United States Court of Appeals for the Federal Circuit

DANISCO US INC.,
Plaintiff-Appellant,

v.

NOVOZYMES A/S AND NOVOZYMES NORTH AMERICA, INC.,
Defendants-Appellees.

2013-1214

Appeal from the United States District Court for the Northern District of California in No. 12-CV-04502, Magistrate Judge Richard G. Seeborg.

Decided: March 11, 2014

THOMAS G. HUNGAR, Gibson, Dunn & Crutcher LLP, of Washington, DC, argued for plaintiff-appellant. With him on the brief were TRACEY B. DAVIES, MICHAEL A. VALEK, and JASON C. MCKENNEY, of Dallas, Texas.

DAVID K. TELLEKSON, Fenwick & West, LLP, of Seattle, Washington, argued for defendants-appellees. With him on the brief were VIRGINIA K. DEMARCHI and EWA M. DAVISON.

Before LOURIE, PROST, and O'MALLEY, *Circuit Judges.*

LOURIE, *Circuit Judge.*

Danisco US Inc. ("Danisco") appeals from the decision of the United States District Court for the Northern District of California dismissing Danisco's declaratory judgment action against Novozymes A/S and Novozymes North America, Inc. (collectively "Novozymes") for lack of subject matter jurisdiction. *See Danisco US Inc. v. Novozymes A/S*, No. 12-4502, 2013 WL 2351723 (N.D. Cal. Jan. 8, 2013) (unpublished). Because we conclude that the totality of the circumstances establishes a justiciable controversy, we reverse and remand.

BACKGROUND

Danisco and Novozymes compete to develop and supply Rapid Starch Liquefaction ("RSL") products, which are genetically modified industrial enzymes used for converting corn and other plant-based material into ethanol. Danisco and Novozymes have patents that claim α-amylase enzymes, which have been genetically engineered through substitution of amino acids in the peptide sequence in order to improve their performance in the liquefaction process.

Since about 2001, Novozymes has sued Danisco or Danisco's predecessors in interest for infringement numerous times. In one instance, Novozymes amended an application then pending at the United States Patent and Trademark Office ("PTO") to claim one of Danisco's new products and then sued Danisco in the United States District Court for the Western District of Wisconsin on the same day that the patent issued. The Wisconsin court invalidated Novozymes's patent because the newly added claim was not supported by the written description, and we affirmed. *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1346 (Fed. Cir. 2013).

Danisco owns U.S. Patent 8,084,240 (the "'240 patent"), issued December 27, 2011 and claiming the benefit of priority from a provisional application filed June 6, 2008. The '240 patent claims a truncated *Geobacillus stearothermophilus* ("BSG") α-amylase variant polypeptide with a substitution from glutamic acid ("E") to proline ("P") at sequence position 188, a so-called "E188P substitution," that exhibits increased viscosity reduction in a starch liquefaction assay compared to the parental α-amylase polypeptide. '240 patent col. 275 l. 25–col. 276 l. 29. The claimed enzyme is the active ingredient in Danisco's RSL products.

Shortly after the PTO issued a Notice of Allowance of the application that matured into Danisco's '240 patent, Novozymes again amended one of its own then-pending patent applications to claim a BSG α-amylase variant polypeptide with an E188P substitution, and subsequently requested an interference contesting entitlement to priority of the invention. J.A. 445–53. Specifically, Novozymes asserted that its amended claim encompassed the same invention as Danisco's claim because both claims: (i) are directed to an isolated BSG α-amylase variant, (ii) specify 99% sequence identity to the parental enzyme, and (iii) require the same E188P substitution. *Id.* at 448. In other words, Novozymes contended that its amended claim covered the same invention as Danisco's '240 patent, namely a BSG α-amylase variant with an E188P mutation, which is the active ingredient in Danisco's RSL products. The PTO examiner rejected Novozymes's interference request on the ground that the truncated BSG α-amylase variant in Danisco's then-pending claim did not meet the specific sequence identity limitations of Novozymes's amended claim. *Id.* at 449–50.

After Danisco's '240 patent issued, Novozymes filed a request for continued examination, challenging the examiner's conclusions and again arguing for priority over

what it described as Danisco's "interfering '240 patent." *Id.* at 457, 462. Novozymes maintained that Danisco's '240 patent covered the same subject matter as Novozymes's amended claim and, in effect, once more represented that its amended claim read on the active ingredient in Danisco's RSL products. *Id.* Novozymes asserted that the examiner had "mistakenly concluded" that Danisco's '240 patent directed to a BSG E188P mutation "d[id] not fall within the scope of" Novozymes's then-pending application. *Id.* The examiner rejected Novozymes's request. *Id.* at 461–67.

Although under no regulatory obligation to do so, Novozymes then submitted public comments to the PTO "in order to clarify [for] the record" its belief that the α-amylase variant claimed by Danisco's '240 patent "fall[s] within the scope" of its own claim, which later issued to Novozymes as the sole claim of U.S. Patent 8,252,573 (the "'573 patent") on August 28, 2012, claiming the benefit of priority from a provisional application filed June 7, 2001. *Id.* at 456–59. Novozymes further commented that it refused to "acquiesce" to or otherwise be "estopped" by what it deemed to be the examiner's erroneous and "overly narrow" view of Novozymes's claim scope, which consequently did not allow Novozymes to invalidate Danisco's '240 patent or to claim priority over the ownership of the BSG E188P α-amylase variant invention. *Id.*

Upon issuance of Novozymes's '573 patent, Danisco filed concurrent actions in the United States District Courts for both the Northern District of Iowa and the Northern District of California seeking declaratory judgments that its RSL products did not infringe Novozymes's '573 patent (Count 1) and that the '573 patent was invalid (Count 2), or alternatively that Danisco's '240 patent had priority over Novozymes's '573 patent pursuant to 35 U.S.C. § 291 (Count 3). J.A. 259–63, 728–32. Following the parties' stipulated dismissal of

the Iowa action in favor of the California action, Novozymes moved to dismiss Danisco's complaint for lack of jurisdiction under Federal Rule of Civil Procedure 12(b)(1) and for failure to state a claim under Rule 12(b)(6). J.A. 468–84, 735–36.

The district court granted Novozymes's motion and dismissed Danisco's declaratory judgment claims, holding as a matter of law that the facts as alleged did not create a justiciable Article III case or controversy as to Counts 1 and 2. *Danisco*, 2013 WL 2351723, at *2. The court acknowledged that Novozymes's '573 patent presented a substantial risk to Danisco, but found that a justiciable controversy did not exist because Danisco had challenged Novozymes's '573 patent on the day that it issued, and thus that Danisco's action "was filed prior to the time Novozymes took, or even could have taken, any affirmative action to enforce its patent rights." *Id.* at *1. The court stated that "[w]hile matters such as a prior litigation history and statements made during prosecutions sometimes *support* a conclusion that an actual controversy exists, there is no precedent for finding jurisdiction based on such pre-patent issuance events alone . . . ." *Id.* at *2 (emphasis in original). The court determined that Danisco was missing "an affirmative act of enforcement" or "some implied or express enforcement threat" by Novozymes because "pre-issuance conduct" could not satisfy that requirement. *Id.* at *3–4.

In a footnote, the district court also summarily dismissed Danisco's § 291 claim, concluding that Danisco's third count requesting a determination of priority of invention was not ripe because it could not stand alone in the absence of the primary noninfringement and invalidity declaratory judgment claims. *Id.* at *4 n.2.

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

DISCUSSION

A district court's decision to dismiss a declaratory judgment action for lack of subject matter jurisdiction is a question of law that we review without deference. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1335–36 (Fed. Cir. 2007); *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1377 (Fed. Cir. 2007). We review the district court's underlying factual findings for clear error. *Id.*

The Declaratory Judgment Act provides that, "[i]n 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(a). The phrase "case of actual controversy" "refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III." *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1283 (Fed. Cir. 2007) (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)). The burden is on the party claiming declaratory judgment jurisdiction, here Danisco, to establish that an Article III case or controversy existed at the time that the claim for declaratory relief was filed and that it has continued since. *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007) (citing *Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974)).

Danisco argues that the standard required for establishing Article III jurisdiction is satisfied by the facts of its case and that the district court therefore erred in dismissing Danisco's complaint for declaratory judgment because there is a substantial controversy implicating adverse legal interests in a manner that is sufficiently definite and concrete to be capable of conclusive judicial resolution.

Novozymes responds that Article III is not satisfied because Danisco's declaratory judgment claims are based on nothing more than speculation and a subjective fear of Novozymes's purported enforcement of its patent rights and not on any real and immediate injury or threat of future injury caused by Novozymes. Novozymes asserts that there is no justiciable controversy because there is no objective evidence that it intends to enforce those rights and that it has not taken any affirmative action from which such an inference can be made. Novozymes seeks a bright line rule that its activity prior to issuance of the '573 patent cannot give rise to a justiciable controversy and thus that a declaratory judgment defendant must first threaten suit on an issued patent or otherwise take action to enforce its rights in an issued patent.

We agree with Danisco that the standard for finding a justiciable controversy is satisfied here. Both Novozymes's argument and the district court's decision rely on the fact that Novozymes had not affirmatively accused Danisco's RSL products of infringing the issued '573 patent, but that fact alone is not dispositive of whether an actual controversy exists, and the district court erred in holding that it was. *See, e.g.*, *Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351, 1357 (Fed. Cir. 2013) (holding that it is not "necessary that a patent holder make specific accusations" of infringement against the declaratory judgment plaintiff); *SanDisk*, 480 F.3d at 1383. The question instead is whether Danisco has demonstrated a "substantial risk" that the harm will occur. *Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 718 F.3d 1350, 1355 (Fed. Cir. 2013), *cert. denied*, 187 L. Ed. 2d 776 (2014) (citing *Clapper v. Amnesty Int'l USA*, 568 U.S. __, 133 S. Ct. 1138, 1150 n.5 (2013)).

Article III does not mandate that the declaratory judgment defendant have threatened litigation or otherwise taken action to enforce its rights before a justiciable controversy can arise, and the Supreme Court has repeat-

edly found the existence of an actual case or controversy even in situations in which there was no indication that the declaratory judgment defendant was preparing to enforce its legal rights. *See MedImmune*, 549 U.S. at 132 n.11 (describing its holdings in *Md. Cas. Co. v. Pac. Coal & Oil Co.,* 312 U.S. 270, 273 (1941) and *Aetna Life Ins. Co. v. Haworth,* 300 U.S. 227, 239 (1937) in which declaratory judgment jurisdiction was held to exist over an insurance coverage dispute "even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit").

The Court has instead only "required that the dispute be 'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be '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 upon a hypothetical state of facts.'" *MedImmune*, 549 U.S. at 127 (quoting *Aetna*, 300 U.S. at 240–41). "'Basically, the question in each case is 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.'" *Id.* (quoting *Md. Cas.,* 312 U.S. at 273); s*ee also Teva*, 482 F.3d at 1337 ("[I]n a declaratory judgment action, all the circumstances must demonstrate that a justiciable Article III controversy exists.") (internal quotations omitted); *C.R. Bard, Inc. v. Schwartz,* 716 F.2d 874, 880 (Fed. Cir. 1983) (holding that "an examination of the totality of the circumstances must be made to determine whether there is a controversy" in a patent declaratory judgment action). That standard is satisfied here.

The record demonstrates that a definite and concrete patent dispute exists between the parties. Novozymes's E188P α-amylase variant claim issued as the sole claim of its '573 patent and is the same claim that Novozymes

described as interfering with the claim in Danisco's '240 patent. Novozymes has insisted on multiple occasions that its '573 patent claim reads on the BSG α-amylase with an E188P mutation, which is the active compound in Danisco's RSL products and is claimed in Novozymes's patent. The record shows that Novozymes sought its patent because it believed that Danisco's products would infringe once the claim issued. Novozymes twice asserted that Danisco's '240 patent was invalid and that Novozymes, not Danisco, is entitled to a patent on the claimed BSG E188P α-amylase invention. Danisco has taken a legal position that is entirely opposed to the position taken by Novozymes, *viz.*, that Danisco successfully prosecuted and obtained the '240 patent, that it is the rightful owner of the claimed invention, and that its RSL products do not infringe the claim of Novozymes's '573 patent. Novozymes has twice sued Danisco or its predecessors in interest for patent infringement regarding related liquefaction products. The parties have plainly been at war over patents involving genetically modified α-amylase enzymes and are likely to be for the foreseeable future. They thus have adverse legal interests over a dispute of sufficient reality that is capable of conclusive resolution through a declaratory judgment.

Novozymes has never withdrawn its allegation that Danisco's α-amylase variant is encompassed by and would infringe the claim that issued in Novozymes's '573 patent. Nor has Novozymes offered any assurance, such as with a covenant not to sue, that it will not accuse Danisco's RSL products of infringement, which could potentially moot a controversy between the parties. *See Already, LLC v. Nike, Inc.*, 568 U.S. __, 133 S. Ct. 721, 732 (2013); *Organic Seed Growers*, 718 F.3d at 1357–58 (holding that patentee's "representations unequivocally disclaim[ing] any intent to sue appellant" were "binding as a matter of judicial estoppel"); *Arris Grp., Inc. v. British Telecomms. PLC*, 639 F.3d 1368, 1381 (Fed. Cir. 2011) ("BT's refusal

to grant Arris a covenant not to sue provides a level of additional support for our finding that an actual controversy exists" in a patent declaratory judgment action.). Moreover, as we have previously noted, and the district court correctly observed, a history of patent litigation between the same parties involving related technologies, products, and patents is another circumstance to be considered, which may weigh in favor of the existence of subject matter jurisdiction, as it does here. *See Arkema*, 706 F.3d at 1357; *3M Co. v. Avery Dennison Corp.*, 673 F.3d 1372, 1380 (Fed. Cir. 2012); *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897 (Fed. Cir. 2008); *Teva*, 482 F.3d at 1344–45 (Fed. Cir. 2007). We see no reason why we should not similarly consider a pattern of administrative challenges in analyzing the totality of the circumstances.

The district court's categorical distinction between pre- and post-issuance conduct is therefore irreconcilable with the Supreme Court's insistence on applying a flexible totality of the circumstances test, its rejection of technical bright line rules in the context of justiciability, and our own precedent. *See, e.g.*, *Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1328 (Fed. Cir. 2012) ("In determining whether a justiciable controversy is present, the analysis must be calibrated to the particular facts of each case."). Contrary to the district court's stated view, we have never held that "pre-issuance conduct" cannot constitute an affirmative act, nor have we held that the only affirmative acts sufficient to create justiciable controversies are "implied or express enforcement threat[s]." *Danisco*, 2013 WL 2351723, at *3–4. Even the district court itself acknowledged that Danisco showed that it was "reasonable to infer that Novozymes obtained the '573 patent with the hopes of asserting it against Danisco's products, and there may even be a probability that it will someday do so." *Id.* at *1. The court also determined that the facts plausibly "support a reasonable inference that

Novozymes pursued the E188P claim in the '573 patent with the hopes of wielding it against [Danisco's] RSL products, and even that Novozymes may *still* be harboring the intent to pursue infringement claims at the time of its own choosing." *Id.* at *2 (emphasis in original). The court likewise recognized that "the prosecution history may strongly support an inference that Novozymes sought to obtain this patent for the purpose of potentially asserting it against Danisco's products . . . ." *Id.* at *3 n.1. Thus, applying a mechanical distinction to the totality of the circumstances inquiry between pre- and post-issuance events is unsound.

Furthermore, the Supreme Court has not articulated a bright line rule for distinguishing those cases that satisfy the Article III case or controversy requirement as it relates to the Declaratory Judgment Act from those that do not. Indeed, the Court has stated that "[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.*, 312 U.S. at 273. We are likewise not inclined to do so now.

Taken together, Novozymes's activities thus demonstrate that it has "engaged in a course of conduct that shows a preparedness and a willingness to enforce its patent rights." *SanDisk*, 480 F.3d at 1383. That is enough to establish subject matter jurisdiction. Novozymes's behavior validates that Danisco, quite reasonably, is more than a "nervous . . . possible infringer," even if Novozymes is not currently "poised on the courthouse steps" to sue Danisco for infringement of the '573 patent. *Vanguard Research, Inc. v. PEAT, Inc.*, 304 F.3d 1249, 1254–55 (Fed. Cir. 2002) (quoting *Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha*, 57 F.3d 1051,

1053–54 (Fed. Cir. 1995)); *accord Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008).

At bottom, Danisco is in the position of either abandoning its RSL products or running the risk of being sued for infringement, which is precisely the type of situation that the Declaratory Judgment Act was intended to remedy. *MedImmune,* 549 U.S. at 129 ("[P]utting the challenger to the choice between abandoning his rights or risking prosecution [] is 'a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate.'" (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 152 (1967))); *accord Medtronic, Inc. v. Mirowski Family Ventures LLC*, 571 U.S. __, 134 S. Ct. 843, 850 (2014).

Accordingly, because a totality of the circumstances shows that Novozymes's posturing put Danisco in a position of either pursuing arguably illegal behavior, *i.e.*, infringement, or abandoning that which it claims a right to do, *i.e.*, make and sell the RSL products that are the embodiments of its '240 patent, we conclude that the district court erred as a matter of law in dismissing Counts 1 and 2 of Danisco's complaint for lack of subject matter jurisdiction. *Arkema*, 706 F.3d at 1357; *SanDisk*, 480 F.3d at 1381.

Finally, because the district court's dismissal of Danisco's third count seeking a declaration of priority pursuant to 35 U.S.C. § 291 was expressly premised on the erroneous dismissal of Counts 1 and 2 as nonjusticiable, we vacate that judgment and remand, reinstating Count 3 as filed in Danisco's complaint in view of our reversal of the court's declaratory judgment jurisdiction as set forth above. The district court dismissed Danisco's § 291 claim for lack of ripeness, which does not preclude a second action after ripeness is found. *Dodd v. Hood River Cnty.*, 59 F.3d 852, 864 (9th Cir. 1995). Following the law of the circuit in which the district court sits, here the Ninth Circuit, we decline to reach the merits of Danisco's claim

or Novozymes's alternative challenges to it because doing so would grant relief more extensive than that which was initially received from the district court. *Id.*; *accord Digital-Vending Servs., Int'l v. Univ. of Phx., Inc.*, 672 F.3d 1270, 1278 (Fed. Cir. 2012) ("As a general rule, a federal appellate court does not consider an issue not passed upon below."); *see also Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 435 F.3d 1356, 1360 (Fed. Cir. 2006) (deferring to regional circuit law in matters not within our exclusive jurisdiction); *Biodex Corp. v. Loredan Biomedical, Inc.*, 946 F.2d 850, 857–58 (Fed. Cir. 1991) ("[O]ur practice has been to defer to regional circuit law when the precise issue involves an interpretation of the Federal Rules of Civil Procedure or the local rules of the district court.").

CONCLUSION

In view of the foregoing, we conclude that the district court erred as a matter of law and that the totality of the circumstances presented here establishes a justiciable controversy. The judgment of the district court dismissing Counts 1 and 2 of Danisco's complaint for lack of subject matter jurisdiction is therefore reversed and the case is remanded for further proceedings. In addition, the district court's dismissal of Danisco's third count for a determination of priority of invention pursuant to 35 U.S.C. § 291 is vacated and remanded.

REVERSED and REMANDED