United States Court of Appeals for the Federal Circuit

TEVA PHARMACEUTICALS USA, INC.,
THROUGH ITS GATE PHARMACEUTICALS DIVISION,
Plaintiff-Appellant,

v.

EISAI CO., LTD. AND EISAI MEDICAL RESEARCH, INC.,
Defendants-Appellees.

2009-1593

Appeal from the United States District Court for the District of New Jersey in case no. 08-CV-2344, Chief Judge Garrett E. Brown, Jr.

Decided: October 6, 2010

FRANCIS C. LYNCH, Goodwin Proctor LLP, of Boston, Massachusetts, argued for plaintiff-appellant. With him on the brief were HENRY C. DINGER and LAURIE S. GILL.

BRUCE M. WEXLER, Paul, Hastings, Janofsky & Walker LLP, of New York, New York, argued for defendants-appellees. With him on the brief were JOSEPH M.

O'MALLEY, JR. and ANTHONY MICHAEL; and STEPHEN B. KINNAIRD, of Washington, DC.

Before RADER, *Chief Judge*[*], DYK and PROST, *Circuit Judges*.

PROST, *Circuit Judge*.

This is a declaratory judgment action arising under the Hatch-Waxman Act. We must decide whether the district court properly dismissed the case for lack of jurisdiction, specifically, lack of a justiciable controversy under Article III of the United States Constitution.

Teva Pharmaceuticals, Inc. ("Teva") seeks to manufacture and market a generic version of the drug donepezil hydrochloride ("donepezil"), an approved treatment for Alzheimer's disease. Eisai Co. and Eisai Medical Research, Inc. (collectively "Eisai") hold the approved New Drug Application ("NDA") for donepezil, which Eisai currently markets as Aricept®. Eisai also owns the five patents listed for Aricept® in the Orange Book. Teva requests a declaratory judgment that its generic version of donepezil does not infringe four of these Orange Book patents, Patent Nos. 5,985,864 ("'864 patent"); 6,140,321 ("'321 patent"); 6,245,911 ("'911 patent"); and 6,372,760 ("'760 patent"), (collectively the "DJ patents").

Aside from the value of such a judgment in itself, a finding of noninfringement has special significance to generic drug manufacturers like Teva under the Hatch-Waxman Act. To market a generic version of a previously-approved drug, manufacturers must file and receive

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[*] Randall R. Rader assumed the position of Chief Judge on June 1, 2010.

approval of an Abbreviated New Drug Application ("ANDA"). In conjunction with an ANDA, manufacturers must also submit a certification with respect to each of the drug's Orange Book patents. The first manufacturer to file what is called a "Paragraph IV Certification" for a given Orange Book patent is entitled to 180 days of generic marketing exclusivity. Until the first-filer's exclusivity period has run, the FDA may not approve ANDA applications by other manufacturers who have filed Paragraph IV certifications for that same patent. The first-filer's exclusivity period can be triggered by either the (1) commercial marketing of the drug by the first Paragraph IV filer or (2) entry of a court judgment finding that patent invalid or not infringed, whichever happens first. A subsequent Paragraph IV filer can thus trigger the first-filer's exclusivity period by obtaining a court judgment.

Teva is a subsequent Paragraph IV filer. This case turns on whether a subsequent Paragraph IV filer has a legally cognizable interest in when the first-filer's exclusivity period begins, such that delay in triggering that period qualifies as "injury-in-fact" for the purposes of Article III.

In this case, the alleged injury-in-fact stems from a pending ANDA filed by Gate Pharmaceuticals ("Gate ANDA" or "second ANDA"), an unincorporated division of Teva. FDA approval of the Gate ANDA has been delayed indefinitely because the exclusivity period of the first-filer, a company called Ranbaxy Laboratories Ltd. ("Ranbaxy"), has not been triggered. Before the district court, patent owner Eisai argued that Teva failed to establish the existence of an Article III controversy. The district court agreed and dismissed the case for lack of jurisdiction. In finding that Teva failed to allege a controversy of

sufficient immediacy and reality for Article III purposes, the district court relied in part on a preliminary injunction entered against Teva and Gate in a separate, still-pending patent infringement action regarding Patent No. 4,895,841 ("'841 patent").[1]

Teva appeals the dismissal of its declaratory judgment action and argues the case should proceed. We agree. Under this court's decision in *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278 (Fed. Cir. 2008), Teva has alleged a sufficiently concrete injury fairly traceable to Eisai's actions. Further, the injury can be redressed by the requested relief: a declaratory judgment of noninfringement would trigger the first-filer's exclusivity period, which currently blocks FDA approval of the Gate ANDA. The district court's decision is reversed and the case remanded for further proceedings consistent with this opinion.

BACKGROUND

Because Teva's declaratory judgment claims were disposed of at the motion to dismiss stage, we take the following facts from Teva's amended complaint and the materials submitted in response to Eisai's motion to dismiss. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 121 (2007).

Eisai holds the approved New Drug Application ("NDA") for donepezil, which it markets as the prescription drug Aricept®. For Aricept®, Eisai listed five patents in the Orange Book, thus attesting that those

[1] The '841 patent is listed in the Orange Book for Aricept®. It is not, however, one of the patents as to which Teva seeks a declaratory judgment of noninfringement in this case.

patents claim either donepezil or a method for using it, and accordingly could reasonably be asserted against any unlicensed party seeking to manufacture, use, or sell the drug. Of the five patents, the '841 patent is the subject of separate patent infringement litigation brought by Eisai against Teva and Gate. The four DJ patents are at issue here.

A significant number of events occurred before Teva brought this action. While the timeline and statutory scheme is complex, for our purposes, only the following facts matter.

The first ANDA for a generic form of donepezil was filed by Ranbaxy in 2003. For the '841 patent, Ranbaxy submitted a Paragraph III certification, thus agreeing not to market a generic version of Aricept® until after the '841 patent expires in November 2010. For the DJ patents, Ranbaxy submitted Paragraph IV certifications, meaning that in Ranbaxy's opinion the four patents are invalid or will not be infringed by its drug. 21 U.S.C. § 355(j)(2)(A)(vii). Because Ranbaxy filed the first Paragraph IV certifications for the DJ patents, Ranbaxy is eligible for 180 days of market exclusivity upon FDA approval of its ANDA. *Id.* § 355(j)(5)(B)(iv). The exclusivity period begins when Ranbaxy begins commercially marketing its drug or upon issuance of a court judgment holding the relevant listed patents invalid or not infringed. *Id.* § 355(j)(5)(B)(iv) (2000).[2]

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[2] In 2003, Congress altered the scheme for triggering the 180-day exclusivity period by amending the Hatch-Waxman Act. As a result, a first-filer can now forfeit its exclusivity period by failing to market its drug within a certain time. *See* 21 U.S.C. § 355(j)(5)(D). These changes do not apply here because Ranbaxy filed its ANDA with the Paragraph IV certifications before enact-

Teva subsequently filed two separate ANDAs for generic donepezil. As initially filed with the FDA, Teva's first ANDA ("first ANDA" or "Teva ANDA") had the same certifications as Ranbaxy's ANDA: For the '841 patent, Teva initially included a Paragraph III certification; for the DJ patents, Teva included Paragraph IV certifications. Teva subsequently amended this first ANDA, changing the '841 patent's certification from Paragraph III to Paragraph IV.

Teva's second ANDA ("second ANDA" or "Gate ANDA") was filed by Gate Pharmaceuticals, a division of Teva. This second ANDA was for a different form of generic donepezil than the one claimed in Teva's first ANDA. According to Teva, the FDA requested separate ANDAs filed under different company names because the forms of donepezil were different and the likelihood of confusion otherwise greater. The Gate ANDA originally included Paragraph III certifications for all five listed patents; following an amendment, however, these were changed to Paragraph IV certifications.

Under the Hatch-Waxman Act, filing a Paragraph IV certification constitutes an act of patent infringement. 35 U.S.C. § 271(e)(2). After Teva filed its first and second ANDAs in 2005 and 2007 respectively, Eisai timely sued Teva for infringement of the '841 patent ("'841 patent infringement litigation"). 21 U.S.C. § 355(c)(3)(C) (2000). Though filed separately, these two infringement actions were consolidated in early 2008. During the course of the litigation, Teva stipulated that its generic forms of done-

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ment of the amendments. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1102(b), Pub. L. No. 108-173, 117 Stat. 2066 (2003).

pezil infringe various claims of the '841 patent unless the patent is invalid or unenforceable.

In February 2008, Eisai moved for a preliminary injunction to prevent Teva and Gate from marketing any form of generic donepezil after expiration of the thirty-month stay invoked by Eisai, thereby initiating the '841 patent infringement litigation. *See id.* § 355(j)(5)(B)(iii). Eisai's motion was granted and a preliminary injunction entered against Teva and Gate. *Eisai Co. v. Teva Pharms. USA, Inc.*, No. 05-5727 (D.N.J. Mar. 28, 2008) (opinion and order granting preliminary injunction). The preliminary injunction bars Teva and Gate from marketing any drug containing donepezil as claimed in the '841 patent. In April 2008, the thirty-month stay expired and the FDA approved Teva's first ANDA. At the time of this appeal, the separate '841 patent infringement litigation is still pending and the related preliminary injunction is still in effect.

In May 2008, Teva filed this action. Here, Teva seeks a declaratory judgment that the manufacture, use, offer for sale, sale, or importation of generic donepezil covered by the Gate ANDA will not infringe the DJ patents. 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5). Eisai has never brought suit to enforce any of the DJ patents against Teva. Rather in 2006 and 2007, before this case arose, Eisai filed statutory disclaimers with the United States Patent and Trademark Office regarding two of the DJ patents, the '321 and '864 patents. *See* 35 U.S.C. § 253. A statutory disclaimer has the effect of cancelling the patent claims, meaning they cannot be reissued or subsequently enforced. *See Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996). What matters for our purposes is that all four of the DJ patents remain listed in the Orange Book.

Eisai moved to dismiss this case for lack of subject matter jurisdiction. While Eisai's motion was pending, the parties negotiated a covenant-not-to-sue covering the two DJ patents Eisai had not disclaimed, the '911 and '760 patents. Pursuant to the covenant, Eisai unconditionally agreed not to assert the '911 and '760 patents against Teva or its successors with respect to any formulation of generic donepezil described in Teva's first or second ANDAs. Before the district court and on appeal, Eisai relies in part on the statutory disclaimers and covenant-not-to-sue in arguing that there is no justiciable controversy.

Teva's amended complaint acknowledges the statutory disclaimers and covenant-not-to-sue. Teva nonetheless maintains that it is suffering an injury cognizable under Article III because the DJ patents remain listed in the Orange Book. Because the DJ patents remain listed, under 21 U.S.C. § 355(j)(5)(B)(4) FDA approval of Teva's Gate ANDA cannot occur until the exclusivity period for the first-filer of the DJ patents, Ranbaxy, has run. As stated previously, the exclusivity period can only be triggered by the first-filer's commercial marketing of the generic drug or a court judgment that the relevant patents are invalid or not infringed. Given the framework of the Hatch-Waxman Act, Teva argues that the only way to redress its "FDA-approval-blocking-injury" is through this action for declaratory judgment.

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

ANALYSIS

We review a district court's dismissal for lack of subject matter jurisdiction de novo. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1359 (Fed. Cir. 2008).

Whether an actual controversy exists for purposes of a declaratory judgment action is a question of law also reviewed de novo. *Teva Pharms. USA v. Novartis Pharms. Corp.* ("*Novartis*"), 482 F.3d 1330, 1336 (Fed. Cir. 2007). We review a district court's decision to decline jurisdiction under the Declaratory Judgment Act for abuse of discretion. *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1287 (Fed. Cir. 2007).

Under the Hatch-Waxman Act, a party that files an ANDA with Paragraph IV certifications may bring suit under the Declaratory Judgment Act, 28 U.S.C. § 2201, against the holder of the corresponding New Drug Application ("NDA"). 35 U.S.C. § 271(e)(5). The Declaratory Judgment Act provides that "[i]n the 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) (emphasis added). Federal courts have subject matter jurisdiction over cases brought by ANDA filers "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). The Constitution requires an Article III case or controversy. *Novartis*, 482 F.3d at 1337.

The Supreme Court has explained that such a controversy exists when the dispute is "definite and concrete, touching the legal relations of parties having adverse legal interests." *MedImmune*, 549 U.S. at 128 (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)). This dispute must be "real and substantial," and of "sufficient immediacy and reality to warrant issuance of a declaratory judgment." *Id.* Further, the plaintiff's injury must be "fairly traceable" to the defendant's conduct. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83,

102-03 (1998). Finally, the requested relief must be likely to redress the alleged injury. *Id.* In other words, the injury must "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 128.

This case presents two questions. First, we must decide whether this case presents an "actual controversy." Should such a controversy exist, we must then decide if the district court abused its discretion under the Declaratory Judgment Act in declining to entertain this suit. We address each question in turn.

I. Actual Controversy

We begin with the jurisdictional question. Teva argues that absent a declaratory judgment with respect to the DJ patents, it suffers (and will continue to suffer) the harm of being unable to launch generic donepezil products covered by the Gate ANDA. Two decisions by this court set out the framework for determining whether an Article III controversy exists in a declaratory judgment action arising under the Hatch-Waxman Act, *Caraco* and *Janssen*. *See also* 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5); 28 U.S.C. § 2201.

Caraco holds that the exclusion of non-infringing generic drugs from the market can be a judicially cognizable injury-in-fact. 527 F.3d at 1291-92. Because a company is not free to manufacture or market drugs until it receives FDA approval, under the Hatch-Waxman framework such an injury occurs when the holder of an approved NDA takes action that delays FDA approval of subsequent ANDAs. *See* 21 U.S.C. § 355(a); *Novartis*, 482 F.3d at 1345. In the cases of *Caraco* and *Janssen*, the

alleged action taken (giving rise to the injury-in-fact) was listing particular patents in the Orange Book. *Caraco*, 527 F.3d at 1292; *Janssen*, 540 F.3d at 1359-60. As we explained in *Caraco*, the generic drug company's injury (i.e., exclusion from the market) is fairly traceable to the defendant's actions because "but-for" the defendant's decision to list a patent in the Orange Book, FDA approval of the generic drug company's ANDA would not have been independently delayed by that patent. 527 F.3d at 1292; *see* 21 U.S.C. § 355(j)(5)(B)(iv). When an Orange Book listing creates an "independent barrier" to entering the marketplace that cannot be overcome without a court judgment that the listed patent is invalid or not infringed—as for Paragraph IV filers—the company manufacturing the generic drug has been deprived of an economic opportunity to compete. *Id.* at 1293; *see also* 21 U.S.C. § 355(j)(5)(B)(4). A declaratory judgment redresses this alleged injury because it eliminates the potential for the corresponding listed patent to exclude the generic drug from the market. *Caraco*, 527 F.3d at 1293 (holding that a declaratory judgment action as to one of the listed patents would "clear the path to FDA approval that [the NDA holder's] actions would otherwise deny [the generic pharmaceutical]").

Though its facts were slightly different, *Janssen* reaffirms *Caraco*'s holding that the injury-in-fact must stem from the actions of the company that listed the patents in the Orange Book, not the inherent framework of the Hatch-Waxman Act. *See Janssen* 540 F.3d at 1360-61.

In *Janssen*, a subsequent Paragraph IV filer sought to trigger the first-filer's exclusivity period by obtaining a declaratory judgment. While the declaratory judgment action was pending, however, this subsequent filer stipulated to the validity, infringement, and enforceability of

another patent listed in the Orange Book for the same drug. *Id.* As a result of the stipulation, even if the subsequent filer had prevailed in its declaratory judgment action, it could not have launched its generic drug before expiration of the patent covered by the stipulation. Accordingly, unlike in *Caraco*, there was no risk that invalid patents were keeping the subsequent filer's generic drugs off the market; regardless, the company could not have marketed its generic drug because of the stipulation. *Id.* at 1361. In other words, the subsequent filer's alleged harm, inability to enter the market, was not "fairly traceable" to the listing of the subject patents in the Orange Book. Rather, the cause was the stipulation. We further held in *Janssen* that the subsequent filer could not proceed with its declaratory judgment action simply to trigger the first-filer's exclusivity period. In contrast to the listing of a patent in the Orange Book, a first-filer's exclusivity period in itself does not give rise to an injury-in-fact because the resulting exclusion of other generic drug companies from the market results from the inherent framework and intended workings of the Hatch-Waxman Act. *Id.* at 1360-61.

We hold that this case presents an actual controversy. Here, as in *Caraco*, a favorable judgment "would eliminate the potential for the [DJ patents] to exclude [Teva] from the drug market." 527 F.3d at 1293. Unlike the generic drug company in *Janssen*, Teva has not stipulated to the validity, infringement, or enforceability of any other patent listed in the Orange Book for donepezil. 540 F.3d at 1360. Nor is Teva subject to any final judgment regarding an Orange Book patent for donepezil that would prevent Teva from selling products covered by the

Gate ANDA. Given the absence of such factors, *Caraco* controls.[3] *See id.*

Eisai is correct that Teva and Gate have been subject to a preliminary injunction arising out of the separate '841 patent litigation, which barred Teva and Gate from marketing any drug containing donepezil as claimed in the '841 patent, including products covered by the Gate ANDA. As the name itself admits, however, that injunction was "preliminary." Indeed, the underlying litigation was still ongoing; there had been no final determination as to the validity, infringement, or enforceability of the '841 patent. Thus, unlike the generic drug company in *Janssen* which stipulated to the validity, enforceability and infringement of an Orange Book patent, there was no equivalent final judgment regarding the '841 patent. Indeed, Teva and Gate would not necessarily remain subject to an injunction, depending on the outcome of the '841 patent infringement litigation.[4]

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[3] Neither the statutory disclaimers nor Eisai's covenant-not-to-sue render this declaratory judgment action moot because the DJ patents remain listed in the Orange Book. *Caraco*, 527 F.3d at 1296-97. Thus, regardless of whether Eisai could bring an infringement action with respect to the DJ patents, under the Hatch-Waxman Act Teva still needs a court judgment of noninfringement or invalidity to obtain FDA approval and enter the market. *Id.*

[4] On September 28, 2010, Teva advised the court of a subsequent stipulation the parties entered into on July 19, 2010 in the '841 patent infringement litigation. The parties agreed that the preliminary injunction would remain in effect until the '841 patent expires on November 25, 2010. This stipulation does not change our analysis in this case for two reasons. First, it does not affect jurisdiction at the outset of this appeal. Second, given

II. Discretionary Dismissal

In the alternative, the district court stated that it would decline to entertain this suit pursuant to its broad discretion under the Declaratory Judgment Act. In support, the court cited the same reasons for finding no jurisdiction under Article III, the need to conserve judicial resources, the multiple ANDAs, and the relationship between Teva and Gate. On appeal, Teva argues that the Hatch-Waxman Act requires district courts to exercise jurisdiction in all declaratory judgment cases, so long as jurisdiction exists. According to Teva, the unequivocal language of 35 U.S.C. § 271(e)(5) overrides the general grant of discretion in 28 U.S.C. § 2201.

We disagree. Section 271(e)(5) (emphasis added) states that "the courts of the United States *shall*, to the extent consistent with the Constitution, have subject matter jurisdiction." The Declaratory Judgment Act provides that "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." 28 U.S.C. § 2201(a) (emphasis added). In our view, § 271(e)(5) speaks only to the power of a court to decide a case, not the prudence. Thus, while § 271(e)(5) clarifies the maximum extent of a court's jurisdiction, it does not govern how the district court may exercise its discretion under § 2201 in deciding whether to declare the

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that the stipulation is only relevant, if at all, until the expiration of the '841 patent on November 25, after that date the DJ patents would bar Teva from obtaining FDA approval earlier and marketing the generic form of donepezil covered by the Gate ANDA. To be sure, in this case, even if the DJ action resulted in a favorable outcome for Teva, the first-filer's 180-day exclusivity period would run after the '841 patent's expiration date.

rights of the litigants. *See MedImmune*, 549 U.S. at 136-37. Section 271(e)(5) thus leaves intact the discretion granted by § 2201 to decline jurisdiction over declaratory judgment actions. *Sony Elecs.*, 497 F.3d at 1288-89. We have thus upheld discretionary decisions declining jurisdiction when the declaratory judgment action was duplicative of other proceedings, the party instituted an action solely to enhance its bargaining power in negotiations, or when reexamination proceedings were pending. *Id.*; *see also EMC Corp. v. Norand Corp.*, 89 F.3d 807, 813-16 (Fed. Cir. 1996), *overruled in part on other grounds*, *MedImmune*, 549 U.S. 118 (2007).

However, while the Declaratory Judgment Act does "confer on federal courts unique and substantial discretion" to decide whether to exercise jurisdiction, that discretion is not unbounded. *See MedImmune*, 549 U.S. at 136; *Sony Elecs.*, 497 F.3d at 1288. In exercising such discretion, the district court must typically consider the usefulness of the declaratory judgment remedy, the fitness of the case for resolution, and the purposes of the Declaratory Judgment Act. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995); *see also Serco Servs. Co. v. Keley Co.*, 51 F.3d 1037, 1039 (Fed. Cir. 1995). A district court abuses its discretion when its decision is (1) clearly unreasonable or arbitrary; (2) was based on an erroneous conclusion of law; (3) the court's findings were clearly erroneous; or (4) the record contains no evidence upon which the court could rationally have based its decision. *Sony Elecs.*, 497 F.3d at 1288.

In this case, we conclude that it was an abuse of discretion to decline jurisdiction. At least two errors infect the district court's exercise of discretion under § 2201(a). First, as explained above, the district court erroneously concluded that it lacked subject matter jurisdiction, a

factor it then relied upon in deciding to decline jurisdiction. The district court should not have considered whether it had subject matter jurisdiction in making the subsequent, discretionary decision of whether to exercise jurisdiction over the case. *See Wilton*, 515 U.S. at 286; *Sony Elecs.*, 497 F.3d at 1271. While a lack of subject matter jurisdiction would require the district court to dismiss the case, the existence of jurisdiction in itself is not probative of the relevant factors under § 2201(a), such as whether the declaratory judgment remedy will be useful or whether the case is fit for resolution.

Second, the district court's exercise of discretion is not supported by the facts. The district court's conclusion that the relationship between Teva and Gate, combined with the multiple ANDAs, amounted to thinly disguised, improper gamesmanship is not what the record shows. Nothing in the Hatch-Waxman Act bars a company from filing multiple ANDAs covering different formulations of the same drug, as Teva (through Gate) did here. Nor was it improper for those ANDAs to be filed under different corporate names, particularly since this filing decision was made at the FDA's request. We agree with Teva that this case presents none of the typical factors that might warrant the exercise of discretion to decline jurisdiction. This case is not duplicative of other pending or decided litigation; in the absence of this action, the validity or infringement of the DJ patents will not be litigated. Further, as explained above, there is an actual controversy. A declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty and insecurity. *See SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1383 (Fed. Cir. 2007); *see also Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993).

Because no "sound basis" for refusing to adjudicate this case has been shown, on remand this case should proceed absent additional facts that might warrant a contrary conclusion. *See Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1345 (Fed. Cir. 2005); *Capo, Inc. v. Dioptics Med. Prods.*, 397 F.3d 1352, 1355 (Fed. Cir. 2004).

CONCLUSION

Because this case presents an actual controversy justiciable under Article III and no well-founded basis for declining jurisdiction has been established, we reverse the district court's dismissal for lack of subject matter jurisdiction. The case is remanded for further proceedings consistent with this opinion.

REVERSED AND REMANDED