United States Court of Appeals for the Federal Circuit

SHOCKWAVE MEDICAL, INC.,
Appellant

v.

CARDIOVASCULAR SYSTEMS, INC.,
Cross-Appellant

COKE MORGAN STEWART, ACTING UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND ACTING DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2023-1864, 2023-1940

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2019-00405.

Decided: July 14, 2025

DAVID C. MCPHIE, Irell & Manella LLP, Newport Beach, CA, argued for appellant. Also represented by STEPHEN PAYNE; MICHAEL RICHARD FLEMING, Washington, DC; COOK ALCIATI, Gardella Grace PA, Washington, DC.

GABRIEL K. BELL, Latham & Watkins LLP, Washington, DC, argued for cross-appellant. Also represented by HANNAH FAN, MICHAEL A. MORIN, JACOB VANNETTE.

MAUREEN DONOVAN QUELER, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by PETER J. AYERS, MAI-TRANG DUC DANG, AMY J. NELSON.

Before LOURIE, DYK, and CUNNINGHAM, *Circuit Judges*.

DYK, *Circuit Judge*.

In an inter partes review ("IPR"), the Patent Trial and Appeal Board ("Board") determined that claims 1–4 and 6–17 of U.S. Patent No. 8,956,371 (the "'371 patent") were shown to be unpatentable as obvious but that claim 5 was not shown to be unpatentable as obvious. Patent owner Shockwave Medical, Inc. ("Shockwave") appeals the Board's determinations as to claims 1–4 and 6–17, and IPR petitioner Cardiovascular Systems, Inc. ("CSI") cross-appeals the Board's determination as to claim 5. We affirm the Board's determination that claims 1–4 and 6–17 were shown to be unpatentable and reverse the Board's determination that claim 5 was not shown to be unpatentable. We accordingly affirm as to Shockwave's direct appeal and reverse as to CSI's cross-appeal.

BACKGROUND

Shockwave owns the '371 patent, entitled "Shockwave Balloon Catheter System," which is directed to the treatment of atherosclerosis through intravascular lithotripsy ("IVL"). Atherosclerosis is a common health condition characterized by the buildup of fatty deposits in blood vessels. These deposits may gradually harden into calcified atherosclerotic plaque and restrict blood flow, causing

coronary artery disease or vascular disease. Balloon angioplasty is a well-known method of treating atherosclerosis and involves guiding a balloon catheter to the location of the blood vessel that contains the calcified plaque buildup: Once in place, the balloon is inflated, widening the blood vessel and increasing blood flow. A typical balloon catheter is the over-the-wire balloon catheter, which consists of a hollow carrier (called a lumen), which is inserted over a wire to guide the balloon catheter to the correct position.

Lithotripsy is a well-known technique used in the treatment of kidney stones. It involves sending shockwaves—a form of high-intensity sonic wave—directly toward kidney stones. These shockwaves are induced by plasma, which is produced either by an electrical charge (known as electrohydraulic lithotripsy) or laser (known as laser lithotripsy). The shockwaves break up larger stones into smaller stones, allowing them to pass through the urinary system. The '371 patent applies this technique to breaking up calcified plaque deposits in the context of treating atherosclerosis, disclosing a method for treating atherosclerosis through electrohydraulic lithotripsy.

The claimed device uses a typical over-the-wire angioplasty balloon catheter and adds electrodes and a pulse generator. *See* '371 patent, col. 4 ll. 10–14. The patent explains that the electrodes within the fluid-filled balloon are attached to the pulse generator and that the electrodes produce electrical arcs that "are used to generate shockwaves in the fluid." '371 patent, col. 4 ll. 17–18. These shockwaves are conducted to the location of the vessel wall containing the calcified plaque deposits, where "the energy . . . break[s] the hardened plaque without the application of excessive pressure by the balloon on the walls of the artery." '371 patent, col. 4 ll. 36–41.

Claim 1 is exemplary as to the claims in Shockwave's appeal and recites:

> 1. An angioplasty catheter comprising:
>
> an elongated carrier sized to fit within a blood vessel,
>
> said carrier having a guide wire lumen extending there through;
>
> an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier near the distal end of the carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon; and
>
> an arc generator including a pair of electrodes,
>
> said electrodes being positioned within and in non-touching relation to the balloon,
>
> said arc generator generating a high voltage pulse sufficient to create a plasma arc between the electrodes resulting in a mechanical shock wave within the balloon that is conducted through the fluid and through the balloon and wherein the balloon is arranged to remain intact during the formation of the shockwave.

'371 patent, col. 6 ll. 21–39.

Claim 2 depends from claim 1 and requires that the "pair of electrodes" include a "pair of metallic electrodes." *See id.* col. 6 ll. 40–41. Claim 5 depends from claim 2 and is the subject of CSI's cross-appeal. Claim 5 recites:

> 5. The catheter of claim 2, wherein the pair of electrodes is disposed adjacent to and outside of the guide wire lumen.

Id. col. 6 ll. 46–47.

In December 2018, CSI filed an IPR petition challenging all 17 claims of the '371 patent as obvious over various prior art combinations. CSI's primary prior art reference was European Patent Application Publication No. EP 0571306 A1 ("Levy"), which describes using laser-generated pulses to disintegrate plaque in blood vessels. CSI also pointed to the '371 patent's disclosure of "typical prior art over-the-wire angioplasty balloon catheters[s] . . . [that] are usually non-compliant with a fixed maximum dimension when expanded with a fluid such as saline." J.A. 354 (quoting '371 patent, col. 3 l. 65–col. 4 l. 2). CSI argued that it would have been obvious to an ordinarily skilled artisan to modify Levy with the well-known angioplasty balloon catheter disclosed by the applicant admitted prior art ("AAPA"). Its proffered prior art combinations (which are the subject of the appeal and cross-appeal) involved "Levy as modified by AAPA" in combination with other prior art references. J.A. 337–38.

In July 2020, the Board issued its Final Written Decision, finding that claims 1–4 and 6–17, but not claim 5, were shown to be unpatentable as obvious. The Board determined that AAPA qualified as "prior art consisting of patents or printed publications" under 35 U.S.C. § 311(b). On August 18, 2020, the Patent and Trademark Office ("PTO") issued binding guidance (the "AAPA Guidance") stating that AAPA is not "prior art consisting of patents or printed publications" under § 311(b). J.A. 10730. The Board thereafter initiated rehearing "to allow the panel to consider and follow the AAPA Guidance." J.A. 1081. In February 2023, the Board issued its Final Decision on Rehearing, relying on AAPA only as evidence of the background knowledge in the art as to typical over-the-wire balloon catheters and again determining that claims 1–4 and 6–17 had been shown to be unpatentable as obvious but that claim 5 had not.

Shockwave appeals, and CSI cross-appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

"Obviousness is a mixed question of fact and law." *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1327 (Fed. Cir. 2017). We review the Board's legal conclusion of obviousness de novo and its factual findings for substantial evidence. *Okajima v. Bourdeau*, 261 F.3d 1350, 1354 (Fed. Cir. 2001). Claim construction is an issue of law that we review de novo when based on intrinsic evidence. *Personalized Media Commc'ns, LLC v. Apple, Inc.*, 952 F.3d 1336, 1339 (Fed. Cir. 2020). "What a prior art reference teaches and whether a skilled artisan would have been motivated to combine references are questions of fact[]" that we review for substantial evidence. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1051 (Fed. Cir. 2016).

I

A

Shockwave argues that both CSI in its petition and the Board in its final written decision improperly relied on AAPA to supply a basis for the petition. We disagree.[1]

Section 311(b) of the Patent Act provides: "A petitioner in an inter partes review may request to cancel as

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[1] CSI contends that that the Board's conclusion that the petition met the threshold requirements under § 311(b) is not appealable under § 314(d). As we explained in *Qualcomm Incorporated v. Apple Inc.*, 134 F.4th 1355 (Fed. Cir. 2025), this type of § 311(b) challenge is directed to the Board's final written decision, not "to the Board's determination about a run-of-the-mill statutory provision of a procedural nature regarding the threshold decision of whether to institute an IPR." *Id.* at 1364.

unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications." 35 U.S.C. § 311(b). We have explained that "[a]lthough the prior art that can be considered in [IPRs] is limited to patents and printed publications, it does not follow that we ignore the skilled artisan's knowledge when determining whether it would have been obvious to modify the prior art." *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337 (Fed. Cir. 2020). This is because the obviousness analysis "requires an assessment of the . . . 'background knowledge possessed by a person having ordinary skill in the art.'" *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1349 (Fed. Cir. 2010) (quoting *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 401 (2007)).

AAPA is art referenced in a patent application that is admitted by the applicant to be prior art. We recently approved the role of AAPA as evidence of general background knowledge of an ordinarily skilled artisan in our decisions in *Qualcomm Incorporated v. Apple Inc.*, 24 F.4th 1367 (Fed. Cir. 2022) ("*Qualcomm I*"), and *Qualcomm Incorporated v. Apple Inc.*, 134 F.4th 1355 (Fed. Cir. 2025) ("*Qualcomm II*").

In *Qualcomm I*, the IPR petitioner challenged a patent's claims as obvious based on the patent's description of a prior art system in combination with a prior art patent, and the Board found the claims to be unpatentable. 24 F.4th at 1371–72. We held that AAPA may be used as evidence of background knowledge of an ordinarily skilled artisan, but that AAPA cannot be the "basis" of a ground in an IPR petition. *Id.* at 1377. Because the Board had not addressed the issue whether the AAPA formed the basis of the petition, we remanded to allow the Board to address this issue in the first instance. *See id.* On remand, the Board held that AAPA does not form the basis of a ground in violation of § 311(b) if the ground relies on the AAPA "in

combination with" permissible prior art patents or printed publications. *Qualcomm II*, 134 F.4th at 1360. Based on this interpretation, the Board found that the ground relied upon by the petitioner was compliant with § 311(b). On a second appeal, we reversed, since the IPR petitioner had expressly labeled the AAPA as part of its "basis" for its obviousness ground. *Id.* at 1368.

Our decisions in *Qualcomm I* and *Qualcomm II* accordingly require that only patents and printed publications form the basis of an IPR petition's unpatentability grounds. However, AAPA can be important evidence of general background knowledge, and general knowledge can be used to supply a missing claim limitation. As we explained in *Qualcomm I*, our case law has long recognized numerous permissible uses for general background knowledge in an IPR such as, "for example, furnishing a motivation to combine, or supplying a missing claim limitation." 24 F.4th at 1376 (first citing *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013); and then citing *Koninklijke*, 948 F.3d at 1337–38). In *Qualcomm II*, we reiterated that AAPA can be used "to indicate the general knowledge of a person of ordinary skill in the art." 134 F.4th at 1365.

This case is quite different from *Qualcomm II*, where the petitioner expressly labeled AAPA as the "basis" for its challenge. 134 F.4th at 1367. Here CSI used AAPA only to show, as the '371 patent itself acknowledged, that the over-the-wire angioplasty balloon catheter was well known in the prior art and that this general background knowledge satisfied the '371 patent's claim limitations relating to an over-the-wire configuration. *See* J.A. 357 ("It would have been obvious for the POSITA to have implemented and utilized the most common angioplasty catheter and balloon design, with predictable and expected results."). This is consistent with our decision in *Koninklijke*, where we held that it is permissible for "general knowledge to supply a missing claim limitation in an [IPR]," 948 F.3d

at 1337–38, and our decision in *Qualcomm I*, where we explained it is permissible for the use of AAPA as general knowledge "supplying a missing claim limitation," 24 F.4th at 1376; *accord Qualcomm II*, 134 F.4th at 1365.

Shockwave also urges that this case is like *Qualcomm II* because the Board's Final Written Decision uses the word "basis" in a table describing the list of prior art references:

Claim(s) Challenged	35 U.S.C. §[1]	Reference(s)/Basis
8, 12	103	Levy, AAPA, and Mantell, Uchiyama, or Willneff, in further view of Duchamp[8]
9	103	Levy, AAPA, and Mantell, Uchiyama, or Willneff, in further view of Naimark[9]
10	103	Levy, AAPA, and Mantell, Uchiyama, or Willneff, in further view of Beyer[10]
13	103	Levy, AAPA, and Mantell, Uchiyama, or Willneff, in further view of Bhatta[11]
17	103	Levy, AAPA, and Mantell, Uchiyama, or Willneff, in further view of Schultheiss[12]
1–4, 6, 11, 15, 16	103	Willneff, AAPA, and Levy or Mantell
5, 14	103	Willneff, AAPA, and Levy or Mantell in further view of Uchiyama
7, 12	103	Willneff, AAPA, and Levy or Mantell in further view of Hayes
8, 12	103	Willneff, AAPA, and Levy or Mantell in further view of Duchamp
9	103	Willneff, AAPA, and Levy or Mantell in further view of Naimark

Appellant's Reply Br. 5 (citing J.A. 3–4 (alterations in original)).

The Board's reference table using the term "Reference(s)/Basis" does not support Shockwave's position. It is true that in *Qualcomm II*, we relied on "the statements from the tables in [the petitioner's] petitions clearly designat[ing] AAPA as included in the basis of Ground 2." 134 F.4th at 1367. But our reasoning in that case was predicated on the notion that an IPR petitioner, not the Board, "should be held to the phrasing of its petition because [it] is the 'master of its own petition.'" *Id.* (quoting *Intuitive Surgical, Inc. v. Ethicon LLC*, 25 F.4th 1035, 1041 (Fed. Cir. 2022)). We have consistently explained that "it

is the petition, not the Board's 'discretion,' that defines the metes and bounds of an [IPR]." *Koninklijke*, 948 F.3d at 1336. What matters for the purposes of § 311(b) is the grounds raised in the petition, and CSI's petition never phrased the AAPA in terms of constituting a basis for its obviousness arguments. In any event, the use of the term "references/basis" in the table suggests that it encompasses the use of AAPA as a "reference" to establish well-known general knowledge.

Shockwave also argues that, even if CSI did not expressly label its use of AAPA as evidence of general knowledge of an over-the-wire balloon catheter as a basis, in "substance" it formed the basis of the IPR petition. *See* Appellant's Br. 22. We have not previously decided whether AAPA improperly forms the basis for a petition when it is used to show that a claim limitation (characterized by the patent as not disclosed in the prior art) would have been obvious over the prior art. That is not the case here, where CSI properly relied on general background knowledge to supply missing claim limitations (which Shockwave does not argue were novel to the invention) and used AAPA as evidence of that general background knowledge. The IPR petition did not violate § 311(b).

B

Shockwave argues that the Board erred in denying its construction for "angioplasty balloon" as "a balloon that displaces the plaque into the vessel wall to expand the lumen of the vessel" and adopting CSI's construction of the term as "an inflatable sac that is configured to be inserted into a blood vessel for use in a medical procedure to widen narrowed or obstructed blood vessels." J.A. 11. According to Shockwave, the Board's adoption of CSI's construction fails to give proper meaning to the word "angioplasty," and Shockwave urges that the Board's construction effectively construes angioplasty to encompass "any type of procedure

that widens obstructed blood vessels and includes a balloon in some capacity." Appellant's Br. 30.

Nothing in the language of the claims or specification supports requiring that an angioplasty balloon press plaque into the vessel wall. In fact, the specification states that, although the balloon can be "expanded to fit snugly to the vessel wall[,] . . . this is not a requirement." '371 patent, col. 5 ll. 31–33. The specification also includes examples that describe widening the blood vessel without displacing plaque "into" the vessel wall. It explains that the plaque is "pulverized by the shock waves," '371 patent col. 5 ll. 45–46, so as to "break the hardened plaque without the application of excessive pressure by the balloon on the walls of the artery," *id.* col. 4 ll. 39–41. These examples contemplate situations where the balloon catheter widens the blood vessel without needing to press the plaque into the vessel wall.

To the extent that Shockwave urges that it "disclaime[d]" claim scope to overcome a prior art rejection and that an "angioplasty balloon" thus requires displacing plaque into the vessel, *see* Appellant's Br. 32, we disagree. Shockwave simply added the term "angioplasty" to the claim language and on appeal does not point to any portion of the prosecution history in which it mentioned requiring the angioplasty balloon to displace the plaque "into the vessel wall" or any equivalent language thereof.

C

Finally, Shockwave challenges three of the Board's fact findings: (1) that an ordinarily skilled artisan would have been motivated to incorporate Levy's shockwave system into the over-the-wire balloon catheter, (2) that Levy discloses shockwaves, and (3) that Shockwave's secondary considerations evidence did not outweigh CSI's obviousness showing. Substantial evidence supports each of these findings.

Shockwave's first two challenges to the Board's factual findings relate to Levy. Levy discloses a method for "removing plaque deposits in blood vessels" using a "pulsed laser radiation [that] is sent to an optical fiber having a distal end immersed in a liquid at the location of such a deposit." JA 1735. This "causes a cavitation of vapor within the liquid, which results in the implosion of gas bubbles, the implosion causing erosion of the deposit exposed to the cavitation phenomenon." JA 1735. Levy builds upon and incorporates a prior reference—U.S. Patent No. 5,116,227 ("Levy '227")—which is directed to a similar use of cavitation for cleaning tooth canals.

First, Shockwave argues that, even if CSI properly relied on the general knowledge to establish the balloon catheter limitations, it failed to provide any evidence or reasoning of a motivation to combine the balloon catheter with Levy. Appellant's Br. 37. But the Board expressly described at least two reasons why an ordinarily skilled artisan would combine the two: (1) "to assist a physician to navigate the catheter to reach the area for treatment" and (2) "to increase the types of treatments Levy could perform." J.A. 39–40. The Board was also entitled to credit CSI's expert witness Dr. Jensen's testimony that "[i]t would have been obvious for the person of ordinary skill in the art to have implemented and utilized the most common angioplasty catheter and balloon design, with predictable and expected results." J.A. 1645.

Second, Shockwave argues that the Board failed to identify evidence in the record that the cavitation disclosed in Levy by pulsed laser radiation is a high-energy shockwave, as opposed to a lower-energy acoustic wave (such as a hydraulic wave). Appellant's Br. 44. Acknowledging that Levy '227 references shockwaves, Shockwave nevertheless contends that shockwaves are only referenced with respect to a tooth canal embodiment.

The Board did not err in finding that Levy discloses the use of shockwaves in blood vessels. There is no question that Levy incorporates Levy '227 by reference. Levy '227 teaches that "cleaning of [tooth] canal 1 is achieved by shockwaves resulting from the laser radiation pulses, producing vapor implosions which detach debris or tissue from the wall of canal 1," and that this same technique "can also be employed in the medical field for cleaning vessels, such as blood vessels." J.A. 3657, col. 4 ll. 64–65. In any event, the Board found that an ordinarily skilled artisan would have been motivated to incorporate the arc generators in any of Japanese Laid Open Application No. JP 62-275446 A ("Uchiyama"), U.S. Application Publication No. 2010/0036294 A1 ("Mantell"), and German Patent Application Publication No. DE 3038445 A1 ("Willneff") into Levy to arrive at the claimed shockwaves. *See* J.A. 30–31.

Finally, Shockwave takes issue with the Board's findings that Shockwave was not entitled to a presumption of nexus with respect to secondary considerations and that its objective indicia evidence did not outweigh CSI's evidence of obviousness. Appellant's Br. 53, 55. Before the Board, Shockwave sought a presumption of nexus based on a single paragraph of its expert Dr. Berger's declaration, who stated that "the Shockwave IVL devices include each feature recited in the claims." J.A. 7539. The Board's conclusion that Dr. Berger's declaration did not sufficiently link the claims to the structure of Shockwave's commercial device was supported by substantial evidence, *see* J.A. 141–44, since Dr. Berger conceded that he had only seen Shockwave's device in pictures and could not identify who prepared the claim charts he cited. *See Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (explaining that a patentee is entitled to a presumption of nexus only "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features'" (quoting *Brown &*

Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1130 (Fed. Cir. 2000)).

We also see no problem in the Board's analysis of Shockwave's purported objective indicia, which it found to be cumulatively "largely weak." J.A. 65. This case is not, as Shockwave contends, like *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1213 (Fed. Cir. 2023), where we concluded that the Board failed to conduct a "reasoned, collective weighing" of secondary considerations evidence because it assigned "only vague weights . . . to the various factors and fail[ed] to explain its overall summation." The Board analyzed each of the factors in detail and explained how much weight it accorded to each of them. *See* J.A. 144–59. And unlike *Volvo*, 81 F.4th at 1213, the Board did explain its summation: It explained that although Shockwave's evidence was "voluminous," it was "largely weak" because it was directed to "excitement about the potential efficacy of the Shockwave IVL or its potential commercial success." J.A. 159.

II

The sole focus of CSI's cross-appeal is the Board's conclusion that claim 5 had not been shown to be unpatentable as obvious over Levy implemented in an over-the-wire balloon catheter in view of Uchiyama. The Board found that the prior art combination did not disclose claim 5's limitation relating to the placement of electrodes. As a threshold matter, Shockwave argues that CSI lacks standing to pursue its appeal in this court. Appellant's Reply Br. 42.

A

"Although a party does not need Article III standing . . . to obtain a Board decision, a party must establish Article III standing once it seeks review of a Board decision in this Court." *Incyte Corp. v. Sun Pharm. Indus., Inc.*, 136 F.4th 1096, 1099 (Fed. Cir. 2025). Parties seeking

relief before this court bear the burden of establishing the existence of an Article III case or controversy "at all times throughout the appeal." *ModernaTx, Inc. v. Arbutus Bio-Pharma Corp.*, 18 F.4th 1352, 1358 (Fed. Cir. 2021). When a party challenging an IPR decision "relies on potential infringement liability as a basis for injury in fact, but is not currently engaging in infringing activity, it must establish that it has concrete plans for future activity that creates a substantial risk of future infringement or would likely cause the patentee to assert a claim of infringement." *Gen. Elec. Co. v. Raytheon Techs. Corp.*, 983 F.3d 1334, 1341 (Fed. Cir. 2020) (quoting *JTEKT Corp. v. GKN Auto, LTD.*, 898 F.3d 1217, 1221 (Fed. Cir. 2018)).

CSI argues that it has standing to bring its cross-appeal because it has developed an IVL device that is in its final stages, *see* ECF No. 20-3 (declaration of Matt Cambronne), at 4, and because Shockwave's President publicly stated that the company would aggressively assert claim 5 of the '371 patent against competitors in the IVL market:

> We are very pleased that the [Board] validated claim 5 of our '371 patent, which protects the broad embodiment of our IVL technologies. Specifically, claim 5 describes a device that is delivered over a guidewire and generates shockwaves with electrodes inside of a balloon catheter. We believe that any viable, much less commercially viable, IVL device must contain these elements[.] . . . We believe that our robust portfolio of 40 issued U.S. patents and 50 issued foreign patents captures and protects the truly unique and sophisticated IVL technology[.]

ECF No. 20-2, at 7 (declaration of Gabriel K. Bell). These facts, according to CSI, demonstrate that it had concrete plans to offer a product that would likely cause Shockwave to assert a claim of infringement of claim 5. Shockwave responds that at the time CSI filed its cross-appeal, CSI's

IVL development was not sufficiently concrete to establish standing. *See* Appellant's Reply Br. 43–44.

Shockwave's arguments rely primarily on CSI's representations to the Board, well before CSI filed this cross-appeal. At the time it filed the cross-appeal, however, CSI had engaged with the Food and Drug Administration several times and was close to initiating clinical trials of an IVL product. ECF No. 20-3 at 4; Cross-Appellant's Reply Br. 5–6. At the time of the cross-appeal, CSI's product was near a design freeze, and "[c]hanges after this point are typically minimal." *Id.* These facts are thus not like those in *Incyte*, where the party had only allocated a small amount of funds a month before filing an appeal and was facing "significant manufacturing, formulation, testing, and regulatory hurdles to bring [the] product to market." 136 F.4th at 1102. Far from merely "amount[ing] to an expression of intent" to create a potentially infringing product, *id.*, the circumstances here constitute sufficiently "concrete plans." *Gen. Elec.*, 983 F.3d at 1341.

CSI also has established a substantial likelihood of a suit for infringement of claim 5. Shockwave has stated that "we believe that any viable, much less commercially viable, IVL device must contain these elements [of claim 5]," ECF No. 20-2, at 6, and that "[w]hile we are extremely bullish about our patent portfolio in the electrohydraulic lithotripsy area, . . . we'll certainly assert that against anybody who tries to copy what we're doing," *id.* at 30. Although a company's representations about its intent to protect its intellectual property do not always give rise to a substantial likelihood of litigation, Shockwave's President's broad claims reflect the company's expansive view of claim 5 as reading broadly on IVL technology. CSI has sufficiently shown that it is engaging in "activity that creates a substantial risk of future infringement" that is "likely [to] cause the patentee to assert a claim of infringement." *Gen. Elec.*, 983 F.3d at 1341; *see also CQV Co.*

v. Merck Pat. GmbH, 130 F.4th 1344, 1349 (Fed. Cir. 2025); *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1357 (Fed. Cir. 2020).

B

On the merits, CSI argues that the Board failed to consider the teachings of the prior art when considered as a whole in analyzing CSI's proffered combination of Levy as implemented in an over-the-wire balloon catheter in view of Uchiyama, as well as that claim 5's pair of electrodes "adjacent to and outside of the guidewire lumen" was a routine design choice that would have been obvious. Cross-Appellant's Br. 71. We agree.

Uchiyama is a printed Japanese Patent Application directed to a "[d]ischarge lithotriptor" that is used "to break a renal calculus formed in a kidney or a urinary duct in a body cavity with impact waves generated by electric discharge." J.A. 1783. This lithotriptor was composed of a pair of electrodes on a tube, with the electrodes located in a fluid-inflatable balloon such that they generated a shockwave through the fluid of the inflated balloon. Uchiyama taught that placing the electrodes within the balloon would prevent discharge sparks from directly hitting human tissue and thus that the shockwaves could be used to disrupt calcifications without damaging surrounding human tissue. J.A. 1785.

In its IPR petition, CSI argued that it would have been obvious to an ordinarily skilled artisan to implement the features of Uchiyama to provide Athat the electrodes are radially spaced away from the lumen tube and that this would be a routine design choice well within the ordinary skill of the art. J.A. 364. CSI's expert Dr. Jensen testified that this modification would be beneficial because an ordinarily skilled artisan "would have understood that calcifications are not distributed uniformly within the circumference of a vessel," that "Uchiyama taught that the

electrodes did not need to be centered within the balloon," and that an ordinarily skilled artisan would thus "have understood from Uchiyama that the electrodes could be displace[d] radially away from the lumen to, for example, permit the shockwaves to obtain greater lateral (i.e., sideways) coverage." J.A. 4071. The Board found that CSI had failed to demonstrate the placement of electrodes claimed by claim 5 was obvious, on the ground that the electrodes in Uchiyama itself were not placed both adjacent to and radially away from the lumen, a finding we do not disturb here. J.A. 69–70.

The problem with the Board's analysis is that it was predicated on its finding that Uchiyama alone did not disclose that the electrodes were positioned "adjacent to and outside of the guidewire lumen," since the argument raised by CSI before the Board was based on the combined teachings of Levy as modified by an over-the-wire catheter balloon and Uchiyama. The standard for obviousness requires consideration of the prior art combination taken as a whole. *In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012).

The Board's failure to consider the combined teachings of the prior art led it to improperly discount CSI's argument in its petition that modifying Uchiyama to place the electrodes outside the lumen would have been a routine design choice. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR*, 550 U.S. at 421. We explained in *Uber Technologies, Inc. v. X One, Inc.*, 957 F.3d 1334, 1338–40 (Fed. Cir. 2020), that when there are a limited number of well-known design choices in the prior art it would have been obvious to substitute one for the other. Such is the case here: CSI's expert Dr. Jensen testified that "it would have been obvious to a person of ordinary skill in the art to implement the features of Uchiyama to

provide the pair of electrodes that are disposed radially spaced away from the lumen tube" and that "[s]uch an implementation is a routine design choice and well within the knowledge and know-how of the person of ordinary skill in the art." *See* J.A. 1653. Shockwave did not present contrary evidence.

The only argument that Shockwave made before the Board against CSI's proposed placement of the electrodes in Levy was that it would have been located too close to the tissue and caused damage. The Board rejected that exact same argument in making its other obviousness findings as to claim 1. There was thus no evidence in the record supporting the Board's obviousness finding as to claim 5, and reversal rather than vacatur is thus appropriate.

CONCLUSION

We have considered Shockwave's remaining arguments and find them unpersuasive. We accordingly affirm the Board's determinations as to claims 1–4 and 6–17 in Shockwave's direct appeal and reverse the Board's determination as to claim 5 in CSI's cross-appeal.

AFFIRMED-IN-PART AND REVERSED-IN-PART

COSTS

Costs to cross-appellant CSI.