of-conduct has an “immediate and substantial impact” on the plaintiff such that withholding court consideration would cause hardship to the plaintiff. Caraco, 527 F.3d at 1294-95 (quoting Gardner v. Tolley Goods Ass’n, 387 U.S. 167, 171 (1967)); see also Hillblom v. United States, 896 F.2d 426, 430 (9th Cir. 1990). In the circumstances of this case, the underlying inquiry, rooted in the requirement that Article III courts cannot issue advisory opinions, is the same regardless of whether labeled standing, ripeness, or the requirement that the controversy have “sufficient immediacy and reality.” See MedImmune, 127 S. Ct. at 772 n.8 (explaining that the justiciability problem at issue could be described in terms of standing or ripeness and that “standing and ripeness boil down to the same question in this case”).

⁷ The situation is different in the highly-regulated pharmaceutical context, in which a manufacturer is not permitted to market a drug without FDA approval. See generally Caraco, 527 F.3d at 1278.

OSCIION™ product. More importantly, the Supreme Court has emphasized that a fear of future harm that is only subjective is not an injury or threat of injury caused by the defendant that can be the basis of an Article III case or controversy. City of L.A. v. Lyons, 461 U.S. 95 (1983); see also Indium Corp. of Am. v. Semi-Alloys, Inc., 781 F.2d 879, 883 (Fed. Cir. 1985) (“A purely subjective apprehension of an infringement suit is insufficient to satisfy the actual controversy requirement.”). Rather, “it is the reality of the threat of . . . injury that is relevant to the standing inquiry, not the plaintiff’s subjective apprehensions.” Lyons, 461 U.S. at 107 n.8 (emphasis in original); see also Laird v. Tatum, 408 U.S. 1, 13-14 (1972) (“Allegations of a subjective ‘chill’ are not an adequate substitute for a claim of specific present objective harm or a threat of specific future harm; ‘the federal courts established pursuant to Article III of the Constitution do not render advisory opinions.’”). Although MedImmune clarified that an injury-in-fact sufficient to create an actual controversy can exist even when there is no apprehension of suit, it did not change the bedrock rule that a case or controversy must be based on a real and immediate injury or threat of future injury that is caused by the defendants—an objective standard that cannot be met by a purely subjective or speculative fear of future harm. Thus, as we explained post-MedImmune, “jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee.” SanDisk, 480 F.3d at 1380-81.

Rather than a purely subjective fear or the mere existence of a potentially adverse patent alone, the alleged injury at the root of most justiciable declaratory judgment controversies in the patent context is a “restraint on the free exploitation of

non-infringing goods,” or an imminent threat of such restraint. Caraco, 527 F.3d at 1291 (quoting Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, Inc., 148 F.3d 1355, 1360 (Fed. Cir. 1998)).

A patentee can cause such an injury in a variety of ways, for example, by creating a reasonable apprehension of an infringement suit, e.g., Arrowhead Indus. Water, 846 F.2d at 737, demanding the right to royalty payments, e.g., MedImmune, 127 S. Ct. at 777, or creating a barrier to the regulatory approval of a product that is necessary for marketing, e.g., Caraco, 527 F.3d at 1292-94. See also Arrowhead Indus. Water, 846 F.2d at 735 (describing the type of “sad and saddening scenario” that led to enactment of the Declaratory Judgment Act in which the “patent owner attempts extrajudicial patent enforcement with scare-the-customer-and-run tactics that infect the competitive environment of the business community with uncertainty and insecurity”).

Prasco does not allege that defendants had actually restrained its right to freely market OSCION™ at the time the supplemental complaint was filed. Rather, it is the threat of future injury that forms the basis for Prasco’s complaint. Thus, there can be no controversy without a showing that this threat was real, imminent, and traceable to defendants.

Taking all the facts into account, Prasco has not met this threshold burden of proving an immediate and real controversy. Important to the totality of the circumstances analysis in the instant case is that which has not occurred. Generally, the Supreme Court has affirmed declaratory judgment jurisdiction when “the parties had taken adverse positions with regard to their obligations, each side presenting a concrete claim of a specific right” prior to the suit. SanDisk Corp., 480 F.3d at 1379 (citing Aetna

Life Ins., 300 U.S. at 240-41 and Md. Casualty, 312 U.S. at 272); see also MedImmune, 127 S. Ct. at 772-77 (concluding that declaratory judgment jurisdiction was proper in the context of a patent licensing agreement when the patentee claimed a right to royalties under the licensing agreement, and the licensee asserted that no royalties were owing because the patent was invalid and not infringed); Altwater v. Freeman, 319 U.S. 359, 365 (1943) (“[T]he requirements of case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where the involuntary or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim.”); Cardinal Chem. Co. v. Morton Int’l, 508 U.S. 83, 96 (1993) (“If . . . a party has actually been charged with infringement of the patent, there is, necessarily, a case or controversy adequate to support jurisdiction of a complaint . . .”). And we have held that “where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise.” SanDisk, 480 F.3d at 1381.

In contrast, here the defendants have not accused Prasco of infringement or asserted any rights to OSCION™, nor have they taken any actions which imply such claims. Instead, all we have before us is Prasco’s allegation that its product does not infringe the defendants’ patents. The defendants’ lack of any “concrete claim of a specific right” is an important factor weighing against a finding of an actual controversy, particularly given that there has been no actual injury. The lack of any evidence that the defendants believe or plan to assert that the plaintiff’s product infringes their patents

creates a high barrier to proving that Prasco faces an imminent risk of injury.⁸ Moreover, not only have the defendants not taken a concrete position adverse to Prasco's, but they also have taken no affirmative actions at all related to Prasco's current product.

None of the facts on which Prasco relies overcome the complete lack of evidence of a defined, preexisting dispute between the parties concerning OSCION™. First, Prasco relies on Medicis' marking of its products with the four patents-in-suit, consistent with the requirements of 35 U.S.C. § 287(a). Under § 287(a), a patentee's marking of its products with the applicable patent numbers serves as notice to the public that the goods are patented. Absent such a marking, the patentee is not entitled to receive damages for infringement that took place before the alleged infringer received actual notice of the infringement. Id. The failure to mark a product under § 287(a) or to provide the requisite notice does not prohibit a patentee from bringing an infringement suit to obtain an injunction or damages occurring after the complaint was served. Id. Nor does it prevent the patentee from demanding a licensing agreement, or otherwise interfering with a competitor's business. Indeed, in the one infringement suit that Medicis has brought against Prasco—regarding unrelated products and unrelated patents—it appears that Medicis' products were not marked with the patents alleged to be infringed. Conversely, Medicis' decision to mark its products with the applicable

⁸ In addition, the lack of clearly delineated, adverse positions by the parties diminishes the “definite[ness] and concrete[ness]” of any potential controversy and its fitness for current judicial resolution. Prasco asks this court to find that its benzoyl peroxide product does not infringe any of the 71 claims of the four patents, each of which have additional limitations beyond benzoyl peroxide being an active ingredient. We have no way of knowing which if any of these claims defendants could or might assert against Prasco.

patents provides little, if any, evidence that it will ever enforce its patents. And in particular, Medicis' decision to mark its products, prior to any knowledge of Prasco's OSCION™ product, is irrelevant to the question of whether Medicis' believes OSCION™ infringes the applicable patents or will attempt to interfere with Prasco's business on the basis of an allegation of infringement. Thus, Medicis' marking of its competing products pursuant to § 287(a) is not a circumstance which supports finding an imminent threat of harm sufficient to create an actual controversy.

Second, Prasco argues that Medicis' past history of enforcing patent rights to protect its "core products" supports a finding of a case or controversy. In particular, Prasco alleges that Medicis' infringement suit against Prasco and another generic company in October 2005 demonstrates a genuine risk that the defendants will also attempt to enforce its patents against Prasco.⁹ Prior litigious conduct is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy. However, one prior suit concerning different products covered by unrelated patents is not the type of pattern of prior conduct that makes reasonable an assumption that Medicis will also take action against Prasco regarding its new product. See Indium Corp., 781 F.2d at 883. Accordingly, Medicis' prior suit premised on other patents cannot alone create a real and immediate controversy, and it

⁹ Prasco also argues in its briefs that Medicis has brought other suits against competitors. However, such conduct is not clearly alleged in its complaint. Accordingly, we will not consider it.

is entitled to only minimal weight in analyzing whether such a controversy has been created.¹⁰

Third, Prasco places significant weight on Medicis' and Imaginative Research Associates' failure to sign covenants not to sue after Prasco sent them samples of OSCION™ in the wake of their initial motion to dismiss. We have explained that “although a patentee’s refusal to give assurances that it will not enforce its patent is relevant to the determination, it is not dispositive.” BP Chems. v. Union Carbide Corp., 4 F.3d 975, 980 (Fed. Cir. 1993). A patentee has no obligation to spend the time and money to test a competitors’ product nor to make a definitive determination, at the time and place of the competitors’ choosing, that it will never bring an infringement suit. And the patentee’s silence does not alone make an infringement action or other interference with the plaintiff’s business imminent. Thus, though a defendant’s failure to sign a covenant not to sue is one circumstance to consider in evaluating the totality of the circumstances, it is not sufficient to create an actual controversy—some affirmative actions by the defendant will also generally be necessary.¹¹

Here, where Prasco has suffered no actual present injury traceable to the defendants, and the defendants have not asserted any rights against Prasco related to the patents nor taken any affirmative actions concerning Prasco’s current product, one prior suit concerning unrelated patents and products and the defendants’ failure to sign a covenant not to sue are simply not sufficient to establish that Prasco is at risk of

¹⁰ Moreover, the prior suit has no relevance to whether there is a case or controversy with Imaginative Research Associates, as Imaginative Research Associates was not a party to the prior suit.

¹¹ Conversely, we have held that in certain situations signing a covenant not to sue is also not sufficient to defeat declaratory judgment jurisdiction if signing the covenant does not negate the underlying injury. See Caraco, 527 F.3d at 1296-97.

imminent harm from the defendants and that there is an actual controversy between the parties of sufficient immediacy and reality to warrant declaratory judgment jurisdiction. Although we understand Prasco's desire to have a definitive answer on whether its products infringe defendants' patents, were the district court to reach the merits of this case, it would merely be providing an advisory opinion. This is impermissible under the Article III.¹²

III.

Considering the totality of the circumstances, Prasco has failed to establish a case or controversy under Article III. Therefore, the judgment of the district court dismissing the case for lack of jurisdiction is affirmed.

AFFIRMED

¹² Prasco had sued only for a declaratory judgment of non-infringement. We thus have no opportunity to consider whether similar facts would be sufficient to establish jurisdiction if, instead, Prasco had conceded infringement and was only arguing invalidity.