United States Court of Appeals for the Federal Circuit

INCEPT LLC,
Appellant

v.

PALETTE LIFE SCIENCES, INC.,
Appellee

KATHERINE K. VIDAL, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2021-2063, 2021-2065

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2020-00002, IPR2020-00004.

Decided: August 16, 2023

TIMOTHY E. GRIMSRUD, Faegre Drinker Biddle & Reath LLP, Minneapolis, MN, argued for appellant. Also represented by LAUREN J.F. BARTA; CHRISTOPHER J. BURRELL, BETHANY N. MIHALIK, Washington, DC.

TUNG ON KONG, Wilson, Sonsini, Goodrich & Rosati,

PC, San Francisco, CA, argued for appellee. Also represented by TASHA THOMAS, RICHARD TORCZON, Washington, DC; LORELEI WESTIN, San Diego, CA.

MARY L. KELLY, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, for intervenor. Also represented by PETER J. AYERS, DANIEL KAZHDAN, THOMAS W. KRAUSE, FARHEENA YASMEEN RASHEED.

Before NEWMAN, SCHALL, and TARANTO, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* SCHALL.

Opinion concurring-in-part and dissenting-in-part filed by *Circuit Judge* NEWMAN.

Incept LLC owns U.S. Patent Nos. 8,257,723 ("the '723 patent") and 7,744,913 ("the '913 patent"). It now appeals from two final written decisions of the U.S. Patent and Trademark Office Patent Trial and Appeal Board ("the Board") holding the claims of the '723 patent and the '913 patent unpatentable as anticipated by, or obvious in view of, the asserted prior art. For the following reasons, we affirm.

BACKGROUND

I

The '723 and '913 patents relate to improved methods for treating cancer, particularly prostate cancer, using radiation. The patents describe methods of introducing a filler between a radiation target tissue and other tissue to increase the distance between the two and thereby decrease the amount of radiation received by the non-targeted tissue. '723 patent at Abstract, col. 2 ll. 28–31; '913

patent at Abstract, col. 2 ll. 28–31.[1] The '723 patent has one independent claim and twenty-three dependent claims. '723 patent col. 16 l. 49–col. 18 l. 23. The '913 patent has two independent claims and twenty-three dependent claims. '913 patent col. 16 l. 43–col. 18 l. 32.

Independent claim 1 of the '723 patent recites:

> 1. A method of delivering a therapeutic dose of radiation to a patient comprising
>
> introducing a biocompatible, biodegradable filler between an organ and a nearby tissue to increase a distance between the organ and the tissue, and
>
> treating the tissue with the therapeutic dose of radiation so that the presence of the filler causes the organ to receive less of the dose of radiation compared to the amount of the dose of radiation the organ would receive in the absence of the filler,
>
> wherein the filler is introduced as an injectable material and is a gel in the patient, and wherein the filler is removable by biodegradation in the patient.

'723 patent col. 16 ll. 49–59. Independent claim 1 of the '913 patent is similar to claim 1 of the '723 patent but includes the additional limitation that the filler is introduced specifically between a patient's prostate gland and rectum. '913 patent col. 16 ll. 43–57. Accordingly, the claims of both patents recite a filler that is (1) biocompatible, (2) injectable, (3) a gel in the patient, (4) biodegradable/removable by biodegradation, and (5) introduced between a radiation target and nearby tissue.[2]

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[1] The '723 patent is a continuation of, and has a specification identical to, the '913 patent.

[2] Independent claim 17 of the '913 patent differs because it recites additional limitations and does not include

II

Palette Life Sciences, Inc. ("Palette") filed petitions for *inter partes* review challenging the claims of the '723 and '913 patents as unpatentable over prior art, including U.S. Patent No. 6,624,245 to Wallace et al. ("Wallace").

Wallace describes a method for the "rapid formation of a biocompatible gel . . . at a selected site within a patient's body." Wallace at Abstract. Wallace explains that its biocompatible gels can be formed from reaction mixtures that are injected at a specific site within a patient's body and allowed to crosslink at the site of the injection. *Id.* col. 10 ll. 8–12. Wallace provides that its gels may be formed from polymers that include biodegradable segments or blocks that are hydrolyzed in the presence of water or enzymatically cleaved *in situ*. *Id.* col. 19 ll. 3–19. According to Wallace, the "preferred application" of its compositions is for use as a "tissue sealant[] and adhesive[]." *Id.* col. 28 ll. 44–62. Wallace explains, however, that "[t]he compositions can also be used as a large space-filling device for organ displacement in a body cavity during surgical or radiation procedures, for example, to protect the intestines during a planned course of radiation to the pelvis." *Id.* col. 33 ll. 64–67.

Palette's petition challenging the '723 patent asserted that claims 1, 6, 8–12, 14, 15, and 17–22 would have been anticipated by Wallace, that claims 1–6, 8–12, and 14–24 would have been obvious in view of Wallace, and that claims 7 and 13 would have been obvious over Wallace in combination with PCT Publication No. WO 94/25080 to

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some of the limitations of independent claim 1 of both patents (e.g., the filler being injectable and a gel in the patient). We need not separately address claim 17, however, because Incept does not provide any argument based on those differences. *See* Appellant's Br. 2–3, 6, 8.

Griffith-Cima et al. ("Griffith-Cima"). J.A. 149. In its petition challenging the '913 patent, Palette asserted that claims 1–18 and 20–24 would have been obvious over Wallace in combination with U.S. Patent No. 6,210,314 to Ein-Gal ("Ein-Gal"), and that claims 19 and 25 would have been obvious over the combination of Wallace, Ein-Gal, and Griffith-Cima. J.A. 5479.

The Board instituted inter partes review and ultimately issued final written decisions in which it held that Palette had established the challenged claims to be unpatentable on the Wallace-based grounds set forth in the two petitions. *Palette Life Scis., Inc. v. Incept LLC*, No. IPR2020-00002, 2021 WL 1393447 (P.T.A.B. April 13, 2021) (*'723 Final Written Decision*); *Palette Life Scis., Inc. v. Incept LLC*, No. IPR2020-00004, 2021 WL 1395258 (P.T.A.B. April 13, 2021) (*'913 Final Written Decision*).[3]

Incept appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

I

We review the Board's legal conclusions de novo and its factual findings for substantial evidence. *Becton, Dickinson & Co. v. Baxter Corp.*, 998 F.3d 1337, 1339 (Fed. Cir. 2021). Anticipation is a question of fact. *Mylan Pharms. Inc. v. Merck Sharp & Dohme Corp.*, 50 F.4th 147, 152 (Fed. Cir. 2022). Obviousness is a question of law based on underlying factual determinations. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007). Those underlying factual determinations include: (1) the scope and content of the prior art; (2) differences between the prior art and the

[3] Palette's petitions set forth other grounds for unpatentability of the '723 and '913 patents' claims that the Board declined to reach in its final written decisions.

claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations such as commercial success, long felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). The possibility of drawing two inconsistent conclusions from the evidence does not prevent the Board's findings from being supported by substantial evidence. *See Consolo v. Fed. Mar. Comm'n*, 383 U.S. 607, 620 (1966).

II

We begin with anticipation. Under 35 U.S.C. § 102, a prior art reference will anticipate a patent claim if it discloses all of the limitations of the claim "arranged or combined in the same way as in the claim." *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369–70 (Fed. Cir. 2008). Incept argues on appeal that the Board committed legal error because it engaged in a "patchwork approach" that involved "picking and choosing" from Wallace's different teachings to piece together the elements of the '723 patent claims. Appellant's Br. 31–33 (citing *In re Arkley*, 455 F.2d 586, 587–88 (CCPA 1972)). According to Incept, Wallace "teaches a complex, multi-step process for its gel that involves picking and choosing among numerous materials and properties," such that Wallace "describes millions, if not billions, of different possible compositions, each with different properties." *Id.* at 34–35. Incept relies on cases from this court explaining that, when a prior art reference describes a genus and the challenged claim recites a species of that genus, anticipation turns on whether the genus was of such a defined and limited class that one of ordinary skill in the art could have "at once envisaged" each member of the genus. *Id.* at 36 (citing *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1376 (Fed. Cir. 2006);

Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 999 (Fed. Cir. 2006); *Metabolite Lab'ys, Inc. v. Lab'y Corp. of Am. Holdings*, 370 F.3d 1354, 1367 (Fed. Cir. 2004)).

We see no legal error in the Board's anticipation analysis. The Board did not engage in "picking and choosing" features from different teachings of Wallace. Instead, it found that Wallace expressly describes compositions that have the claimed characteristics of, and are used for the same displacement purpose as, the compositions referred to in the '723 patent claims challenged as anticipated. As the Board explained, although Wallace discloses various options for each component of its compositions, the characteristics of those compositions required for anticipation would remain, even if the degree to which those characteristics would be present could vary (in ways immaterial to anticipation). *'723 Final Written Decision*, 2021 WL 1393447, at *12 ("Wallace's disclosure of various options for each component of its composition does not change those characteristics of its filler composition that are recited by claim 1 [of the '723 patent]."). Moreover, the claims of the '723 patent are not directed to a "species" of fillers that fall within the "genus" of compositions described in Wallace. Rather, the '723 patent claims are directed to a method of introducing fillers having certain general qualities, which general qualities Wallace's compositions are also described as having. Incept cannot use the fact that Wallace describes multiple compositions to evade an anticipation finding where Wallace provides "as complete detail as is contained in the patent claim," such that a skilled artisan would have understood that Wallace's compositions had the same generic properties as those in the '723 patent claims. *See Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) (providing that, to anticipate, "[t]he identical invention must be shown in as complete detail as is contained in the patent claim").

Incept next takes issue with what it refers to as the Board's failure to identify a teaching in Wallace that any of

its compositions are "*entirely* removable by biodegradation." Appellant's Br. 40 (emphasis added). Wallace's teaching of "biodegradable *segments*," Incept contends, "[a]t most . . . suggests only that, at least in some applications, a portion of the polymer may be biodegradable," particularly because Wallace elsewhere teaches that its compositions "are not readily degradable in vivo." *Id.* at 40–41 (citing Wallace col. 19 ll. 3–9, ll. col. 34 ll. 11–14). We are not persuaded that the Board's finding of biodegradability was insufficient. To begin, the Board expressly found Wallace's filler compositions not only to be "biodegradable" but also to specifically be "removable by biodegradation," as the claims require. *'723 Final Written Decision*, 2021 WL 1393447, at *12. In support of this finding, the Board relied on the below excerpt of Wallace:

> The polymer may include biodegradable segments and blocks, either distributed throughout the polymer's molecular structure or present as a single block, as in a block copolymer. Biodegradable segments are those that degrade so as to break covalent bonds. Typically, biodegradable segments are segments that are hydrolyzed in the presence of water and/or enzymatically cleaved in situ.

Wallace col. 19 ll. 3–9. Thus, Wallace teaches that a polymer can have "biodegradable segments," distributed throughout its molecular structure, that degrade so as to break the polymer's covalent bonds. While this excerpt of Wallace alone constitutes substantial evidence to support the Board's finding, the finding is also supported by Palette's expert's testimony, noted by the Board, that a skilled artisan would have appreciated that Wallace teaches that the filler is removable by biodegradation. *'723 Final Written Decision*, 2021 WL 1393447, at *7 (citing J.A. 1083 (¶ 126)). Incept points to a statement in Wallace to the effect that polymers, generally, are "essentially nondegradable in vivo over a period of at least several months" and another statement in Wallace to the effect that its

compositions are "not *readily* degradable." *See* Appellant's Br. 17, 40–41 (quoting Wallace col. 7 ll. 25–29, col. 34 ll. 11–14 (emphasis added)). But the Board could reasonably read those statements as not contradicting the Board's finding that Wallace teaches compositions that have the only biodegradability properties required by the claims at issue, for which no narrowing construction of the biodegradability term was adopted by the Board. Our role is not to reweigh evidence or make factual findings, but to review the Board's findings for substantial evidence. *Roku, Inc. v. Universal Elecs., Inc.*, 63 F.4th 1319, 1326 (Fed. Cir. 2023); *Consolo*, 383 U.S. at 620 ("[T]he possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence.").

Incept next contends that the Board failed to identify a teaching in Wallace that any of its compositions are placed "between an organ and a nearby tissue," as required by the '723 patent claims. As the Board explained, however, "Wallace states that '[t]he compositions can also be used as a large space-filling device for organ displacement in a body cavity during surgical or radiation procedures, for example, to protect the intestines during a planned course of radiation to the pelvis.'" *'723 Final Written Decision*, 2021 WL 1393447, at *8 (citing Wallace col. 33 ll. 64–67). Before the Board, Incept argued that Wallace's "space-filling device" use did not apply to all of Wallace's compositions. *See* J.A. 442–44, 923–26. The Board expressly found, though, that a skilled artisan "would have understood Wallace's disclosure that its compositions may be used as a space-filling device applies generally to all its compositions." *'723 Final Written Decision*, 2021 WL 1393447, at *9. This finding is supported by substantial evidence in the form of Wallace's teachings that its "compositions of the present invention can be used in a variety of different applications" and Wallace's general statement that "[t]he compositions,"

generally, can serve as a space-filling device. Wallace col. 28 ll. 30–31, col. 33 ll. 64–67.

In sum, we see no legal error in the Board's anticipation analysis for the '723 patent, and substantial evidence supports the Board's findings that Wallace discloses each element of claim 1 of the '723 patent, arranged as in that claim. We therefore affirm the Board's determination that claims 1, 6, 8–12, 14, 15, and 17–22 of the '723 patent are anticipated by Wallace.

III

We turn now to obviousness.[4] Incept argues that the Board's obviousness analysis for both patents was erroneous because the Board: (1) merely reiterated its anticipation analysis; (2) disregarded statements in Wallace that teach away from the claimed biodegradable compositions; (3) did not separately analyze the obviousness of the dependent claims; and (4) improperly disregarded Incept's evidence of commercial success. We address each argument in turn.

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[4] Having held that claims 1, 6, 8–12, 14, 15, and 17–22 of the '723 patent are anticipated by Wallace, we need not address whether those claims are also rendered obvious by Wallace. *See In re Paulsen*, 30 F.3d 1475, 1481 (Fed. Cir. 1994) ("[S]ince anticipation is the ultimate of obviousness, the subject matter of these claims is necessarily obvious and we need not consider them further." (quoting *In re Baxter Travenol Lab'ys*, 952 F.2d 388, 391 (Fed. Cir. 1992))). Therefore, this section of our opinion pertains to those claims of the '723 patent (claims 2–5, 7, 13, 16, 23, and 24) for which the Board made only obviousness-based unpatentability determinations.

A

Incept first contends that the Board's obviousness analysis for both patents was based entirely on its "flawed" anticipation analysis for the '723 patent claims. Appellant's Br. 48. Incept takes issue with what it contends is a "conclusory" finding of motivation to combine, particularly with respect to the combination of Wallace with Ein-Gal for the '913 patent. *Id.* at 50–51.

To begin, having found no error in the Board's anticipation analysis, we fail to see how the Board's reliance upon that analysis was in error. As discussed above, Wallace discloses, and thereby renders obvious, the use of a gel that is both biocompatible and biodegradable. *See '723 Final Written Decision*, 2021 WL 1393447, at *13–14; *'913 Final Written Decision*, 2021 WL 1395258, at *8, *14 (noting Palette's assertion that, "to the extent Wallace does not explicitly disclose the use of a gel that is both biocompatible and biodegradable, Wallace teaches use of such a gel, rendering it obvious.").

We also disagree that the Board's obviousness analysis for the '913 patent was based *entirely* on its anticipation analysis for the '723 patent claims. Instead, in its obviousness analysis for the claims of the '913 patent, the Board explained that the petition relied on Ein-Gal as teaching the '913 patent's limitation of displacement of the rectum relative to the prostate gland. *'913 Final Written Decision*, 2021 WL 1395258, at *7. In addition, the Board noted Palette's contention that "[b]oth Wallace and Ein-Gal recognize and appreciate the benefit of displacing tissue away from a site intended to be irradiated, as doing so would protect the tissue from the harmful effects of radiation." *Id.* at *8 (citing J.A. 5508). The Board ultimately determined:

> Petitioner has shown by a preponderance of the evidence that the combined teachings of Wallace and Ein-Gal teach or suggest each limitation of independent claim 1, and that based on those teachings,

> along with the knowledge in the art, a person of ordinary skill in the art would have been motivated, with a reasonable expectation of success, to use Wallace's compositions for its disclosed purpose of displacing an organ for radiation therapy, including displacing the rectum relative to the prostate gland, wherein the composition is eventually removed by biodegradation, as required by claim 1.

'913 Final Written Decision, 2021 WL 1395258, at *13. The Board therefore made findings of motivation to combine that are not merely conclusory. Those findings are supported by substantial evidence in the form of the references themselves and Palette's expert's detailed testimony, which the Board found to be "persuasive." *Id.* at *14; *'723 Final Written Decision*, 2021 WL 1393447, at *14; *see* Wallace col. 33 ll. 64–67; Ein-Gal col. 1 ll. 31–36; J.A. 1091–98 (¶¶ 143–57), 6376–90 (¶¶ 132–52).

B

In an argument parallel to its argument regarding anticipation, Incept contends that the Board ignored Wallace's teaching away from biodegradable compositions. Appellant's Br. 52–54 (citing Wallace col. 34 ll. 11–14, col. 7 ll. 25–29). We disagree. The Board specifically noted that "Wallace's teaching that all suitable polymers disclosed are 'essentially nondegradable in vivo over a period of at least several months,' . . . teaches, or at least suggests, that those polymers are essentially *degradable* in the body over a period of *more than* at least several months." *'723 Final Written Decision*, 2021 WL 1393447, at *14; *'913 Final Written Decision*, 2021 WL 1395258, at *14 (both citing Wallace col. 7 ll. 25–29). In any event, "a reference does not teach away if it 'merely expresses a general preference for an alternative invention but does not criticize, discredit or otherwise discourage investigation into the invention claimed.'" *UCB, Inc. v. Actavis Laby's UT, Inc.*, 65 F.4th 679, 692 (Fed. Cir. 2023) (quoting *DePuy Spine, Inc. v.*

Medtronic Sofamor Danek, Inc., 567 F.3d 1314, 1327 (2009)). The portions of Wallace that Incept points to clearly lack such a teaching. As discussed above, substantial evidence supports the Board's finding with respect to the scope of Wallace's teaching. Wallace col. 19 ll. 3–19.

C

Incept next contends that the Board did not separately analyze certain dependent claims of the two patents, for example, dependent claim 16 of the '723 patent and dependent claim 6 of the '913 patent, both of which provide biodegradability time limits. Appellant's Br. 54–56 & n.7 (addressing claims 2–6, 8–12, and 14–24 of the '723 patent, and claims 2–16, 18, and 20–24 of the '913 patent); '723 patent col. 17 ll. 24–25; '913 patent col. 17 ll. 3–4. Palette, however, identified disclosures in the prior art that teach each of the elements of these claims, and Incept did not separately argue their patentability before the Board. *'723 Final Written Decision*, 2021 WL 1393447, at *14; *'913 Final Written Decision*, 2021 WL 1395258, at *14 & n.13. Where a party "does not raise any arguments with respect to any other claim limitation, nor does it separately argue [the] dependent claim," "[the] dependent claim . . . stands or falls together with [the] independent claim." *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1340 (Fed. Cir. 2020).[5]

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[5] For claim 16 of the '723 patent and claim 6 of the '913 patent, Incept did note that these claims require particular biodegradation properties. It did so in the context of its argument (pertaining to the independent claims) that "the range of compositions within the ambit of Wallace's disclosure is so vast that a [skilled artisan] could neither have 'at once envisaged' all of them nor have known what properties any particular one of them would have." J.A. 467–68, 5814–15. As the Board noted, however, Incept discussed claim 16 of the '723 patent only in its discussion of

D

Incept's final argument is that the Board erred in its obviousness analysis because it "imposed an overly stringent standard for showing commercial success." Appellant's Br. 57. Incept contends that it presented "clear[] evidence of commercial success that the Board was not entitled to ignore." *Id.* at 59. According to Incept, that evidence was (1) a table reflecting "annual unit shipments" to external customers (i.e., physicians and hospitals) in the United States" of SpaceOAR®, an injectable synthetic hydrogel marketed by Boston Scientific Corporation through its subsidiary Augmentix, Inc., the exclusive licensee of the

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anticipation by Wallace, J.A. 467–68, *'723 Final Written Decision*, 2021 WL 1393447, at *13 n.12, despite claim 16 not having been challenged as anticipated.

And, as for claim 6 of the '913 patent, the Board explained that Palette had "established persuasively, through the teachings of Wallace and the testimony of [Palette's expert] Dr. Dicker, that a [skilled artisan] would have known how to configure Wallace's compositions to biodegrade within a predetermined time, such as less than approximately 90 days." *'913 Final Written Decision*, 2021 WL 1395258, at *14 n.13. This finding is supported by substantial evidence. *See* Wallace col. 1 ll. 34–38 (acknowledging that it was known that "synthetic polymer compositions can be formulated to exhibit predetermined . . . biological characteristics, such as biodegradability"), col. 20 ll. 44–47 ("Gelatin may have the added benefit of being degradable faster than collagen."); J.A. 6400–01 (¶ 175) (Dr. Dicker explaining that a skilled artisan "would have known how to configure the gel compositions taught by Wallace to biodegrade within a predetermined time, including less than approximately 90 days."). Therefore, even if it could be said that Incept argued this claim separately, we agree with the Board's ultimate obviousness conclusion.

'723 and '913 patents, for the years 2015–2019; and (2) testimonial evidence from Incept's expert that he estimated about 55% of all prostate cancer radiation therapy treatments in 2019 to have included SpaceOar® placement. *'723 Final Written Decision*, 2021 WL 1393447, at *15–17; *'913 Final Written Decision*, 2021 WL 1395258, at *15–17; Appellant's Br. 8.

In its final written decisions, the Board concluded that the evidence Incept relied upon was insufficient. We see no reversible error in that determination, whether viewed as a factual one about the level of success or a legal one about the weight of any such success in the overall obviousness analysis. Commercial success is "usually shown by significant sales in a relevant market." *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997). Incept relied on its table of "annual unit shipments" to support its assertion that the "case volume" of SpaceOAR® "in the U.S. ha[d] roughly doubled year-on-year through 2019." J.A. 480, 5827; *see also* J.A. 632, 5980. A senior accountant for Boston Scientific explained, however, that Incept's table reflected not only SpaceOAR® sales numbers, but also replacement units and free sample units. *See* J.A. 5110–13, 5117.[6] Moreover, for two of the years in the table, 2018 and 2019, Incept did not provide a breakdown of the number of units sold as compared to those given away for free or provided as a replacement, and instead merely relied upon testimony that the number of replacement and sample units was "small." J.A. 5113–16 (¶¶ 16–21). Thus, as the Board noted, "the record does not demonstrate whether the year-

[6] As the Boston Scientific accountant explained, units requiring "replacement" would include units where, for example, the delivery syringe clogged. J.A. 5110–11 (¶ 7). In addition, "free sample units" were "sent to customers (i.e., physicians or hospitals) at the discretion of the sales and customer service teams." *Id.*

over-year increase in units shipped is attributable to increased sales as opposed to an increase in samples and replacements that were shipped." *'723 Final Written Decision*, 2021 WL 1393447, at *17; *'913 Final Written Decision*, 2021 WL 1395258, at *16. And, while Incept did provide a breakdown of the units "sold" for the years 2015–2017, it did not argue before the Board in its Patent Owner Response or Sur-Reply that the data for these years demonstrated commercial success. J.A. 480, 632, 5827, 5980.

Finally, Incept takes issue with the Board's statement that Incept did not provide "commercial success in the context of the market as a whole." *'723 Final Written Decision*, 2021 WL 1393447, at *17; *'913 Final Written Decision*, 2021 WL 1395258, at *16. This statement is contrary to our holding in *Chemours Co. FC, LLC v. Daikin Industries, Ltd.*, 4 F.4th 1370, 1378 (Fed. Cir. 2021), Incept asserts. In *Chemours*, we held that "market share data, though potentially useful, is not required to show commercial success." *Id.* Contrary to Incept's argument, the Board did not require Incept to provide market share data. Instead, the Board weighed the evidence provided by Incept and merely found that evidence insufficient, alone, to show commercial success. *See id.* ("The Board is certainly entitled to weigh evidence and find, if appropriate, that Chemours's gross sales data were insufficient to show commercial success without market share data."). To the extent Incept also contends that the Board improperly dismissed the market share data that Incept *did* provide, we defer to the Board's findings concerning the credibility of expert witnesses, *see Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010), and Incept has not otherwise demonstrated that those findings are unsupported by substantial evidence.[7]

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[7] Incept provided testimonial evidence from an expert, Dr. Timothy Showalter, estimating that 55% of all prostate cancer radiation therapy treatments in the United

CONCLUSION

We have considered Incept's remaining arguments and find them unpersuasive. Accordingly, and for the reasons set forth above, we affirm the Board's final written decisions.

AFFIRMED

States in 2019 included SpaceOAR® placement. J.A. 5121. The Board found this testimony to be not credible because it found Dr. Showalter's calculations to be insufficiently supported by the evidence. As the Board noted, in his calculations, Dr. Showalter inexplicably relied on (a) a radiation therapy rate from a United Kingdom trial and (b) the number of new cases of prostate cancer in 2019, as opposed to all existing cases. *'723 Final Written Decision*, 2021 WL 1393447, at *17; *'913 Final Written Decision*, 2021 WL 1395258, at *17.

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NEWMAN, *Circuit Judge*, concurring-in-part and dissenting-in-part.

I share the conclusion that claim 1 of Incept's U.S. Patent No. 8,257,723 ("the '723 patent") and claim 1 of U.S. Patent No. 7,744,913 ("the '913 patent") are invalid, for these broadest claims can reasonably be read to include prior art. Whether viewed under section 102 or 103 of Title 35, these claims are not patentable. I would sustain the

Board's decision invalidating claim 1 of both patents.[1] However, for the more detailed claims of these patents, written in dependent form, neither the Board nor the panel majority adequately determined patentability of their claimed inventions as a whole. I respectfully dissent from the panel majority's affirmance of the Board's invalidation of all the challenged claims.

DISCUSSION

The Board held, and the majority agrees, that the Wallace reference (U.S. Patent No. 6,624,245) shows all the limitations of claim 1, the broadest claim, of the '723 patent, and that the combination of the Wallace and Ein-Gal references (U.S. Patent No. 6,210,314) shows all the limitations stated in the broadest claims. Claim 1 of the '723 patent is illustrative:

> 1. A method of delivering a therapeutic dose of radiation to a patient comprising
> introducing a biocompatible, biodegradable filler between an organ and a nearby tissue to increase a distance between the organ and the tissue, and
> treating the tissue with the therapeutic dose of radiation so that the presence of the filler causes the organ to receive less of the dose of radiation compared to the amount of the dose of radiation the organ would receive in the absence of the filler,
> wherein the filler is introduced as an injectable material and is a gel in the

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[1] *Palette Life Sciences, Inc. v. Incept LLC*, 2021 WL 1393447 (P.T.A.B. Apr. 13, 2021) ("Board '723 Op."); 2021 WL 1395258 (P.T.A.B. Apr. 13. 2021) ("Board '913 Op.").

> patient, and wherein the filler is removable by biodegradation in the patient.

Incept argues that all the challenged claims of the '723 and '913 patents, including the broadest claims, when construed in light of the specification and the prosecution history, are distinguished from Wallace and thus are neither anticipated nor obvious. I respectfully dissent from the panel majority's applications of the laws of anticipation and obviousness to invalidate all of the challenged claims of the '723 and '913 patents.

I

ANTICIPATION

Anticipation requires that the invention was previously known; that is, that the invention as claimed is not new. *See, e.g.*, *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (to anticipate, a single reference must disclose the same invention, including each claimed limitation).

My concern is with the invalidation of the dependent claims, without analysis of these claims' additional limitations in view of the prior art. The panel majority states:

> In sum, we see no legal error in the Board's anticipation analysis for the '723 patent, and substantial evidence supports the Board's findings that Wallace discloses each element of claim 1 of the '723 patent, arranged as in that claim. We therefore affirm the Board's determination that claims 1, 6, 8–12, 14, 15, and 17–22 of the '723 patent are anticipated by Wallace.

Maj. Op. at 10. The majority appears to hold that, when the broader claim is anticipated, the dependent claims are automatically anticipated. That is not the law. Each claim must be considered as a whole, including all its limitations.

The panel majority observes that the Wallace reference generically discloses "multiple compositions," *id.* at 7, described by Incept as embracing "millions, if not billions, of different possible compositions, each with different properties," *id.* at 6, *quoting* Incept Br. 34–35. A generic prior disclosure does not anticipate all of its embodiments, including novel specific embodiments, whether or not the facts are such that the generic disclosure may render the embodiment obvious.

Precedent illustrates an assortment of considerations relevant to patentability of such discoveries as a new species of a known genus, but these precedents establish the different rule for anticipation in comparison to obviousness. For example, it is relevant whether the disclosure of a genus in the prior art was so specific that it would reasonably be understood that the genus encompasses all potential species, as in *Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals, Inc.*, 471 F.3d 1369, 1376 (Fed. Cir. 2006). *Compare Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1285–86 (Fed. Cir. 2017) (finding no anticipation by a genus disclosure that was "too ambiguous" and too broad for an ordinary skilled artisan to "at once envisage" every member of the genus).

Here the majority expands the law of anticipation by holding that, if "Wallace expressly describes compositions that have the claimed characteristics of, and are used for the same displacement purpose as, the compositions referred to in the '723 patent claims challenged as anticipated," then it is irrelevant whether all the elements of the dependent claims are shown in the "anticipating" reference. The majority concludes that "a skilled artisan would have understood that Wallace's compositions had the same generic properties as those in the '723 patent claims." Maj. Op. at 7–8. However, Wallace does not support anticipation of claim limitations that are not explicitly described in the reference.

This departure from the law of anticipation is manifest in the majority's treatment of the limitation concerning "biodegradation." Wallace states: "The polymer may include biodegradable segments and blocks, either distributed throughout the polymer's molecular structure or present in a single block, as in a block copolymer." Wallace, col.19, ll.3–9. But Wallace also states that polymers "generally, are 'essentially nondegradable in vivo over a period of at least several months.'" Maj. Op. at 8, *quoting* Wallace, col. 7, ll. 25-29. Nonetheless, the majority concludes that "substantial evidence supports the Board's findings that Wallace discloses each element of claim 1 of the '723 patent" and thus anticipates the biodegradability of the Incept polymers, Maj. Op. at 10, even though Wallace states that its compositions are "not readily degradable[,]" *id.* at 8, 9, *quoting* Wallace, col. 34, ll.11-14.

The majority holds that Wallace's teaching that a polymer can have biodegradable segments "alone constitutes substantial evidence to support the Board's finding" that the '723 patent's limitation of biodegradation is anticipated. *Id.* at 8. This holding disregards Wallace's statements of the difficulties and uncertainties of biodegradation, and concludes, without analysis, that since the broadest claim 1 of the '723 patent is anticipated, the narrower dependent claims are also anticipated.

The majority discusses some of the dependent claims, noting "dependent claim 16 of the '723 patent and dependent claim 6 of the '913 patent both of which provide biodegradability time limits," although the majority also states that Incept did not separately argue the dependent claims before the board (noting that the record shows such argument for at least some claims). *Id.* at 13. The majority recites that "Palette, however, identified disclosures in the prior art that teach each of the elements of these claims[.]" *Id.* Although the appeal briefing is sparse for the dependent claims, the majority acknowledges that "[f]or claim 16 of the '723 patent and claim 6 of the '913 patent, Incept did

note that these claims require particular biodegradation properties." *Id*. at 13 n.5. The majority misstates that Incept did not argue any claims separately.

For anticipation in patent law terms, an anticipating reference must describe the same invention in reasonable detail and clarity as appropriate to the subject matter. The panel majority recognizes that Wallace states that its polymers are not degradable, yet the majority does not find fault with the Board's statement that "Wallace's teaching that all suitable polymers disclosed are 'essentially nondegradable in vivo over a period of at least several months,' . . . teaches, or at least suggests, that those polymers are essentially degradable in the body over a period of more than at least several months." *Id.* at 12, *quoting* Board '723 Op at *14, 'Board 913 Op. at *14. We are not told how a nondegradable polymer anticipates a degradable polymer.

Incept stresses Wallace's recognition that most polymers are not biodegradable and that controlled degradation is not easy.[2] The Board observed that petitioner Palette had "established persuasively, through the teachings of Wallace (U.S. Patent No. 6,624,245) and the testimony of [Palette's expert] Dr. Dicker, that a POSITA would have known how to configure Wallace's compositions to biodegrade within a predetermined time, such as less than approximately 90 days." Maj. Op. at 13 n.5, *quoting* Board '913 Op. at *14 n.13. However, neither the Board nor the panel majority explains how the cited references teach this knowledge.

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[2] One need only peruse the news reports of fouling of oceans, rivers, and reefs with non-degradable polymers.

I would remand to the Board for determination, on the correct law, of whether the limitations of the challenged dependent claims are anticipated.

II

OBVIOUSNESS – COMMERCIAL SUCCESS

The law of obviousness has extensive precedent, providing guidance in a vast variety of technological situations. The majority holds that for the claims that the Board found anticipated, this court need not consider the question of obviousness. I agree that claims properly invalidated need not be reviewed on other grounds. However, since the Board erred in finding all the claims anticipated, determination of obviousness is appropriate and warrants remand to the Board for full consideration.

On remand, it will also be appropriate to instruct the Board to correct its application of the objective factor of commercial success. Commercial success is one of the "secondary considerations" that guide the ultimate determination of obviousness. *See Graham v. John Deere Co.*, 383 U.S. 1 (1966). However, the majority adopts a new rule for commercial success, a rule that does not conform to routine market measures. It is undisputed that the Incept product experienced regular increases in annual commercial sales, and at the time of trial Incept had obtained 55% of the market for comparable products. Palette's only criticism of Incept's commercial information was that Incept also gave free samples. The majority now holds that Incept's commercial sales cannot be considered as a measure of commercial success because some product was provided free of charge. Maj. Op. at 15–16.

It is not correct that because free samples were provided, the commercial sales and market share data are not relevant measures of commercial success. The majority's concern that "the Board did not require Incept to provide market share data," *id.* at 16, does not warrant ignoring

the evidence of commercial sales and increases in market share. I respectfully dissent from the finding that there was not substantial evidence of commercial success, for commercial success is measured by commercial sales, not free samples. I would remand for the Board to apply the evidence of commercial activity and market growth to the determination of obviousness.

CONCLUSION

I concur in the holdings of invalidity of claim 1 of both the '723 and '913 patents, for these claims, in their breadth, do not distinguish from the prior art. However, the subordinate claims of both patents were incorrectly analyzed under the laws of anticipation and obviousness. I would vacate the Board's decisions as to the subordinate claims, and remand for redetermination of anticipation and obviousness on correct law. From my colleagues' contrary rulings, I respectfully dissent.