

Filed: May 2, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,
Petitioner,

v.

THE FOUNDRY, LLC,
Patent Owner.

Case IPR2024-00669
Patent No. 11,679,077

PATENT OWNER'S PRELIMINARY RESPONSE

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I. Introduction

Pursuant to 37 C.F.R. § 42.107(a), The Foundry LLC (“Patent Owner” or “Foundry”) submits this Preliminary Response to the Petition for *Inter Partes* Review of U.S. Patent No. 11,679,077 (“the ’077 patent”). Because Petitioner fails to meet its burden of showing a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition, institution should be denied.

Petitioner’s challenges to the ’077 patent can be separated into two groups: (i) Grounds 1-4, and (ii) Grounds 5-6. Grounds 1-4 are each premised on Petitioner’s misconception that Foundry added new matter to the drawings and specification during prosecution, thereby stripping the ’077 patent of its priority claims to any application before October 22, 2019. Petitioner therefore relies on the wrong priority date as the entire basis for its Grounds 1-4 analysis, setting forth a lack of written description theory that is factually and legally incorrect. Because all of the subject matter claimed in the ’077 patent is entitled to a priority date of at least July 21, 2006, the priority date of U.S. Patent Application No. 11/459,090 for U.S. Patent No. 7,608,275, none of the asserted references in Grounds 1-4 are prior art. Consequently, the allegations that the asserted references anticipate or render obvious the claims fail.

Grounds 5-6 fare no better because they suffer critically from 35 U.S.C. § 325(d) and misinterpret the relied-upon references. Petitioner’s theory on

Grounds 5-6 assumes that the '077 patent can claim priority to a date before October 22, 2019, (which it does) and argues that, even with priority, the '077 patent would have been obvious based on a combination of Makower, U.S. Pub. 2005/0240147 (Ex. 1005), Fang, “Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis” 25(7) J. First Mil. Med. Univ. 876 (July 20, 2005) (Ex. 1006), and Edwards-535, U.S. Patent No. 6,517,535 (Ex. 1008), and Makower, Fang, Edwards-535, and Stern, U.S. Patent 5,562,720 (Ex. 1009). In these Grounds, Petitioner relies on the reference the Patent Office has already considered and deemed the “closest prior art” to the '077 patent’s grandparent patent—Makower—before allowing the challenged claims.

Turning to the merits of Grounds 5-6, Petitioner fails to establish a motivation to combine the references and a reasonable expectation of success in doing so. Instead, Petitioner shows a misunderstanding of the cited references and an oversimplification of the art at issue.

II. The '077 Patent

The '077 patent claims an apparatus for “treating rhinitis in a nasal cavity” by “supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.” *See, e.g.*, Ex. 1001-'077 patent at claim 1. The '077 patent describes “an energy transmission element in the distal portion configured to delivery energy to target tissue in the

nasopharyngeal passage.” *Id.* The ’011 patent describes that the treatment device “may be sized and positioned to target an area of high goblet cell (G) concentration, for example in the back of the nasal passages in the area of the nasopharynx. *Id.*, 24:4-11. The ’077 patent also describes that the energy applicator may include “an external electrode array for delivery radiofrequency” energy. *Id.*, 7:4-12; *See also id.*, 5:44-46, claims 1-9. The ’077 patent describes that its apparatus “provides treatments for any disease or condition for which rhinorrhea is a result or symptom,” such as rhinitis. *Id.*, 7:41-54.

III. The Asserted Art

A. Saadat

U.S. Patent No. 10,307,200 to Saadat (“Saadat”) discloses an apparatus and method for treating conditions such as rhinitis. It first published on September 20, 2018, over twelve years after the ’077 patent’s priority date.

B. Stern

U.S. Patent 5,562,720 to Stern (“Stern”) discloses “a method and an apparatus for in situ destruction of the inner lining of body organs, and more particularly the providing of a selective destruction of the endometrium,” the thin layer of tissue lining the uterus. Ex. 1009-Stern, 1:17-20, 6:56-59. Stern explains that its “goal” is “destruction of the endometrial cells.” *Id.*, 6:60-62. Stern describes destroying the endometrium by using RF energy to heat it to an ablative temperature while maintaining the average temperature of the myometrium, which

is the tissue beneath the endometrium surrounding the uterine cavity. *See id.*, 2:15-18 (describing “heat[ing] the endometrium” and “destroy[ing] the cells of the lining while maintaining the average temperature of the myometrium”); *id.*, 7:29-33 (explaining that “the temperature of the endometrium 22 can be heated to a destructive temperature faster than the myometrium 14 and the rest of the uterus”); *id.*, 6:66-7:6 (“Radio frequency electric current passes through the dilated endometrial surface for a time sufficient to destroy the endometrial cells by elevating the temperature of the endometrium The temperature is maintained until the endometrial tissue is destroyed.”); *id.*, Figs. 1 and 3, 6:51-59, 7:62-67 (showing and describing the myometrial tissue beneath the endometrial lining).

C. Deem

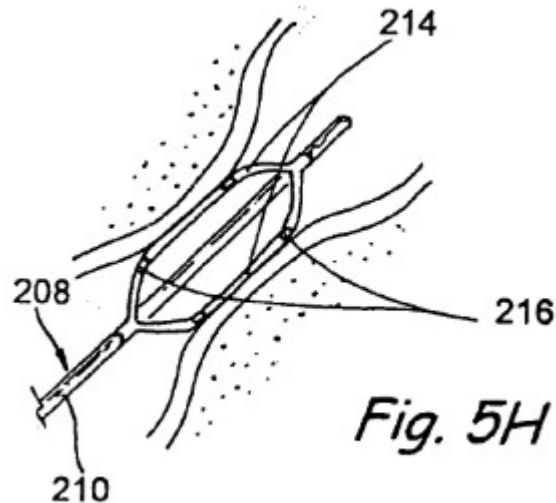
U.S. Pub. 2008/0021369 to Deem (“Deem”) is a prior published application from the same named inventors as the ’077 patent. It first published on January 24, 2008, about a year and a half after the ’077 patent’s priority date. As Petitioner alleges, Deem is a published application that includes the written description and figures of the ’771 provisional, which was incorporated by reference in its entirety into the ’077 patent’s priority applications.

D. Makower

U.S. Pub. 2005/0240147 to Makower (“Makower”) discloses a smattering of embodiments of devices used to perform diagnostic or therapeutic procedures for

ear, nose, and throat disorders. Ex. 1005-Makower, [0001], [0042], [0161]. For example, Makower discloses various occluder, suction, and access devices (Figs. 2A-2R, Figs. 3A-3M''), an occluder/endotracheal tube device (Fig. 4), a cutting or ablation device (Fig. 5A), devices with laterally deployable projections (Figs. 5B, 5D), a drill (Fig. 5C), a catheter (Fig. 5D), various balloon catheters (Figs. 5E-5G'''), a tissue shrinking electrode (Fig. 5H), a cryogenic device (Fig. 5I), a tissue expanding device (Fig. 5J), various forward cutting/suction catheter/endoscope devices (Figs. 5K-5O), various balloon catheter/stent/endoscope devices (Figs. 5P-5R''), a snare catheter (Fig. 5S), forceps (Fig. 5T), a guide catheter and guidewire and endoscope (Fig. 5U-5U'), a microbrider catheter (Fig. 5V), various bone remodeling devices (Figs. 5W-5X'''''), a substance delivering implant device (Figs. 5Y-5Y'''''), various guide catheters (Figs. 6A-6D), a plugging guide catheter (Fig. 6E), and various other catheters (Figs. 7A-7G), and a cochlear implant procedure (Figs. 9A-9C). *Id.*, [0049]-[0128].

In one of these embodiments, Figure 5H shown below, Makower depicts a non-invasive device that can be inserted into the nasal cavity and cauterize or heat adjacent tissue, which it describes in one paragraph. *Id.*, [0092], [0187], Fig. 5H.



Id., Fig. 5H.

Makower alleges that a benefit of the “present invention” is that its devices are “delivered and positioned to perform the desired diagnostic or therapeutic procedures with *minimal trauma* to other tissues, as can result from the insertion of rigid scopes and rigid instruments in accordance with the methodology of the prior art.” *Id.*, [0161] (emphasis added). In fact, causing “minimal damage to the surrounding tissues” is one of the objectives of Makower’s devices. *Id.*, [0016].

Makower further explains that removing too much tissue from the turbinates can impair the function of the turbinates:

It is typically desirable to remove only as much tissue as necessary to restore normal breathing and drainage, as removal of too much tissue from the turbinates can impair the ability of the turbinates to perform their physiological functions of warming and humidifying inspired air and conserving warmth and moisture from expired air.

Id., [0030].

E. Fang

Fang discloses clinical results of treating patients with nasal septum surgery combined with radiofrequency in the treatment of perennial allergic rhinitis.

Ex. 1006-Fang, 876. While the article does not detail the surgical device used, it discusses the results after performing submucous resection of the nasal septum combined with radiofrequency ablation of the sphenopalatine foramen, anterior ethmoidal nerve, and inferior nasal concha. *Id.*, 876-77. It concluded that for treatment of perennial allergic rhinitis, “[r]easonable surgical interventions should be carried out based on the specific structural characteristics.” *Id.*, 877. It also stated that “radiofrequency technique was used to process multiple parts in the nasal cavity.” And it concluded that, “[t]hrough the joint action of multiple links, the therapeutic effect of perennial allergic rhinitis is significantly improved.” *Id.*

F. Edwards-535

U.S. Patent No. 6,517,535 to Edwards (“Edwards-535”) discloses “a method and apparatus for treating airway obstructions,” like those caused by “[s]leep apnea syndrome,” by “reducing the volume of the turbinates in order to reduce nasal airway obstructions.” Ex. 1008-Edwards-535 at 1:22-26, 1:30-33. In all embodiments of Edwards-535, “the . . . invention provides a method for reducing the size of a nasal concha without the formation of a wound on the surface of the nasal concha.” *Id.* at 4:63-66.

Edwards-535 describes providing cooling to the surface of the nasal concha to deliver energy to ablate the internal portion of the nasal concha while preventing ablation of the surface of the nasal concha. *See id.* at 4:60-63 (“By cooling the surface of the nasal concha being ablated, ablation can be performed to remove an internal section of a nasal concha without damaging the surface of the nasal concha.”); *see also id.* at 6:12-16 (“The extent of cooling provided is preferably sufficient to prevent the nasal concha surface from being ablated. As a result, an interior portion of a nasal concha is ablated without ablating the surface of the nasal concha.”); *id.* at 6:26-27 (“[A]n exposed wound site is not generated during the method”); *see also id.* at 6:23-25, 7:2-4. Edwards-535 describes how its “procedure can be performed bloodlessly and without the need to penetrate tissue” and “eliminates the need for surgical cutting.” *Id.* at 4:58-60, 4:55-56.

IV. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Grounds 1-3

Petitioner challenges claims 1-8, and 11 under two anticipation theories (Grounds 1 and 4), relying on Saadat and Deem, respectively. Petitioner also challenges claims 3, 4, and 11 under obviousness theories (Grounds 2 and 3), relying on either Saadat alone or Saadat in combination with Stern. Petitioner’s invalidity theories for Grounds 1-4 rely on an assertion that the challenged claims of the ’077 patent are not entitled to a priority date earlier than October 22, 2019, the filing date of U.S. Patent Application 16/659,893 (“the ’893 application”), the

grandparent application for the '077 patent. Pet., 18. Only under this theory is Petitioner able to contend that Saadat and Deem are prior art to the challenged claims.

Contrary to Petitioner's assertion, the challenged claims of the '077 patent are entitled to a priority date of at least July 21, 2006, the filing date of U.S. Patent Application No. 11/459,090 ("the '090 application"), issuing as U.S. Patent 7,608,275 ("the '275 patent"). Indeed, the '077 patent includes a clear chain of priority to the '090 application, and the challenged claims are fully supported by the '090 application. *See* Ex. 1001-'077 patent.

Petitioner focuses entirely on the priority claim to U.S. Provisional Application No. 60/702,077 ("the '077 provisional"), filed on July 22, 2005, while fatally ignoring the claim of priority to the '090 application, which also antedates the cited references in Grounds 1-4. Because the chain of priority is proper and the challenged claims are supported by the '090 application, neither Saadat nor Deem are prior art and Grounds 1-4 fail.

A. The Petition's Arguments Regarding Priority Date Fail Because the '077 Patent Is Entitled to a Filing Date of at Least July 21, 2006

The '077 patent was filed on January 19, 2021, as a continuation of U.S. Patent 10,894,011, which is a continuation of the '893 application, issuing as the '675 patent. The Petition focuses on the '077 patent's ultimate claim of priority to

the '077 provisional, filed on July 22, 2005. Pet., 19. In doing so, it ignores that the '077 patent also claims priority through a string of continuations and a divisional to at least the '090 application, filed on July 21, 2006, and issuing as the '275 patent. Ex. 1001-'077 patent. As shown in the '275 patent, the '090 application claims the benefit of U.S. Provisional Application No. 60/747,771 ("the '771 provisional"), filed on May 19, 2006, and the '077 provisional, and also incorporates by reference in their entireties the '077 provisional and the '771 provisional. Ex. 1012-'275 patent, 1:7-10. And as the '077 patent shows, all intervening applications claimed priority to the '090 application for the '275 patent. Ex. 1001-'077 patent, 1:6-32.

Petitioner asserts that the '077 patent cannot claim priority to the '771 provisional because the priority chain to this provisional was broken during prosecution of an earlier application in the patent family.¹ Pet., 21-24. Petitioner

¹ The application for U.S. Patent 10,729,897 ("the '897 patent"), which is a patent in the priority chain, did not include a claim of priority to the '771 provisional. During prosecution of the '897 patent's application, Applicant amended the specification to add priority claim to the '771 provisional. The Examiner rejected this attempt. In response to the rejection, Applicant removed the claim of priority and the incorporation by reference of the '771 provisional "[s]olely to advance prosecution, and without acquiescing to the rejections or without prejudice."

further asserts that the '077 patent claims are not entitled to the July 2005 priority claim because the '077 provisional does not provide written description support for the challenged claims. *Id.*, 19-20.

The Board need not address these arguments because they are irrelevant. The Petition fails to consider that the '077 patent also claims priority to the '090 application, that the priority chain to the '090 application is intact and unbroken, and that the '090 application provides the necessary written description support for the challenged claims. Therefore, regardless of the priority chain to the '771 provisional and the written description of the '077 provisional, the '077 patent claims priority to at least July 21, 2006, years before the alleged prior art in Grounds 1-4.

The Petition does not dispute that the '077 patent has a clear chain of priority back to the '090 application. Nor could it. Indeed, the '077 patent is a continuation of U.S. Patent 10,894,011, which is a continuation of U.S. Patent 10,610,675, which is a continuation of U.S. Patent 10,729,897, which is a

Ex. 1020, 218. Applicant “recogniz[ed] that the subject matter was originally incorporated by reference in at least U.S. Pat. No. 7,608,275,” citing MPEP § 608.01(p)(I)(B), and therefore, as more fully explained below, did not also need to be included in the '897 patent’s application. *Id.*; *see also id.*, 190.

continuation of U.S. Patent 10,022,529, which is a continuation of U.S. Patent 9,498,283, which is a continuation of U.S. Patent 8,961,391, which is a continuation of U.S. Patent 8,338,164, which is a continuation of U.S. Patent 8,133,497, which is a divisional of the '275 patent, originally filed as the '090 application.² As a result, the '077 patent can claim priority to at least July 21, 2006, rendering Petitioner's arguments that there is no priority to the '771 provisional application moot. *See* Pet., 21-23.

Petitioner's argument that a break in the priority chain to the '771 provisional during prosecution prevents the '077 patent from claiming priority to the '771 provisional is therefore inapplicable because the '077 patent can claim priority to the '090 application and does not need to claim priority to the '771 provisional. Pet., 22-23.³ Moreover, the Petition's argument that the '077

² The intervening applications confirm that the priority claim to the '090 application is intact. *See* Ex. 1019 (U.S. Patent No. 10,729,897), 1:6-21; Ex. 1017 (U.S. Patent No. 10,022,529), 1:6-19; Ex. 1016 (U.S. Patent No. 9,498,283), 1:7-17; Ex. 1015 (U.S. Patent No. 8,961,391), 1:7-15; Ex. 1014 (U.S. Patent No. 8,338,164), 1:7-14; Ex. 1013 (U.S. Patent No. 8,133,497), 1:7-12.

³ As support for the argument that the '077 patent is not entitled to priority to the '771 provisional, the Petition cites *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d

provisional does not provide written description support for the challenged claims is equally inapplicable because the '090 application provides the necessary support, as further explained below.

In sum, the priority chain to the '090 application is complete and intact. Each application in the priority chain claims priority to the '090 application, and each application in the priority chain also expressly incorporates by reference the '090 application, providing the necessary priority for the '077 patent of at least July 21, 2006.

B. The Challenged Claims Are Fully Supported by the '090 Application, Which Properly Incorporated by Reference the '771 Provisional

The '090 application not only claims the benefit of the '771 provisional and the '077 provisional, but it also incorporates by reference each provisional application into the specification in their entireties. As a result, every application in

1309, 1320 (Fed. Cir. 2018); *Encyclopaedia Britannica, Inc. v. Alpine Elecs. of Am. Inc.*, 609 F.3d 1345, 1351 (Fed. Cir. 2010); *Hollmer v. Harari*, 681 F.3d 1351, 1355 (Fed. Cir. 2012); and *Akeva L.L.C. v. Nike, Inc.*, 817 F. App'x 1005, 1012 (Fed. Cir. Jul. 16, 2020). Pet., 21-23 and n.11. Each of these cases are inapposite because the Petition focuses only on the priority claim to the '771 provisional and ignores the unbroken priority claim to the '090 application.

the priority chain includes a priority claim to the '090 application, which includes the disclosures of the '771 provisional and the '077 provisional.

The provisional applications disclose two similar but different subject matters. For instance, the '077 provisional contains disclosure of using the invention to treat “various regions within the body,” including “the mucosal and muscular lining of the lung, cholinergic cells in the region of tumors, myofacial [sic] regions, vascular smooth muscle cells, musculoskeletal regions and the like.” Ex. 1010-'077 Provisional, [0001], [0044]-[0045], [0068]-[0070]. The '771 provisional contains disclosure of using the invention to “target cells in a nasal cavity,” and thus treat the nasal cavity, thus supporting the claims of the '077 patent, along with the other disclosure of the '090 application. Ex. 1011-'771 Provisional, [0001]-[0004], [0043]-[0044]. Because each provisional is entirely incorporated by reference into the '090 application, the claims of the '077 patent are fully supported by the earlier '090 application.

1. The '077 Patent Can Rely on the Disclosure of the '090 Application, Including Its Incorporation by Reference of the '771 Provisional

Petitioner contends that the '077 patent cannot rely, for written description support, on the incorporation by reference of the '771 provisional into any application before the '893 application. Pet., 23-24. This is incorrect and is

unsupported by the law, rules, and the Manual of Patent Examining Procedure (“MPEP”).

The ’077 patent is entitled to rely on the ’090 application’s filing date even if the ’090 application only incorporates by reference the ’771 provisional. *See Samsung Elecs. Co., Ltd. et al. v. ACQIS LLC*, IPR2021-00608, Paper 10 at 6-11 (P.T.A.B. Dec. 8, 2021); *Ex parte Maziere*, 27 U.S.P.Q.2d 1705, 1706-07 (BPAI Jan. 26, 1993); MPEP § 608.01(p). Indeed, there is no requirement that every priority application in the chain expressly discloses the subject matter of the ’771 provisional. Instead, the material from the ’771 provisional can be incorporated by reference in the ’090 application without breaking the chain of priority. *See Samsung*, Paper 10 at 10 (“an application is entitled to rely upon the filing date of an earlier application, even if the earlier application itself incorporates essential material by reference to another document”).

Once a reference is incorporated into an application in the manner required by MPEP §§ 2163.07(b) and 601.07(p), “[t]he information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed.” MPEP § 2163.07(b); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001) (an incorporated-by-reference “document becomes effectively part of the host document as if it were explicitly contained therein”).

Therefore, because the '090 application incorporated by reference the '771 provisional in its entirety in the manner required by MPEP §§ 2163.07(b) and 601.07(p), the '771 provisional is treated as part of the '090 application (and thus the '275 patent) when originally filed. And every application in the chain claimed priority to the '090 application, which includes the disclosure of the '771 provisional. As a result, the '077 patent did not add new matter when disclosure from the '771 provisional was added to the grandparent application for the '675 patent.

Indeed, the Board has expressly held that where, as here, the patent in question expressly includes the claimed subject matter, the fact that the patent's parent application did not expressly include that subject matter but rather incorporated it by reference does not defeat the claim to priority. *Maziere*, 27 U.S.P.Q.2d at 1706-07. Therefore, the fact that the '771 provisional subject matter was not set forth explicitly in the '090 application but rather was incorporated by reference into the application does not change the fact that the '077 patent is entitled to the priority date of the '090 application and can incorporate material from that application without it being new matter.

In *Maziere*, just as in the present case, two references were available as prior art only if the application in question was not entitled to the priority date of an earlier application. *Id.*, 1706. The Examiner in *Maziere* decided that the application

on appeal was not entitled to the benefit of the earlier filing date of a parent application because that parent application referred to the claimed subject matter only by the incorporation by reference of another application. *Id.*, 1706-07. The Examiner believed that “since the [claimed] subject matter is so-called ‘essential material’, it was improper for [the parent application] to incorporate the [claimed] subject matter by reference.” *Id.*, 1707.

The Board disagreed and found that the application on appeal was entitled to the priority of the parent application. *Id.* Notably, the Board determined that: (1) “the present application fully describes and enables the subject matter now claimed,” (2) the subject matter in question was not “essential material” to the parent application because the parent application did not claim that subject matter, and (3) the priority statute (35 U.S.C. § 120) does not place any restrictions or limitations as to how the claimed invention must be disclosed in the earlier application to comply with 35 U.S.C. § 112. *Id.* Accordingly, the Board found that the application on appeal was entitled to the priority date of the parent application even though the parent application disclosed the subject matter claimed in the application on appeal only through incorporation by reference. Thus, nonessential subject matter incorporated by reference in the earlier parent applications can serve as essential material for claims in a descendant application without disrupting the continuity of disclosure required by 35 U.S.C. § 120. *Id.*

The MPEP, which cites *Maziere* with approval, states the following:

The limitations on the material which may be incorporated by reference in U.S. patent applications which are to issue as U.S. patents do not apply to applications relied on only to establish an earlier effective filing date under 35 U.S.C. 119 or 35 U.S.C. 120. Neither 35 U.S.C. 119(a) nor 35 U.S.C. 120 places any restrictions or limitations as to how the claimed invention must be disclosed in the earlier application to comply with 35 U.S.C. 112(a). Accordingly, an application is entitled to rely upon the filing date of an earlier application, even if the earlier application itself incorporates essential material by reference to another document. See *Ex parte Maziere*, 27 USPQ2d 1705, 1706-07 (Bd. Pat. App. & Inter. 1993).

MPEP § 608.01(p).

Applying *Maziere* and MPEP § 608.01(p), the '077 patent is entitled to rely upon the filing date of the '090 application. Specifically, the '077 patent expressly includes supporting subject matter⁴ and relies on the '090 application only to establish an earlier effective filing date under 35 U.S.C. § 120.

⁴ Petitioner appears to agree that the '077 patent, once the passages and figures were copied into the specification from the '771 provisional, includes support for the subject matter claimed. Pet., 20-21. Moreover, any argument to the contrary contradicts Petitioner's challenge in Ground 3 where it alleges that Deem, which is substantially identical to the '771 provisional, anticipates the challenged claims.

As the MPEP explains, the “inclusion of such an incorporation by reference statement in the later-filed application will permit applicant to include the subject matter from the prior application into the later-filed application without the subject matter being considered as new matter.” MPEP § 608(p)(I)(B). Thus, the addition of material from the ’771 provisional into the grandparent application for the ’077 patent was expressly contemplated by and permitted by the MPEP because it was already fully incorporated by reference in the ’090 application. *See* MPEP § 608(p). Because “limitations on the material which may be incorporated by reference in U.S. patent applications ... do not apply to applications relied on only to establish an earlier effective filing date,” (*Id.*), the ’077 patent is entitled to rely upon the July 21, 2006, filing date of the ’090 application, even if the ’090 application “itself incorporates essential material by reference to” the ’077 patent. The Petition ignores this section of the MPEP.

Petitioner asserts without explanation that, “by rule, PO cannot rely on incorporation by reference of the ’771 Provisional into any utility application before the ’893 Application for written description support.” Pet., 23-24. As discussed above, that is legally incorrect. Petitioner cites 37 C.F.R. § 1.57(d), so it appears to be attempting to make an argument about incorporating by reference essential material. But the ’893 application did not just incorporate the ’771 provisional by reference. It included the description of the ’771 provisional so that

material was fully disclosed in the '893 application. Petitioner has not argued, let alone shown, that the '771 provisional application was essential material to the '275 patent, which incorporated it by reference. Nor could it. For instance, claim 1 of the '275 is fully supported by the '090 application without reference to '771 provisional application. *See, e.g.*, Ex. 1012-'275 patent, 1:15-38, 13:4-13, 3:17-52, 4:9-12, 5:44-67, 6:56-65, 7:7-11, 10:19-23, 11:33-41, 13:4-13.

Therefore, under 37 C.F.R. § 1.57(e), Foundry was permitted to incorporate nonessential material by reference to the “prior and concurrently filed commonly owned U.S. applications.”⁵ 37 C.F.R. § 1.57(e). Accordingly, because the '771 provisional was properly incorporated by reference and not essential to the '090 application's resulting patent, the '675 patent, the '077 patent is entitled to rely on the '090 application's earlier effective filing date under MPEP § 608.01(p).⁶

⁵ There is no dispute that the '771 provisional constitutes a prior commonly owned U.S. application.

⁶ Petitioner's other cited case law is equally inapposite. First, in *NRG Energy*, the provisional application was neither incorporated by reference into nor was its disclosure added to the patent at issue. *NRG Energy, Inc. v. Midwest Energy Emissions Corp.*, IPR2020-00832, Paper 17 (P.T.A.B. Oct. 26, 2020). This is unlike the present situation, where the material from the '077 provisional was

Further, even if the '771 provisional did contain essential material for the '275 patent, the incorporation by reference of that material would still be permitted. MPEP § 608(p)(I) gives the Director considerable discretion in what may or may not be incorporated by reference. The purpose of the incorporation by reference requirement is so that the public knows what is included in the application. The '771 provisional is publicly available, 37 C.F.R. § 1.14, and could have been easily located by the public. Indeed, the '275 patent expressly incorporated the '771 provisional by reference, correctly identified the application by number, and thus allowed the public to locate the '771 provisional application and review its disclosure. Ex. 1012-'275 patent, 1:7-10.

To incorporate by reference, the host document must identify with particularity what specific material it incorporates and where that material is found.

added to the '893 application, as expressly permitted by the MPEP because it was properly incorporated by reference into, and was thus a part of, the original '090 application. Second, in *Focal*, the priority chain to the parent application was broken because one patent in the chain did not claim priority to an earlier patent. *Focal Therapeutics, Inc. v. Senorx, Inc.*, IPR2014-00116, Paper 8 at 10-12 (P.T.A.B. Apr. 22, 2014). This is unlike the present situation because the priority chain back to the '275 patent was not broken and remains intact.

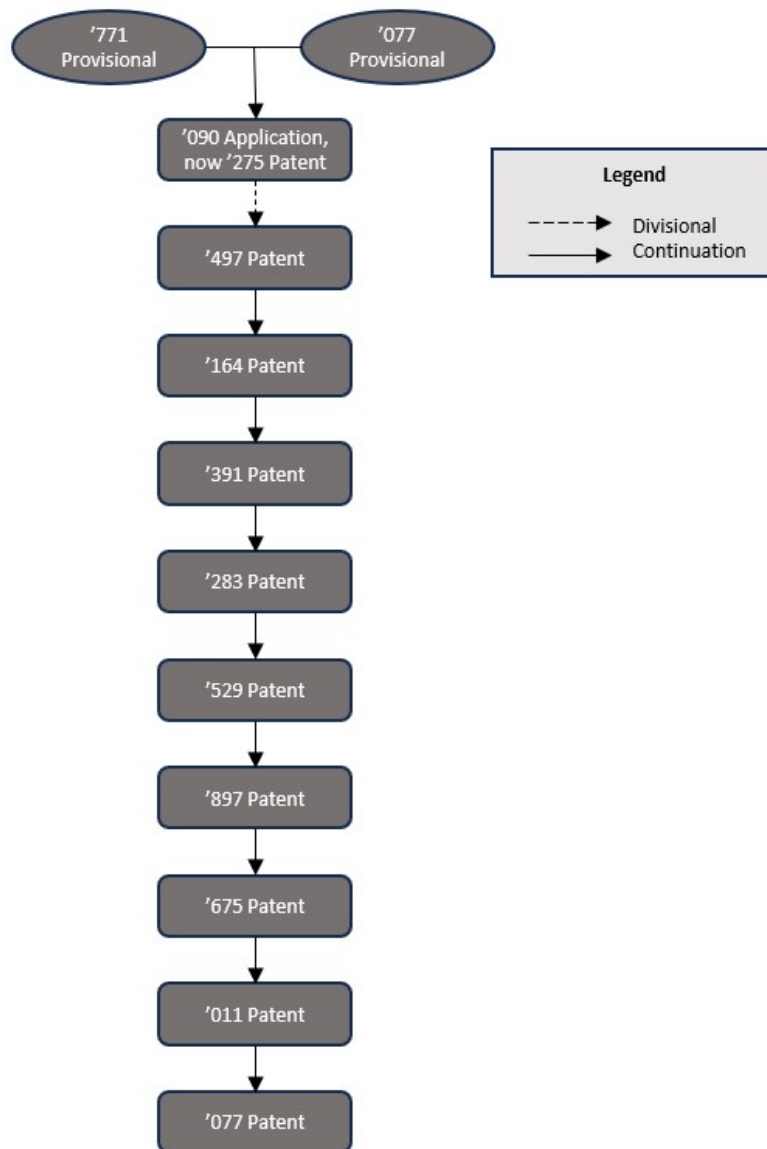
Id. The Federal Circuit has long held that patent applicants can incorporate references in their entirety. *See, e.g., Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 906-07 (finding that the language “[reference] is incorporated herein by this reference” sufficiently incorporated the reference in its entirety); *see also Harari v. Lee*, 656 F.3d 1331, 1335-36 (Fed. Cir. 2011) (finding references were incorporated in their entirety based on the “broad and unequivocal language” that “[t]he disclosures of the two applications are hereby incorporate[d] by reference”).

Here, the '090 application both (1) identified with detailed particularity the specific material it incorporates (i.e., “incorporat[ing] ... by reference” the enumerated applications), and (2) clearly indicated where that material is found (i.e., the “entirety” of those listed applications). Therefore, the '090 application is able to claim priority and incorporate by reference the '771 provisional, even if it was essential to the '275 patent claims.

2. The Claims of the '077 Patent Have Written Description Support

Lastly, the Petition argues that even if the subject matter of the '771 provisional could be incorporated into the application for the '675 patent (it could), the subject matter from the '771 provisional does not support the challenged claims. Pet., 24-26. The Petition asserts that '771 provisional does not disclose “a radiofrequency generator . . . for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat

rhinitis.” *Id.*, 24-25 (emphases removed). Petitioner, however, misstates the test for written description support. The issue is whether the claims have support in ’090 application, including the ’771 provisional incorporated by reference. Support is not required to be solely from the ’771 provisional. And Petitioner has thus legally erred by focusing only on the ’771 provisional. See the following summary of the ’077 patent’s priority chain and family:



In any event, the '771 provisional as a whole supports the claims. *See, e.g.*, Ex. 1011-'771 Provisional, Figs. 5-6, 24-25, and 31-32. The specification of the '077 patent further supports this as it notes that energy used to ablate the tissue can be applied from a device separate from the device used to deliver a toxin. *See, e.g.*, Ex. 1001-'077 patent,⁷ 9:1-17 (“The energy may be applied using the same catheters or other structures which are used for delivering the toxins. Alternatively, the energy may be applied using separate external or internal sources, such as using separate external ultrasonic transducers and/or ultrasound wave guides capable of delivering focused or unfocused ultrasound into the target tissues of the nasal cavity.”); *see also id.*, 5:31-34, 5:41-48, 7:7-12; 9:31-34, 9:39-47. Indeed, the Petition itself asserts in Ground 4 that Deem, containing largely the same disclosure as the '771 provisional and the '090 application, satisfies each limitation

⁷ Because the subject matter of the '771 provisional was added to the grandparent application for the '077 patent, the specification of the '077 patent constitutes the specification for the '090 application, including its incorporation by reference of the '771 provisional, and can be referenced to show written description support in the '090 application.

of the claims.⁸ Pet., 56-66. And more specifically, the Petition sets forth written description for the limitation requiring “a radiofrequency generator . . . for supplying radiofrequency energy electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.” *Id.*, 56-61.

Notably, during prosecution of the '077 patent, the Examiner raised no written description rejections and determined that the prior art failed to teach the challenged claim limitations. *See generally*, Ex. 1025.

Petitioner asserts that Applicant argued during prosecution of a separate application that the “sole purpose of applying energy described by [U.S. Patent No. 7,655,243 to Deem] is to porate target cells to enhance uptake of a nerve toxin.” Pet., 25-26. Applicant’s remarks were with respect to claims requiring “cryotherapy treatment.” Ex. 1034, 786. Thus, Applicant’s argument that U.S. Patent No. 7,655,243 to Deem did not use cryotherapy is not a broad admission that the '771 provisional did not consider using RF energy to treat a nasal condition. As discussed above, it did.

⁸ Petitioner asserts that Deem provides “identical disclosures” to the '771 Provisional. Pet., 56.

Because the '077 patent has priority to the '090 application and the claims are supported by the '090 application, the claims have a priority date of July 21, 2006.

C. Saadat and Deem Are Not Prior Art

Because, as explained above, the '077 patent claims priority to and is entitled to rely upon the July 21, 2006, filing date of the '090 application, neither Saadat nor Deem are prior art. Thus, Grounds 1-4 of the Petition fail, and Petitioner has not demonstrated a reasonable likelihood of prevailing on any challenged claim.

V. Institution Should Be Denied Under 35 U.S.C. § 325(d) Because the Petition Recycles Art That Was Already Considered by the Examiner

Institution of inter partes review is discretionary. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016). The Patent Office may elect to deny instituting a proceeding if the Petition relies on matters the Office previously considered. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential).

Discretionary denial is appropriate here because Grounds 4-6⁹ are based on a reference that was considered during prosecution, or is substantially the same as, or

⁹ And also Ground 4.

cumulative of, references considered during prosecution. Further, the Petition fails to demonstrate how the Examiner erred in evaluating the prior art.

A. 35 U.S.C. § 325(d) Is Governed by Precedential Board Decisions

In determining whether to institute an inter partes review, the Board “may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d); *see* 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.4(a). The Board uses a two-part framework in determining whether to exercise its discretion under § 325(d): first, determining whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and second, if either condition of the first part of the framework is satisfied, determining whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8.

In applying the two-part framework, the Board considers several nonexclusive factors, including: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during

examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art or patent owner distinguishes the prior art; (e) whether petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (P.T.A.B. Dec. 15, 2017) (precedential as to § III.C.5, first paragraph).

Factors (a), (b), and (d) relate to whether the art or arguments presented in the petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics*, Paper 6 at 10. Factors (c), (e), and (f) “relate to whether the petitioner has demonstrated a material error by the Office” in its prior consideration of that art or arguments. *Id.* Only if the same or substantially the same art or arguments were previously presented to the Office will the Board consider whether a petitioner has demonstrated a material error by the Office. *Id.* “At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.*, 9.

1. The Petition Relies on the Same Prior Art That the Examiner Evaluated During Prosecution—*Becton* Factors (a), (b), (d)

In Grounds 5-6, the Petition asserts that claims 1-8, and 11 would have been obvious over the combination of Makower and Fang and others. There is no dispute that Makower was fully considered by the Office during prosecution of the grandparent application. Pet., 79-80, 96. Indeed, the Office identified Makower as the “closest prior art” to the challenged claims and issued a notice of allowance for the ’675 patent over Makower. Ex. 1022, 122; *Advanced Bionics*, Paper 6 at 7-8.

The Petition’s inclusion of Fang in the purported combinations of Grounds 5-6 does not overcome the § 325(d) flaw because the Petition primarily relies on Makower. It is only with the elements relating to treating rhinitis in a nasal cavity where the Petition relies on Fang. Pet., 67-70, 74-75 In doing so, it argues that Makower teaches most of the elements, but that Fang teaches the specific limitation relating to treating rhinitis symptoms in the nasal cavity. Pet., 68-70, 74, 78. Specifically, the Petition appears to argue that the combination of Makower and Fang is the result of modifying Makower’s device and method with Fang’s known outcome of application of RF therapy. *Id.*, 78. The Petition adds Fang for these elements (1[pre] and 1[c]) because it notes that the Examiner found Makower did “not teach ‘treating nasal conditions with a device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage,’” and

thus argues that a person of skill “would have understood from Fang” that “Makower’s electrodes . . . would treat nasal disorders by disrupting neural activity in the same way as Fang. *Id.*, 79.

This meager addition of Fang fails to elevate Grounds 5-6 to an argument that was not previously before and considered by the Office. The present situation is similar to that of *Gator Bio, Inc. v. Sartorius Bioanalytical Instruments, Inc.*, IPR2023-00215, Paper 19 (P.T.A.B. June 20, 2023), in which the Board denied institution under § 325(d), finding that the Petition cited “almost exclusively to” the main reference that was already considered by the Examiner and added a second reference for only a small aspect of one limitation. *Id.*, 15. As the Board explained, “even if we accept Petitioner’s view that Yu [a reference not before the Examiner during prosecution] is not cumulative of any reference cited during examination,” it would not “mov[e] the needle much in favor of instituting review.” *Id.*, 16. This was because the Board found that the petitioner relied on Yu for one aspect of a claim limitation and otherwise relied on Yu only “to bolster Petitioner’s argument that Yang disclose[d]” the claim limitations. *Id.*, 15.

Here, the Petition relies almost entirely on Makower and cites to Fang only for a part of a single limitation. Pet., 68-70, 74, 78. Indeed, the Petition asserts that “Makower already teaches” the claim limitations and purports that “Fang *simply clarifies* Makower operates in the same way as claimed.” *Id.*, 79 (emphasis added).

Thus, by Petitioner’s own admission, Fang is cumulative to the disclosure of Makower already consider by the Office.

The Board should deny institution here because the substantive disclosures in the prior art and arguments presented in the Petition, in the context of *Becton* factors (a), (b), and (d), are the same or substantially the same as those previously considered and applied by the Office during prosecution. These factors therefore weigh in favor of denying the Petition.

2. The Petition Fails to Demonstrate That the Examiner Erred in a Manner Material to Patentability — *Becton* Factors (c), (e), and (f)

Moving to part two of the *Advanced Bionics* framework, the Board need not independently review and assess the merits of each petitioned ground to conclude whether and how any material error occurred where, as here, Petitioner does not adequately identify any alleged material error. *Google LLC v. Valtrus Innovations Ltd.*, IPR2022-01197, Paper 18 at 21 (P.T.A.B. June 13, 2023); *see also Roku, Inc. v. Universal Elecs., Inc.*, IPR2019-01619, Paper 11 at 11, 19 (P.T.A.B. Apr. 2, 2020) (declining to consider merits of a patentability challenge where the petitioner did not “explain adequately how the Examiner erred in a manner material to patentability”).

The Petition has not explained how the Examiner erred in allowing the claims to issue, let alone erred in a way material to the patentability of the

challenged claims. Indeed, the Petition is silent as to any alleged error on the Office's part with respect to Makower and Fang (Grounds 5-6). First, there is no dispute that Makower was extensively evaluated during prosecution of the grandparent application and that the Examiner noted that it was the "closest prior art." Pet., 79-80, 96; Ex. 1022, 122. Second, as explained above, Fang's disclosure is no more relevant than the disclosures in Makower, which the Examiner considered during prosecution. *See* Pet., 79 (Petitioner arguing that "Fang *simply clarifies* Makower" (emphasis added)). At best, the Petition simply disagrees with the Examiner's ultimate conclusion. But mere disagreement is not sufficient to support the allegation that there was an error in a manner material to the patentability of the claims.

Moreover, Petitioner's Grounds 5-6 simply walks through the prosecution history, identifies one or more limitations the Examiner said were not present in Makower, and then directs the Board to its Grounds in the Petition adding Fang, et al. This approach is inadequate under *Becton, Dickinson* factors (c), (e), and (f), which Petitioner does not even mention, much less satisfy. Indeed, as the Board has explained: "Petitioner's alleged grounds of unpatentability cannot establish material error *per se* under our binding precedent.... Otherwise, the reasonable likelihood standard of § 314(a) and the second part of the *Advanced Bionics* framework ('material error') would collapse into one." *Vital Connect, Inc. v. Bardy*

Diagnostics, Inc., IPR2023-00381, Paper 7, 20 (P.T.A.B. July 11, 2023). Thus, the Board has sufficient bases to find that factors (c) and (e) weigh in favor of denying the Petition.

With respect to factor (f), at most the Petition relies on declaration testimony of an expert witness. Notably, the Petition does not explain how (if at all) this testimony shows that the Examiner erred in allowing the claims. Regardless, expert testimony should not, by itself, overcome the other five *Becton* factors that weigh in favor of denying the Petition.

B. The Petition Cannot Use the '077 Patent as a Blueprint for Its Motivation to Combine Argument

Finally, any motivation to modify Makower pursuant to Fang is grounded in impermissible hindsight. The Board regularly rejects combinations infected with hindsight. These rejections hold particular weight when a petitioner relies on the challenged patent itself as a roadmap for its proposed invalidity theories, as Petitioner does here. *See Grain Processing Corp. v. Am. Maize-Prods. Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988) (*quoting Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983) (“Care must be taken to avoid hindsight reconstruction by using ‘the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.’”); *Cf. Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004) (“This form of hindsight reasoning, using the invention as a

roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result — often the very definition of invention”); *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (“A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning”).

As Petitioner admits, the Examiner deemed Makower to be the closest prior art but allowed the claims in the grandparent application because it did not teach “treating nasal conditions with a device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage . . . , and wherein the target tissue has a change in temperature.” Pet., 79. Armed with this information, the Petition is nothing more than an allegation that this very same prior art reference (Makower) can be combined with an obscure clinical study (Fang) to satisfy the missing limitation. This uses the specific claim limitations of the patent as a blueprint for the petitioned ground and is the epitome of impermissible hindsight.

Aside from the hindsight reason that the Examiner applied Makower, the Petition presents no reason at all that a person of ordinary skill in the art would have looked to Makower. As discussed in Section III.D, Makower discloses a smattering of embodiments of devices used to perform diagnostic or therapeutic

procedures for ear, nose, and throat disorders. Ex. 1005-Makower, [0001], [0042], [0161]. It discloses devices and procedures as far ranging as various occluder, suction, and access devices (Figs. 2A-2R, Figs. 3A-3M''), occluder/endotracheal tube devices (Fig. 4), cutting or ablation devices (Fig. 5A), devices with laterally deployable projections (Figs. 5B, 5D), a drill (Fig. 5C), a catheter (Fig. 5D), various balloon catheters (Figs. 5E-5G'''), a tissue shrinking electrode (Fig. 5H), a cryogenic device (Fig. 5I), a tissue expanding device (Fig. 5J), various forward cutting/suction catheter/endoscope devices (Figs. 5K-5O), various balloon catheter/stent/endoscope devices (Figs. 5P-5R''), a snare catheter (Fig. 5S), forceps (Fig. 5T), a guide catheter and guidewire and endoscope (Fig. 5U-5U'), a microbrider catheter (Fig. 5V), various bone remodeling devices (Figs. 5W-5X'''''), a substance delivering implant device (Figs. 5Y-5Y'''''), various guide catheters (Figs. 6A-6D), a plugging guide catheter (Fig. 6E), and various other catheters (Figs. 7A-7G), and a cochlear implant procedure (Figs. 9A-9C). *Id.*, [0049]-[0128].

Other than the hindsight reason that the Examiner applied Makower, there is no reason that a person of ordinary skill in the art would have looked to Makower, much less plucked the single Figure 5H embodiment, for which Makower provides incredibly little detail, to use in the combination presented in the Petition. *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-994 (Fed. Cir. 2017) (requiring

“a motivation to pick out [the] two references and combine them”); *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017) (“[W]e cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention.”).

Makower provides no detail about the procedure using the embodiment shown in Figure 5H other than stating that the Figure 5H device can be “advanced into a passageway” and that “current is applied to the electrodes 216, causing tissue adjacent to the struts 214 to be cauterized or heated.” *Id.*, [0187]. And as Petitioner admits, Makower “omits details on how to implement” its energy delivery. Pet. at 84. Considering the sheer number of embodiments in Makower and the lack of detail about this Figure 5H embodiment, the Petition fails to make any argument, other than hindsight, as to why a person of ordinary skill in the art would be looking at Makower in the first place, much less the Figure 5H embodiment, and much less combining it with Fang, as discussed in the next section. *See Shire LLC v. Amneal Pharms., LLC*, 802 F.3d 1301, 1307-09 (Fed. Cir. 2015) (affirming summary judgment that claims directed to methods of using amphetamine derivatives having a mesylate salt of LDX to treat ADHD were not obvious, where the primary prior art reference, which had been considered by the PTO, did not disclose the LDX ingredient, but broadly disclosed a series of compounds that could include the claimed LDX ingredient, however, only with

hindsight knowledge of the claimed invention would one of skill know to apply the LDX ingredient as the prior art did not teach a “finite and limited class including LDX”).

VI. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Grounds 5-6

A. The Petition Fails to Establish a Motivation to Combine

It is Petitioner’s burden to demonstrate “that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367-68 (Fed. Cir. 2016) (citations omitted). Petitioner has not met that burden for its combination of Makower and Fang, et al., used in Grounds 5-6.

As an initial matter, the Petition does not explain what the combination of Makower and Fang would have been. Instead, it alleges that “Makower [a reference considered by the Office and determined to be the ‘closest prior art’] already teaches its device treats a nasal disorder, and Fang simply clarifies Makower operates in the same way as claimed.” Pet., 79; *see also id.*, 80 (“Fang provides additional details regarding the well-known design, construction, and operation of Makower’s RF device.”). Thus, it is not clear from the Petition what

Fang purports to add to Makower that the Examiner did not already consider or understand.

Moreover, a person of ordinary skill in the art would not have combined Makower and Fang because those references have diametrically opposed objectives and effects on the areas they treat. Makower describes “a variety of apparatus that may be inserted into the nasal cavity” to perform diagnostic or therapeutic procedures. Ex. 1005-Makower, [0161]. Makower explains that it is desirable to “perform the desired diagnostic or therapeutic procedures with minimal trauma to other tissues, as can result from the insertion of rigid scopes and rigid instruments in accordance with the methodology of the prior art.” *Id.* The Petition relies on an embodiment of Makower depicted in Figure 5H that shows a tissue shrinking electrode device that does not cut or penetrate the nasal tissue. *Id.*, [0092].

In contrast, Fang describes clinical studies of a nasal endoscopic surgery to treat perennial rhinitis and deviated nasal septums. Fang does not detail the treatment device that was used but discloses that submucous resection of the nasal septum was performed as well as other cuts and resections of the nasal ridge and walls of the nasal cavity. Ex. 1006-Fang, 876-77. And Fang intended that any radiofrequency treatment be conducted with a surgical procedure, contrary to the purpose of Makower. *Id.*, 877 (Fang stating that surgical interventions should be

carried out and referencing surgical interventions when concluding that, “[t]hrough the joint action of multiple links, the therapeutic effect of perennial allergic rhinitis is significantly improved.”).

The Petition fails to acknowledge the fundamental difference between Makower—disclosing devices intended for diagnostic or therapeutic procedures with minimal trauma to other tissue—and Fang—disclosing a surgical procedure—and fails to explain why a person of ordinary skill in the art, looking at Makower, would have been motivated to combine it with a paper detailing the clinical results achieved during a nasal endoscopy surgery. “The obviousness inquiry does not merely ask whether a skilled artisan could combine the references, but instead asks whether ‘they would have been motivated to do so.’ ... *Fundamental differences* between the references are *central* to this motivation to combine inquiry.” *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) (emphases added) (quoting *InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014)) (affirming Board’s finding of no motivation to combine where there were “fundamental differences” in the references, which the “Board properly considered” in its motivation to combine analysis).

The Board has denied institution in similar cases where the references were so fundamentally different that there was insufficient motivation to combine. *See, e.g., Johns Manville Corp. v. Knauf Insulation, Inc.*, IPR2018-00827, Paper 9 at

11-12 (P.T.A.B. Oct. 16, 2018) (informative) (denying institution for insufficient reasons to combine references where the petitioner failed “to show that one of ordinary skill in the art would have had a reason to substitute [one reference’s] binder for the binder disclosed in [the other reference]” when the two references taught “considerably different binding systems”).

Petitioner advances several purported reasons that a person of ordinary skill in the art would have been motivated to combine Makower and Fang, Pet., 78-85, but none are sufficient, especially considering the fundamental differences between Makower and Fang discussed above.

First, Petitioner argues that Makower and Fang “are analogous art to the Challenged Claims.” Pet., 78. Even assuming for purposes of argument that is the case, however, “[a]nalogous art is merely a threshold inquiry as to whether a reference can be considered in an obviousness analysis.” *Johns Manville*, IPR2018-00827, Paper 9 at 10. “Demonstrating that a reference is analogous art or relevant to the field of endeavor of the challenged patent *is not sufficient* to establish that one of ordinary skill would have had reason to combine its teachings with other prior art in the manner set forth in the claim.” *Id.* (emphasis added) (citing *Securus Techs., Inc. v. Global Tel*Link Corp.*, 701 F. App’x 971, 977 (Fed. Cir. 2017) (“a broad characterization of [prior art references] as both falling within

the same alleged field ... without more, is not enough for [Petitioner] to meet its burden of presenting a sufficient rationale to support an obviousness conclusion”).

Second, Petitioner argues that a person of ordinary skill in the art “would have found it obvious to apply Fang’s method (disrupting neural activity using ablation) with Makower’s device and method (using electrosurgical device in nasopharynx) to treat rhinitis.” Pet., 78-79. Petitioner relies entirely on the prosecution history of the grandparent application for this position. It argues that because the Examiner found that Makower does not teach “treating nasal conditions with a device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage, and wherein the target tissue has a change in temperature,” a person of ordinary skill in the art would have looked to Fang and understood, from Fang, that Makower’s purported device does disclose this claim limitation. *Id.*, 79-80. As explained above, this is a quintessential example of impermissible hindsight.

Regardless, the Petition fails to explain why a person of ordinary skill in the art would have been motivated to look to Fang—a research paper outlining the results of endoscopic nasal surgeries—in the first place. *See Nichia Corp. v. Everlight Americas, Inc.*, 855 F.3d 1328, 1137 (Fed. Cir. 2017) (finding that a person of ordinary skill would not have considered the secondary references because “the different considerations in the design and manufacture of [devices]

result in substantial differences in the manufacturing processes and materials used in the different technologies”). The present case is similar to *Nichia* because a person of ordinary skill in the art would not have considered Fang to modify (or understand) Makower due to the substantial differences between Makower’s non-invasive device and Fang’s surgical resection procedure.

Third,¹⁰ Petitioner argues that a person of ordinary skill in the art “would have reasonably expected Makower’s electrosurgical device to obtain Fang’s clinical results.” Pet., 83. But that is not a reason to combine the references—it is merely an allegation that the combination may work. Also, Petitioner fails to acknowledge the issues explained above, namely that a person of ordinary skill in the art would not have looked to modify Makower’s device with Fang’s surgical tools used in a nasal septum surgery, and arguing otherwise uses nothing more than hindsight reasoning. See *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*,

¹⁰ Petitioner’s third purported reason that a person of ordinary skill in the art would have been motivated to make the Ground 5 combination focuses on the combination of Edwards-535 into the Makower and Fang combination. Pet., 82-83. The arguments regarding Edwards-535 are limited to Edward-535’s energy source and do not cure the fatal deficiencies between Makower and Fang. Thus, Patent Owner need not address this purported motivation here.

694 F.3d 1312, 1328 (Fed. Cir. 2012) (merely stating that the purported combination allows you to do something new that you had not been able to do before “fails to explain why a person of ordinary skill in the art would have combined the elements from *specific references* in the way that the claimed invention does”).

VII. Conclusion

Based on the deficiencies identified above, Petitioner has not shown that it has a reasonable likelihood of prevailing on any of its proposed grounds. The Board should decline to institute an IPR proceeding based on the Petition.

Respectfully submitted,

Dated: May 2, 2024

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Kathleen A. Daley, certify that
PATENT OWNER'S PRELIMINARY RESPONSE contains 9,507 words,
excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the
word-processing system used to prepare this paper.

Dated: May 2, 2024

By: /Kathleen A. Daley/
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on May 2, 2024, a copy of
PATENT OWNER'S PRELIMINARY RESPONSE was served upon the
below-listed counsel by electronic mail:

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