NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

OTONOMY, INC.,
Appellant

v.

AURIS MEDICAL, AG,
Cross-Appellant

2017-1850, 2017-1880

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 106,030.

Decided: August 1, 2018

RICHARD TORCZON, Wilson, Sonsini, Goodrich & Rosati, PC, Washington, DC, argued for appellant. Also represented by ADAM WILLIAM BURROWBRIDGE; MICHAEL T. ROSATO, Seattle, WA.

JONATHAN GARWOOD GRAVES, Cooley LLP, Reston, VA, argued for cross-appellant. Also represented by JOSEPH VAN TASSEL; BONNIE WEISS MCLEOD, Washington, DC.

Before MOORE, O'MALLEY, and WALLACH, *Circuit Judges.*

O'MALLEY, *Circuit Judge.*

Otonomy, Inc. ("Otonomy") appeals the decision of the Patent Trial and Appeal Board ("the Board"), which entered judgment against it on the sole count of an interference between Auris Medical, AG's U.S. Patent No. 9,066,865 ("the '865 patent") and Otonomy's U.S. Patent Application No. 13/848,636 ("the '636 application"). *Otonomy, Inc. v. Auris Medical, AG*, Interference No. 106,030, 2017 WL 394237, at *28 (P.T.A.B. Jan. 26, 2017). In reaching this decision, the Board: (1) found that Otonomy failed to show that the '865 patent was unpatentable for lack of written description under 35 U.S.C. § 112; (2) accorded Auris the benefit of a filing date before Otonomy's earliest alleged priority date; and (3) denied Auris's motion for judgment that Otonomy's involved claims are unpatentable as anticipated under 35 U.S.C. § 102(b) by Auris's PCT Publication No. WO 2007/038949 ("the WO '949").

On appeal, Otonomy challenges the Board's decision denying its motion for unpatentability with respect to claim 9 of the '865 patent (the sole remaining claim) and its decision according Auris the benefit of its earlier-filed application for purposes of priority. Auris conditionally cross-appeals, arguing that, if we disagree with the Board's priority determination, we should reverse the Board's anticipation decision and find that the WO '949 anticipates Otonomy's involved claims.

We *reverse* the Board's accorded benefit decision and find that Auris is not entitled to an effective filing date before June 2014. Given that the '865 patent would have, at best, a June 27, 2014 filing date, which post-dates Otonomy's publication, we find that the Board erred in entering judgment on priority against Otonomy. With respect to the cross-appeal, because substantial evidence

supports the Board's determination that Otonomy's involved claims are not anticipated by the WO '949, we *affirm*.

I. BACKGROUND

A. Factual Background

The commonly claimed invention is a method of using a suspended-fluoroquinolone composition to treat middle and inner ear disorders. Otonomy filed its '636 application on March 21, 2013. That application discloses "compositions and methods for the treatment of otic diseases or conditions with antimicrobial agent compositions and formulations administered locally . . . through direct application of these compositions and formulations onto or via perfusion into" targeted portions of the ear. '636 application, Abstract. Otonomy's involved claims are claims 38, 43, and 46–50 of the '636 application ("Otonomy's involved claims").

The '865 patent, which issued to Auris on June 30, 2015, "relates to compositions of one or more pharmaceutical compounds for the prevention and/or treatment of tinnitus and other disorders of the inner ear." '865 patent, col. 1, ll. 17–19. Specifically, the claimed invention "provides compositions containing (i) a pharmaceutically active agent selected from a group consisting of an arylcycloalkylamine or a derivative, analogue or pharmaceutically active salt thereof, and (ii) a biocompatible polymer or a combination of biocompatible polymers." *Id*. at col. 3, ll. 28–32. The '865 patent has one independent claim—claim 1, set forth below—and eight dependent claims.

The '865 patent issued from U.S. Patent Application No. 14/317,319 ("the '319 application"), filed on June 27,

2014.[1] That same day, Auris submitted a preliminary amendment that added several claims directed to therapeutic compositions containing various claimed active ingredients, including fluoroquinolones, for use in the claimed methods. The '319 application is a continuation of U.S. Patent No. 11/992,632, which is the national stage application of international application PCT/EP2005/010478 ("the '478 PCT"). It is undisputed that the specifications of the '319 application, the '632 application, and the '478 PCT are substantially identical. *Otonomy*, 2017 WL 394237, at *20. The '478 PCT was filed on September 28, 2005, and was published as the WO '949 on April 12, 2007.

B. Procedural History

On July 20, 2015, the Board declared an interference between the parties. The Board initially identified Otonomy as the senior party, based on the March 2013 filing date of the '636 application, and Auris as the junior party, based on the June 2014 filing date of the Auris '319 application. *Otonomy*, 2017 WL 394237, at *2.

The Board designated claim 1 of the '865 patent as the sole count of the interference and indicated that all of Auris's '865 patent claims (claims 1–9) and all of Otonomy's involved claims (claims 38, 43, 46–50) corresponded to the count.

Auris claim 1 provides as follows:

> 1. A method of treating a middle or inner ear disease comprising intratympanically administering to a patient in need thereof a controlled release

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[1] Because Auris certified that its 2014 application was not subject to the provisions of the America Invents Act ("AIA"), the Patent and Trademark Office examined it under pre-AIA rules. Joint Appendix (J.A.) 693-94.

> composition comprising a pharmaceutically active agent and a thermosetting polymer; wherein the pharmaceutically active agent is selected from antibiotics and is suspended in the composition, and the thermosetting polymer has a gelation temperature of at least about 15° C.,
>
> wherein the thermosetting polymer is poloxamer 407 and is present at a concentration of about 20% (w/w), and
>
> wherein the antibiotic is fluoroquinolone.

'865 patent, col. 17, ll. 13–23.

Both parties sought approval to file several motions with the Board. The Board authorized four motions, two for each party:

- Auris Motion 1: requesting that the Board accord benefit to the '632 application and the '478 PCT;
- Auris Motion 2: seeking judgment that Otonomy's involved claims are anticipated under 35 U.S.C. § 102(b);
- Otonomy Motions 1 and 2: seeking judgment that the claims of the '865 patent are unpatentable based on the written description and enablement requirements of 35 U.S.C. § 112;[2] and
- Otonomy Motion 6: requesting that the Board accord benefit to a chain of previously filed applications and provisional applications.

Otonomy, 2017 WL 394237, at *2–3.[3]

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[2] The Board authorized Otonomy to file Motions 1 and 2 jointly in a single motion.

[3] The Board did not authorize Otonomy Motion 3, which sought judgment against Auris based on unpatent-

On January 26, 2017, the Board issued the decision now on appeal. At the outset, the Board denied Auris Motion 2, finding that, although the WO '949 disclosed each of the elements found within Otonomy involved claim 38, there "is no discernable *single* embodiment which teaches all of the claim elements as arranged." *Id.* at *5. The Board concluded that there was "too much picking and choosing among embodiments for one of ordinary skill in the art to envision the claimed invention." *Id.* at *7.

Next, the Board granted in part and denied in part Otonomy's Motions 1 and 2. As to Motion 1, the Board denied Otonomy's written description challenge to all nine claims of the '865 patent, relying exclusively on Auris's June 27, 2014 preliminary amendment to provide the necessary disclosure. *Id.* at *13. As to Motion 2, the Board found that Auris claim 9, which is directed to the treatment of a viral or bacterial infection, was enabled, but that Auris claims 1–8 were not. *Id.* at *17–19. Accordingly, the Board granted Otonomy Motion 2 in part, concluding that claims 1–8 were unpatentable. *Id.* at *19.[4] This left claim 9 as Auris's sole remaining claim and grounds for asserting priority.

The Board then granted Auris Motion 1, for benefit of the '632 application and the '478 PCT, finding that the '478 PCT "describe[s] the addition of fluoroquinolone for use as an antibiotic in the delivery composition for treating inner ear diseases" and that "at least one specific example (Example 2) includes 20% poloxamer 407 and ketamine." *Id.* at *20. The Board concluded that the combination of these two elements met the limitations of

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ability under 35 U.S.C. § 103 over certain prior art references.

[4] The Board's decision with respect to enablement is not at issue on appeal.

the count, and accorded benefit of the '478 PCT's September 28, 2005 filing date to Auris. *Id.* at *21, *28.

Finally, the Board granted in part Otonomy Motion 6, finding that the '636 application is entitled to the benefit of its parent nonprovisional applications, the earliest of which had a filing date of May 14, 2009. *Id.* at *28. Neither party disputes that priority date on appeal.

Given the Board's determinations regarding accorded benefit, the Board issued a redeclaration identifying Auris as the senior party. *Id.* Because the Board accorded Auris the benefit of a filing date before Otonomy's earliest alleged priority date, the Board entered judgment against Otonomy on count 1.

Otonomy timely appealed and Auris timely cross-appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

II. OTONOMY'S APPEAL

On appeal, Otonomy argues that the Board erred in denying Otonomy Motion 1 with respect to Auris's sole remaining claim—claim 9 of the '865 patent. Specifically, Otonomy argues that the Board erred in relying on a theory that neither party advanced: "that the Auris 2014 application supported the present claims on the basis of the preliminary amendment (rather than the body of the specification itself)." Appellant Br. 12. Otonomy submits that, had the Board found Auris claim 9 unpatentable for lack of written description, there would not have been a priority contest. Accordingly, Otonomy requests that we reverse the Board's decision on claim 9 of the '865 patent, and remand for entry of judgment in favor of Otonomy. In the alternative, Otonomy maintains that the Board "misapprehended the Auris PCT '478 disclosure and the controlling law in granting Auris Motion 1 and thus according benefit to Auris." *Id.* at 14.

As explained below, we agree with Otonomy's alternative argument and conclude that Auris is not entitled to the benefit of the '478 PCT's 2005 filing date. We therefore reverse the Board's decision on Auris Motion 1. Consistent with the Board's analysis with respect to Otonomy Motion 1, wherein the Board found that the *only* written description support for the commonly claimed invention is set forth in the claims added by the 2014 preliminary amendment, we further find that Auris is not entitled to an effective filing date prior to 2014. Accordingly, the Board erred in awarding priority to Auris.

A. Auris is Not Entitled to the Benefit of the '478 PCT's 2005 Filing Date

Accorded benefit is defined as "Board recognition that a patent application provides a proper constructive reduction to practice under 35 U.S.C. § 102(g)(1)." 37 C.F.R. § 41.201. Constructive reduction to practice "means a described and enabled anticipation under 35 U.S.C. § 102(g)(1), in a patent application of the subject matter of a count." *Id.* To establish a constructive reduction to practice and thereby the right to benefit of an earlier-filed application for priority purposes, the movant need only show that the earlier-filed application discloses a single embodiment within the scope of the interference count that complies with 35 U.S.C. § 112. *Hunt v. Treppschuh*, 523 F.2d 1386, 1389 (CCPA 1975) (holding that, where a "parent application is relied upon as a prior constructive reduction to practice[,] . . . the § 112, first paragraph requirements need only be met for an embodiment within the count").

Priority and reduction to practice are questions of law based on subsidiary fact findings. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). We review the Board's legal conclusions de novo, and its factual findings for substantial evidence. *Singh v. Brake*, 317 F.3d 1334, 1340 (Fed. Cir. 2003) (citations omitted).

In Auris Motion 1, Auris argued that it was entitled to priority benefit of the '478 PCT, filed on September 28, 2005.[5] According to Auris, the '478 PCT demonstrates that it possessed at least a single embodiment within the scope of the interference count. The Board agreed, finding that Example 2 of the '478 PCT, which includes 20% poloxamer 407 and ketamine, together with a separate teaching that an antibiotic such as fluoroquinolone could be used as an additional ingredient, "me[t] the limitations of the count." *Otonomy*, 2017 WL 394237, at *20–21.

Otonomy argued to the Board that the '478 PCT does not teach the requisite suspension of fluoroquinolone. *Id.* at *21. Although the Board recognized that this argument was "literally correct" based on the passages Otonomy cited, it found that, because the "dissolved ketamine was stirred overnight," it was "at least suspended in the stirred mixture." *Id.* Given the "description of fluoroquinolone as an antibiotic ingredient," the Board found that, absent "persuasive evidence to the contrary we are of the view that if both were included they would be 'suspended' in that embodiment if mixed in the described manner of Example 2." *Id.* at *22. The Board concluded that, because "there is an example of ketamine suspended in poloxamer" together with a "clear teaching of an additional embodiment with an additional ingredient, including fluoroquinolones," the '478 PCT described an embodiment that satisfied the count. *Id.*

On appeal, Otonomy argues that the Board erred in permitting Auris to piece together disparate bits of disclo-

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[5] Auris also argued that it was entitled to the benefit of the '632 application, but conceded that the '478 PCT and the '632 application have the same specification as the '319 application, and proffered no separate grounds for entitlement to the 2008 filing date of the '632 application. *See Otonomy*, 2017 WL 394237, at *20.

sure and that, regardless of "[w]hether accorded benefit is viewed as an anticipation or written description analysis, the result is the same: unguided post hoc selection is not the proper standard." Appellant Br. 26. We agree.

It is undisputed that the '478 PCT lacks any explicit disclosure of a single embodiment of a suspended-fluoroquinolone composition or its use. Counsel for Auris conceded as much at oral argument. Oral Arg. at 20:03-17, *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2017-1850.mp3 ("There is no single express embodiment" including suspension and fluoroquinolone."). The relevant question on appeal is whether the disclosure in the '478 PCT nevertheless shows that Auris possessed at least a single embodiment within the scope of the interference count. *See Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006) (stating that constructive reduction to practice of a single embodiment requires compliance with both the enablement and written description requirements 35 U.S.C. § 112, first paragraph).

The interference count requires, in relevant part, "intratympanically administering to a patient in need thereof a controlled release composition comprising a pharmaceutically active agent and a thermosetting polymer; *wherein the pharmaceutically active agent . . . is suspended in the composition*." *Otonomy*, 2017 WL 394237, at *8 (emphasis added). Auris and the Board relied on Example 2 of the '478 PCT as providing support for an active agent that is suspended. *Id.* at *21–22. But Example 2 discloses that "[k]etamine was *dissolved* in the poloxamer solution at a concentration of 1 mM with a magnetic stirrer over night." *Id.* at *21 (emphasis added). Indeed, Otonomy's expert, Dr. Salt, testified that Example 2 teaches dissolved ketamine, rather than a suspended active agent. J.A. 3423.

The Board did not address Dr. Salt's testimony, and instead stated that, because the "dissolved ketamine was stirred overnight," it was "at least suspended in the stirred mixture." *Otonomy*, 2017 WL 394237, at *21. Given that the '478 PCT describes the addition of fluoroquinolone for use as an antibiotic, the Board found that, if both ketamine and fluoroquinolone were included they would be "suspended" if mixed. *Id*. at *21–22. Neither party advanced that theory, and the Board cited no evidence to support it. Indeed, counsel for Auris conceded at oral argument that Example 2 does not teach suspension and that the Board erred in concluding otherwise. Oral Arg. at 17:24–37 ("The Board seemed to find, and we are not sure what they were doing here, but they seemed to find teaching of suspension in Example 2 . . . which is not correct."). The Board's own unsupported conjecture cannot supply the requisite substantial evidence to accord benefit to Auris. *See In re Kao*, 639 F.3d 1057, 1067 (Fed. Cir. 2011) (finding that Board "conjecture does not supply the requisite substantial evidence"). As Otonomy points out, moreover, to the extent the Board assumed that *ketamine* would have been suspended at some point during the overnight stirring step, that assumption is irrelevant because the count requires that the *fluoroquinolone* be suspended *at the time of treatment*. *See Otonomy*, 2017 WL 394237, at *8.

Auris maintains that, even if the Board erred in its analysis of what Example 2 teaches regarding how the ingredient is mixed within the polymer material, "any such error was harmless." Cross-Appellant Br. 11. According to Auris, Example 2 "meets the limitations of the count, except for the limitation that provides that the pharmaceutically active agent [fluoroquinolone] is suspended in the composition." *Id*. at 43. Because the '478 PCT provides an "express teaching of a limited number of ways (specifically, three ways) of mixing an active agent within a polymer," Auris argues that a person of ordinary

skill would "immediately envisage" using a suspended-fluoroquinolone composition. *Id.* at 45.

Although the Board did not consider this argument in its analysis of Auris Motion 1, it expressly rejected it in the context of Auris Motion 2.[6] Specifically, in connection with Auris Motion 2, the Board found that "too much picking and choosing among the embodiments" is required to anticipate the claimed suspended-fluoroquinolone composition. *Otonomy*, 2017 WL 394237, at *7. As discussed below in conjunction with Auris's cross-appeal, substantial evidence supports the Board's finding that the '478 PCT (and its corresponding publication, the WO '949) does not describe a suspended-fluoroquinolone composition.

We conclude that the Board erred in finding that the '478 PCT discloses an embodiment that meets all of the limitations of the count. Accordingly, Auris is not entitled to the benefit of the '478 PCT's September 2005 filing date. We therefore reverse the Board's decision on Auris Motion 1.

B. Auris is Not Entitled to an Effective Filing Date Before June 2014

In ruling on Otonomy Motion 1, the Board found that the original specification of the '319 application, which is substantially identical to that of the '478 PCT, does not

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[6] Auris Motion 1 and Auris Motion 2 were decided in view of the same substantive disclosure: the '478 PCT and its corresponding publication WO '949. And the standard by which the Board reviewed each motion was the same: whether the '478 PCT or WO '949 sufficiently discloses a suspended-fluoroquinolone composition. Despite the common question, the Board reached opposite—and in these circumstances, irreconcilable—conclusions.

provide full scope written description support for the commonly-claimed invention. *Otonomy*, 2017 WL 394237, at *11. The test for sufficiency of written description "is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Sufficiency of written description is a question of fact, which we review for substantial evidence. *Gen. Hosp. Corp. v. Sienna Biopharm., Inc.*, 888 F.3d 1368, 1371 (Fed. Cir. 2018).

In Otonomy Motion 1, Otonomy argued to the Board that "ketamine treatment of the inner ear is the invention of the '865 patent, and prior to the filing of a preliminary amendment no Auris application disclosed or claimed a method of administering a composition without an arylcycloalkylamine such as ketamine." *Otonomy*, 2017 WL 394237, at *8. The Board agreed that the "specification consistently describes the use of ketamine" and includes "fluoroquinolone only as a potential adjunct pharmaceutical, in a variety of formulations." *Id.* at *13.

The Board found that the "only description of the invention as presently claimed is in the claims filed by amendment, and it is in fact somewhat divorced from the entirety of the rest of the description in making the invention, and the only description of this embodiment without inclusion of arylcycloalkylamine." *Id.* at *11. In reaching this conclusion, the Board emphasized that the "only objective factual support for the claim requiring only fluoroquinolone" was provided in the 2014 preliminary amendment, and that the amendment was necessary to "overcom[e]" the "specification's clear focus on inclusion of another medicament." *Id.* at *13.

Substantial evidence supports the Board's decision that the original specification of the '319 application does

not provide sufficient written description support for the claimed suspended-fluoroquinolone composition. As the Board explained, it took the June 2014 preliminary amendment introducing a claim with no express arylcycloalkylamine limitation to suggest the commonly-claimed invention. Setting aside the question of whether the Board was entitled to rely exclusively on a preliminary amendment in its written description analysis—particularly where neither party requested it do so[7]—the record shows that Auris is not entitled to an effective filing date prior to June 27, 2014, the date on which it filed the preliminary amendment. *See Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346 (Fed. Cir. 2000) ("[C]laims to subject matter in a later-filed application not supported by an ancestor application in terms of § 112 ¶ 1 . . .do not

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[7] On appeal, the parties seem to agree that the Board's decision to rely *solely* on the preliminary amendment for written description support was in error. Otonomy explains that Auris never argued that the 2014 preliminary amendment provided written description support because it was faced with a strategic decision—Auris could either: (1) rely on the 2005 priority date of its '478 PCT and shield itself from nine years of intervening prior art; or (2) broaden the scope of its invention beyond what was claimed in the '478 PCT, but only claim a 2014 priority date. Auris selected the former option, and claimed priority to the '478 PCT. On appeal, Auris submits that, "although it reached the correct result in finding that the Auris claims met the written description requirement, the Board erred in relying solely on the Preliminary Amendment in reaching this conclusion." Cross-Appellant Br. 31. Auris maintains that the error was harmless, however, because the original specification provides sufficient written description support. We accept the parties' agreement that the Board erred, but disagree with Auris that any such error would have been harmless.

receive the benefit of the earlier application's filing date.").

C. The Board Erred in Awarding Priority to Auris

In sum, as described in connection with our review of Auris Motion 1, Auris is not entitled to the benefit of the '478 PCT's 2005 filing date. And, as described in connection with our review of Otonomy Motion 1, the '865 patent cannot claim priority any earlier than June 2014, when Auris filed its preliminary amendment to the '319 application.

Given that the effective filing date of the '865 patent is, at best, the 2014 filing date of the '319 application, which post-dates Otonomy's published application, we find that the Board erred in awarding priority to Auris. We therefore reverse the judgment of priority against Otonomy and remand for entry of judgment on priority against Auris.

III. AURIS'S CROSS-APPEAL

Auris conditionally cross-appeals, arguing that the Board erred when it concluded that the WO '949 (the published version of the '478 PCT) did not anticipate Otonomy's involved claims. "A patent claim is invalid for anticipation under 35 U.S.C. § 102 when a prior art reference describes 'each and every claim limitation and enable[s] one of skill in the art to practice an embodiment of the claimed invention without undue experimentation.'" *In re Chudik*, 851 F.3d 1365, 1372 (Fed. Cir. 2017) (quoting *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1344 (Fed. Cir. 2012)). Anticipation is a question of fact, which we review for substantial evidence. *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016). "Substantial evidence is more than a mere scintilla," it is evidence that a "reasonable mind might accept as adequate to support a conclusion." *Id.* at 1337.

In Auris Motion 2, Auris contended that WO '949 anticipated Otonomy claim 38 (Otonomy's sole independent claim) by disclosing each and every element of the claim as arranged. Specifically, Auris argued that the WO '949 contains: (1) Example 2, which discloses most of the limitations of claim 38, except for a suspension of fluoroquinolone; and (2) "specific teachings that compositions in accordance with the present invention can comprise other biologically active agents including antibiotics, such as fluoroquinolone." Cross-Appellant Br. 33. Given these disclosures, Auris argued that a person of ordinary skill in the art would have been able to practice an embodiment within the scope of claim 38 without undue experimentation.

Looking at the WO '949, the Board found that it "does in fact individually teach [the claimed] elements, and in the structure of a composition for treatment of inner ear diseases," but that there "is no discernable *single* embodiment which teaches all of the claim elements as arranged." *Otonomy*, 2017 WL 394237, at *5. Specifically, the Board found that the WO '949 "describes pharmaceutical compositions for the treatment of inner ear disorders," and that, in terms of selecting a pharmaceutical, "there are potentially infinite" options available. *Id.* at *6. In terms of delivery vehicles, the Board found that the WO '949 describes that the "composition can be solid, liquid, semi-solid, or gel-like" and that the delivery vehicle can be "a solution, suspension, or thermosetting gel." *Id.* Given these different options, the Board found that there was "too much picking and choosing among embodiments for one of ordinary skill in the art to envision the claimed invention." *Id.* at *7.

On appeal, Auris argues that the Board's anticipation analysis "improperly focused on the relatively large number of theoretical combinations disclosed" in the WO '949 and failed to consider key teachings that would allow a person of skill in the art "to immediately narrow down

or look past these theoretical combinations and recognize a single disclosed embodiment that anticipates Otonomy's broad claims." Cross-Appellant Reply 1. Auris maintains that, when the teachings of the WO '949 are considered in context, there are relatively few potential combinations.

Where a combination of disclosed elements is concerned, "a reference can anticipate a claim even if it 'd[oes] not expressly spell out' all the limitations arranged or combined as in the claim." *Blue Calypso*, 815 F.3d at 1343 (quoting *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015)). We have recognized that "a reference may still anticipate if that reference teaches that the disclosed components or functionalities may be combined and one of skill in the art would be able to implement the combination." *Id.* at 1344.

While Auris points to multiple, distinct teachings within the WO '949, it does not identify guidance in the disclosure to link them together. And, although Auris contends that the Board erred by ignoring key embodiments and teachings from WO '949, including Example 2 and a separate teaching that a fluoroquinolone could be an additional ingredient, anticipation requires that the reference provide specific guidance that would lead a person of ordinary skill to an embodiment within the claim. *See In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) (noting that an anticipating reference "must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference").

Looking at the number of possible formulations and combinations disclosed in the WO '949, the Board found that nothing therein would lead a person of ordinary skill in the art to pick and choose among the elements of the

disclosure to arrive at a suspended-fluoroquinolone composition as claimed. *Otonomy*, 2017 WL 394237, at *5–7. We conclude that substantial evidence supports the Board's findings. Accordingly, we affirm the Board's determination that the WO '949 does not anticipate Otonomy claim 38.

IV. CONCLUSION

We have reviewed the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we *reverse* the Board's decision according Auris the benefit of priority to its '478 PCT. Because we conclude that the '865 patent is not entitled to an effective filing date prior to June 2014—which is after Otonomy's 2009 accorded benefit date—we *reverse* the Board's priority determination and *remand* for entry of judgment on priority in favor of Otonomy. With respect to the cross-appeal, we *affirm* the Board's decision that Otonomy's involved claims are not anticipated by the WO '949.

REVERSED AND REMANDED IN NO. 17-1850; AFFIRMED IN NO. 17-1880

COSTS

No costs.