NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

STRECK, INC., STRECK LLC,
Appellants

v.

RAVGEN, INC.,
Appellee

2023-1989

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2021-01577.

Decided: January 22, 2025

THOMAS LEE DUSTON, Marshall, Gerstein & Borun LLP, Chicago, IL, argued for appellants. Also represented by THOMAS BURNS, SANDIP PATEL, ISHA S. SHAH.

BRIAN MATTY, Desmarais LLP, New York, NY, argued for appellee. Also represented by JOHN M. DESMARAIS, KERRI-ANN LIMBEEK; GABRIELLE E. HIGGINS, San Francisco, CA.

Before LOURIE, BRYSON, and STARK, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Streck LLC[1] ("Streck") appeals from a final decision of the U.S. Patent Trial and Appeal Board ("the Board") holding that all challenged claims of U.S. Patent 7,332,277 ("the '277 patent") were not shown to have been obvious. *Streck, Inc. v. Ravgen, Inc.*, No. IPR2021-01577, (P.T.A.B. April 18, 2023) (holding that claims 55–61, 68, 69, 80–86, 89–92, 94, 126–130, 132, and 133 had not been shown to be unpatentable) ("*Decision*"). For the following reasons, we *affirm*.

BACKGROUND

The instant case is a companion case to *Laboratory Corporation of America Holdings, v. Ravgen, Inc.*, No. 2023–1342, –1136, 2025 WL 32904 (Fed. Cir. Jan. 6, 2025) ("*Labcorp*") addressing the same patent and decided by this court on January 6, 2025. In that case, we affirmed the upholding of an overlapping set of claims against different prior art. As in that case, claims 55 and 132 are illustrative for the issues on appeal.

Claim 55 reads as follows:

> 55. A method comprising determining the sequence of a locus of interest on free fetal DNA isolated from a sample obtained from a pregnant female, wherein said sample comprises free fetal DNA and an agent that inhibits lysis of cells, if cells are present, wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor.

'277 patent, col. 472, l. 66–col. 473, l. 5.

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[1] Streck LLC is the successor in interest to Streck, Inc.

Claim 132 reads as follows:

> 132. The method of claim 60, wherein said cell lysis inhibitor is selected from glutaraldehyde, formaldehyde, and formalin.

Id. at col. 478, ll. 12–14.

Streck asserted unpatentability based on three grounds in its *inter partes* review petition; however, only the Board's decision with respect to obviousness over Pertl[2] in combination with Granger[3] is challenged on appeal. Streck's Pertl-Granger combination also relied on background teachings of Chiu[4] to establish a motivation to combine the references. Pertl reports a study on a fetal DNA detection method that can be used to detect both male and female fetal DNA from a maternal blood sample. J.A. 3038–42. Granger discloses a method for preserving blood samples for later analysis using formaldehyde. J.A. 3054–58. Chiu reports a study on the effects of blood-processing protocols on fetal and total DNA quantification in maternal plasma. J.A. 3043–49.

The Board determined that none of the challenged claims had been shown to be obvious over Pertl and Granger. *Decision*, at J.A. 87. The Board found that a person of ordinary skill in the art would not have been

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[2] Pertl et al., *Detection of Male and Female Fetal DNA in Maternal Plasma by Multiplex Fluorescent Polymerase Chain Reaction Amplification of Short Tandem Repeats*, 106 HUM. GENETICS 45 (2000) ("Pertl"), J.A. 3038–42.

[3] Granger et al., WO 97/45729, published Dec. 4, 1997 ("Granger"), J.A. 3050–96.

[4] Chiu et al., *Effects of Blood-Processing Protocols on Fetal and Total DNA Quantification in Maternal Plasma*, 47 CLINICAL CHEMISTRY 1607 (2001) ("Chiu"), J.A. 3043–49.

motivated to combine the prior art references because "Pertl does not express concerns that cell lysis would interfere with its method or report increased background DNA released due to lysis (contrary to Petitioner's assertion)." *Id.* at J.A. 67. The Board also concluded that a person of ordinary skill in the art "would have had significant and unresolved concerns about expanding formaldehyde's use to applications involving rare circulating cell-free fetal DNA in maternal plasma as such use could damage the cffDNA analyte in the sample itself." *Id.* at J.A. 87. The Board credited expert testimony that "such concerns would have dissuaded a [person of ordinary skill in the art] from modifying Pertl's method with Granger'[s] formaldehyde as proposed by [Streck]." *Id.* Streck timely appealed, and we have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

On appeal, Streck argues that the Board committed a variety of legal errors and that its findings were not supported by substantial evidence. In response, Ravgen defends the Board's decision and further asserts that Streck lacks standing to appeal the Board's final written decision.

I

We begin with the standing issue. To meet Article III standing requirements, the party seeking relief "must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). To establish an injury in fact sufficient to appeal a final written decision of the Board, an appellant "need not meet all the normal standards for redressability and immediacy." *Grit Energy Sols., LLC v. Oren Techs., LLC*, 957 F.3d 1309, 1319 (Fed. Cir. 2020) (cleaned up). It is generally sufficient for the appellant to show that "it has engaged in, is engaging in, or will likely engage in activity that would give rise to a possible infringement suit." *Id.* (cleaned up).

Ravgen argues that Streck lacks Article III standing to appeal the Board's decision because it cannot show the required injury in fact. Ravgen Br. 22–27. Streck responds that infringement accusations by Ravgen and Streck's customers' indemnity demands both establish injury in fact under the proper standard. Reply Br. 2–7.

The facts of this case clearly establish a genuine risk of an infringement suit against Streck. Ravgen filed an expert report with the Board that includes claim charts and an express accusation of both direct and indirect infringement of its patent by Streck. J.A. 14219 ("[I]t is my opinion that Streck's use of Cell-Free DNA BCT ('Streck BCT') meets each and every limitation of, and therefore practices, Claims 55, 59–60, 81, 89–91, and 132–133 of the '277 Patent. Additionally, Streck induces third parties to practice the method of Claims 55, 59–60, 81, 89–91, and 132–133 of the '277 Patent."); *see also* J.A. 14219–323 (claim charts). Additionally, Ravgen has sued multiple Streck customers alleging infringement of the '277 patent. *See* Reply Br. 3 n.1. The claim charts and accompanying statements filed with the Board, coupled with Ravgen's history of filing infringement suits against Streck's customers, establish the risk of an infringement suit against Streck sufficient to grant standing to appeal a final written decision of the Board.

Because the risk of an infringement suit is clear, we need not determine if Streck's customers' indemnity demands independently grant Streck standing to appeal the Board's decision.

II

Having determined that Streck possesses standing to appeal the Board's decision, we now address Streck's arguments relating to the Board's obviousness determination. Obviousness is a question of law based on underlying findings of fact. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007). We review the Board's legal conclusion on

obviousness *de novo* and its findings of fact for substantial evidence. *HTC Corp. v. Cellular Commc'ns Equip., LLC*, 877 F.3d 1361, 1369 (Fed. Cir. 2017). What a reference teaches and the presence or absence of a motivation to combine references are questions of fact. *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196–97 (Fed. Cir. 2014).

A

Streck raises a variety of legal challenges to the Board's analysis of motivation to combine, but they all similarly mischaracterize the Board's analysis. For example, Streck argues that the Board erred by requiring Granger's solution to be superior to other techniques. Streck Br. 40–45. However, the Board expressly stated that it was doing no such thing. *See Decision* at J.A. 75 ("To be clear, we are not suggesting that a [person of ordinary skill in the art] must choose only the 'best' solution to prove obviousness."). Similarly, Streck argues that the Board erred by requiring Pertl alone to disclose a motivation to combine the references and finding that it discouraged improvement upon its method. Streck Br. 29–34. However, the Board committed no such legal error and simply disagreed with Streck about the teachings of Pertl. *See, e.g.*, *Decision* at J.A. 64 ("[W]e find that [Streck] overstates Pertl's alleged concerns with 'background' maternal DNA and misstates the purported 'increases' in background DNA from cell lysis in Pertl's method.").

As in the companion case, Streck's arguments "attempt to recast factual issues as legal ones." *See Labcorp*, 2025 WL 32904, at *2. At bottom, the Board made factual determinations regarding what the references teach and the presence or absence of a motivation to combine. *See, e.g.*, *Decision*, at J.A. 69 ("[W]e are not persuaded the [person of ordinary skill in the art] would have understood from Chiu that up to 25% cffDNA was available in maternal blood for analysis. . . . [T]he prevailing view at the time of Chiu's

publication, and for years afterward, was that circulating cell-free fetal DNA in maternal plasma varied from between about 3–6%."); *id.* at J.A. 76 ("We find that Srinivasan provides strong evidence that formaldehyde was known to have detrimental effects on nucleic acids."). And, as in the companion case, "disagreement with the Board's interpretations of [a reference] does not amount to a demonstration that the Board somehow failed to use the proper analysis." *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1347 (Fed. Cir. 2021). We have considered Streck's additional legal arguments and find them similarly flawed.

B

Finally, Streck argues that the Board's findings were not supported by substantial evidence. Specifically, Streck argues that "[n]o evidence supports the finding that a [person of ordinary skill in the art] would have been dissuaded from using Granger's formaldehyde solution in Pertl's method." Streck Br. 45. We disagree.

The Board's conclusions were adequately supported. The Board credited documentary evidence that "formaldehyde induces DNA degradation." *Decision*, at J.A. 77. It also relied on Ravgen's expert's testimony to find that these issues "would have discouraged [formaldehyde's] use in a modified Pertl method." *Id.* The Board concluded that the disclosures of Granger did not alleviate those concerns because Streck's expert "admit[ed] that Granger describes '*intra*cellular nucleic acids,' that Granger 'does not disclose any interactions between its stabilizers and nucleic acids,' and that Granger is '*silent* on cell-free nucleic acids.'" *Id.* at J.A. 83 (original emphasis). These findings were reasonable and are adequate to support its conclusion that Streck failed to demonstrate that a person of ordinary skill in the art would have been motivated to combine Pertl and Granger to arrive at the claimed invention. *See id.* at J.A. 87.

CONCLUSION

We have considered Streck's remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm the Board's decision in IPR2021-01577.

AFFIRMED