Paper 20

Entered: 12 February 2013

## UNITED STATES PATENT AND TRADEMARK OFFICE

### BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ARIOSA DIAGNOSTICS. Petitioner,

v.

ISIS INNOVATION LIMITED Patent Owner.

Case IPR2012-00022 (MPT)
Patent 6,258,540

Before MICHAEL P. TIERNEY, LORA M. GREEN and JEFFREY B. ROBERTSON, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

# DECISION Institution of Inter Partes Review 37 C.F.R. § 42.108

#### **STANDING**

Ariosa Diagnostics (Ariosa) has filed a petition for Inter Partes Review of Isis Innovation Limited's (Isis) Patent No. 6,258,540. Isis challenges Ariosa's standing to file the Petition.

#### PRINCIPLES OF LAW

35 U.S.C. § 315 addresses the relationship of inter partes review to other proceedings or actions. It states, in relevant part:

- (a) Infringer's civil action.
- (1) Inter partes review barred by civil action.—An inter partes review may not be instituted if, before the date on which the petition for such review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

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(3) Treatment of counterclaim.—A counterclaim challenging the validity of a claim of a patent does not constitute a civil action challenging the validity of a claim of a patent for purposes of this subsection.

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#### CONTENTIONS

Ariosa, in its Petition, states that it has not, before the petition was filed, filed a civil action challenging the validity of a claim of the patent; the petition was not filed more than one year after Ariosa was served with complaint alleging infringement of the patent; and it is not estopped on other grounds from filing the petition. (Petition i.)

Isis argues that Ariosa lacks standing on the basis of Ariosa's filing of a civil action challenging the validity of the '540 patent before filing of the Petition for Inter Partes Review (Response 6). Specifically, Isis asserts that Ariosa, prior to filing its petition, filed a civil action against Sequenom, the exclusive licensee of the '540 patent, seeking a declaration that it did not infringe any claim of the '540 patent (*id.* at 3-4). Sequenom counterclaimed for infringement, and Ariosa

answered by raising the affirmative defense of invalidity of the '540 patent (*id.* at 4).

Isis argues that it "is of no moment" that Ariosa's challenge of the '540 patent in civil litigation is in the form of an affirmative defense (*id.* at 6). Isis asserts that the bar in section 315 does not require that the challenge be placed in the complaint, but "is directed to a petitioner-initiated 'civil action'—in other words the entire civil lawsuit—that challenges patent validity" (*id.* at 6-7).

Isis argues further that the exception in section 315(a)(3) does not apply, as that exception is limited to a counterclaim (*id.* at 7). According to Isis, Ariosa could have only brought a counterclaim for invalidity if Isis and Sequenom had initiated the civil action (*id.*). Isis cites *Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (U.S. 1993) ("*Expressio unius est exclusio alterius*") for the "canon of statutory interpretation 'the express mention of one thing excludes all others," arguing that canon excludes additional exceptions, such as the filing of an affirmative defense of patent invalidity (*id.* at 7-8).

Isis also asserts that to allow Ariosa to file an inter partes review proceeding would thwart the intent of Congress (*id.* at 5-6). According to Isis, section 315 was enacted to "avoid patent-owner harassment and to further the central purpose of IPRs to provide a cost-effective alternative to district-court patent validity litigation" (*id.* at 5). Thus, Isis asserts, a "key directive" of the statute is that the party that wishes to challenge the validity of a patent "must choose a single forum," with the only narrow exception being if the challenge is in the form of a counterclaim in a patent owner-initiated civil action (*id.* at 5-6).

The issue thus before us is whether filing a Declaratory Judgment of noninfringement in District Court bars Ariosa from later filing a petition for Inter Partes Review under 35 U.S.C. § 315(a), and whether the express mention of a counterclaim of invalidity in 35 U.S.C. § 315(a)(3) mandates interpreting the statute such that raising an affirmative defense of invalidity in response to a compulsory counterclaim of infringement deprives Ariosa of standing to file for inter partes review.

## **ANALYSIS**

Statutory construction "begins with 'the language of the statute.' And where the statutory language provides a clear answer, it ends there as well." *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999) (citations omitted).

"Beyond the statute's text, [the 'traditional tools of statutory construction'] include the statute's structure, canons of statutory construction, and legislative history." *Timex V.I. v. United States*, 157 F.3d 879, 882 (Fed.Cir.1998) (quoting *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 n. 9, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984)). "If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect" *Chevron*, 467 U.S. at 843 n. 9, 104 S.Ct. 2778 . . . .

Bull v. U.S., 479 F.3d 1365, 1376 (Fed. Cir. 2007).

The first issue to be decided is what is meant by "the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent" in (a)(1) of the statute. Under the Patent Owner's interpretation of the statute, "filing" extends beyond the commencement of the civil action and includes raising the affirmative defense of invalidity. As a guide to interpreting the plain meaning of the statute, we look to the Federal Rules of Civil Procedure.

Rule 2 of the Federal Rules of Civil Procedure<sup>1</sup> states that "[t]here is one form of action—the civil action," and Rule 3 states that "[a] civil action is commenced by filing a complaint with court." Defenses are raised in answer to the complaint or in answer to a counterclaim. Fed. R. Civ. P. 12. We thus conclude that when the statute refers to filing a civil action, it refers to filing a complaint with the court to commence the civil action. *See, e.g., Baldwin Cnty Welcome Ctr v. Brown*, 466 U.S. 147, 149 (1984) (citing Fed. R. Civ. P. 3 for the proposition that a civil action is brought upon the filing of a complaint with the court).

The next issue then becomes whether the above interpretation of what constitutes filing a civil action for purposes of section 315(a)(1) can be reconciled with the explicit exception of filing a counterclaim for invalidity in section 315(a)(3).

The Supreme Court distinguished an affirmative defense of invalidity from a counterclaim of invalidity in *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993). The question before the Court in that case was whether the Court of Appeals for the Federal Circuit properly vacated a declaratory judgment of invalidity after finding that there was no infringement. *Id.* at 85. Quoting *Altvater v. Freeman*, 319 U.S. 359, 363-364 (1943), the Court stated:

"To hold a patent valid if it is not infringed is to decide a hypothetical case. But the situation in the present case is quite different. We have here not only bill and answer but a counterclaim. Though the decision of non-infringement disposes of the bill and answer, it does not dispose of the counterclaim which raises the question of validity.... [T]he issue of validity may be raised by a counterclaim in an infringement suit. The requirements of case or controversy are of course no less strict under the Declaratory Judgments Act (48 Stat. 955, 28 U.S.C. § 400) than in case of other suits. But we are of the view that the issues raised by the present counterclaim were

<sup>&</sup>lt;sup>1</sup> As amended December 1, 2010.

justiciable and that the controversy between the parties did not come to an end on the dismissal of the bill for non-infringement, since their dispute went beyond the single claim and the particular accused devices involved in that suit."

Cardinal Chem. Co., 508 U.S. at 94. The Court noted, however, that Altvater did not answer the question of whether, when there is no further infringement dispute between the parties, an adjudication of invalidity would be moot.

In answering that question, the Court observed that "[a] party seeking a declaratory judgment of invalidity presents a claim independent of the patentee's charge of infringement." *Id.* at 96. The Court also emphasized that there are public policy reasons to resolve questions of patent validity. *Id.* at 100-101. The Court thus rejected the Federal Circuit's practice of vacating a declaratory judgment of invalidity after a finding of noninfringement. *Id.* at 102.

Thus, it is clear from *Cardinal Chem. Co.* that there is a fundamental difference between an affirmative defense of invalidity and a counterclaim of invalidity. The affirmative defense of invalidity is tied to the claim of infringement, whereas a counterclaim of invalidity is independent from the claim of infringement, which survives a finding of noninfringement. Section 315(a)(3) makes clear that if a party is faced with a claim of infringement, it can bring the independent claim of invalidity as a counterclaim and still avail itself of interpartes review.

Given the above analysis as a backdrop, we conclude that the statutory language provides a clear answer to the issue of whether filing a civil action for a declaratory judgment of noninfringement by a party deprives that party of standing to file an inter partes review as a result of raising the affirmative defense of invalidity in response to a counter claim of infringement.

As discussed supra, the statute clearly defines which civil actions, when filed, bar a party from filing an inter partes review—civil actions challenging the validity of a patent. A civil action for a declaratory judgment of non-infringement is not a civil action challenging the validity of a patent. Moreover, as discussed above, asserting an affirmative defense of invalidity is treated differently than a counterclaim for invalidity, and thus for the purposes of 315(a)(1) cannot be considered a filing of a civil action for invalidity. And as also discussed above, that interpretation of section 315(a)(1) does not conflict with the explicit exclusion in 315(a)(3) of filing a counterclaim for invalidity.

We have considered Patent Owner's argument that to allow Petitioner to file a declaratory judgment action for noninfringement and also file a petition for inter parties review allows petitioner to thwart the intent of Congress, but it does not convince us otherwise.

Senator Kyl stated in discussing the Leahy-Smith America Invents Act:

Another set of changes made by the House bill concerns the coordination of inter partes and postgrant review with civil litigation. The Senate bill, at proposed sections 315(a) and 325(a), would have barred a party or his real party in interest from seeking or maintaining an inter partes or postgrant review after he has filed a declaratory-judgment action challenging the validity of the patent. The final bill will still bar seeking IPR or PGR after a declaratory-judgment action has been filed, but will allow a declaratory-judgment action to be filed on the same day or after the petition for IPR or PGR was filed. Such a declaratory-judgment action, however, will be automatically stayed by the court unless the patent owner countersues for infringement. The purpose of allowing the declaratory-judgment action to be filed is to allow the accused infringer to file the first action and thus be presumptively entitled to his choice of venue.

157 Cong. Rec. S5429 (daily ed Sept. 8, 2011)).

Thus, as made clear by Senator Kyl, section 315(a) was amended to allow a petitioner to file an inter partes review, and still have their choice of venue by allowing the petitioner to file a declaratory judgment action that same day.

Moreover, a party cannot just bring a declaratory judgment action of noninfringement without any basis for doing so.

Although there is no bright line rule to determine whether a declaratory judgment action satisfies Article III's case-or-controversy requirements, 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 upon a hypothetical state of facts." *MedImmune*, 549 U.S. at 127, 127 S.Ct. 764 (quoting *Aetna Life*, 300 U.S. at 240–41, 57 S.Ct. 461). "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. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273, 61 S.Ct. 510, 85 L.Ed. 826 (1941)).

3M Co. v. Avery Dennison Corp., 673 F.3d 1372, 1376 (Fed. Cir. 2012). And even when there is a case or controversy, the district court still has discretion in deciding whether it will entertain the declaratory judgment action. *Id*.

Thus, allowing a party to file a both a declaratory judgment action for noninfringement and an inter partes review does not allow for harassment of a patent owner, because in order to bring the declaratory judgment action for noninfringement, a party must still satisfy Article III's case-or-controversy requirements.

We thus conclude that section 315(a) does not deprive the petitioner Isis of standing to bring the instant inter partes review.

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Accordingly, it is

**ORDERED** that the request of Patent Owner Isis that inter partes review should not be instituted on the basis that Petitioner Ariosa lacks standing to file the petition is **denied**.

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