

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FISHER & PAYKEL HEALTHCARE LIMITED,
Petitioner,

v.

RESMED LIMITED,
Patent Owner.

Case
IPR2017-00632
Patent 8,944,061 B2

Before BARRY L. GROSSMAN, BEVERLY M. BUNTING, and
JAMES J. MAYBERRY, *Administrative Patent Judges*.

BUNTING, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Fisher & Paykel Healthcare Limited (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, and 48–91 (“the challenged claims”) of U.S. Patent No. 8,944,061 B2 (Ex. 1001, “the ’061 patent”). ResMed Ltd. (“Patent Owner”) filed a preliminary response to the Petition. Paper 7 (“Prelim. Resp.”). On July 25, 2017, we entered a Decision on Institution (Paper 8, “Decision” or “Dec.”), determining that Petitioner had presented sufficient arguments and evidence demonstrating a reasonable likelihood that it would prevail in showing claims 17, 18, 20, 21, 23, 28–30, 32, 33, 35, 36, 38, 43–46, 81, 84, 85, 87, and 88 of the ’061 patent would be unpatentable, but not claims 22, 26, 27, 37, 41, 42, 48–80, 82, 83, 86, 89–91. Petitioner timely filed a Request for Rehearing (Paper 10), which we denied (Paper 26).

Subsequent to institution, Patent Owner filed a Patent Owner Response (Paper 14, “PO Resp.”), and Petitioner filed a Reply (Paper 16, “Reply”).¹ Pursuant to the U.S. Supreme Court’s decision on April 24, 2018, in *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018), we modified our Decision on Institution on May 3, 2018, to include the challenge to claims 22, 26, 27, 37, 41, 42, 48–80, 82, 83, 86, and 89–91.² Paper 29 (modifying the Decision on Institution to include all claims and all grounds presented in the Petition). Based on the parties’ requests for additional briefing to

¹ Patent Owner filed a Motion for Observations (Paper 34), and Petitioner filed a Response (Paper 38).

² In our Decision Denying Petitioner’s Request for Hearing, we recognized that the Decision on Institution erroneously listed claim 91 as an instituted claim. (Paper 26).

address the newly-added challenges, we determined that good cause existed to permit additional briefing addressing the newly added challenges. Paper 31. Patent Owner submitted a Supplemental Response (Paper 32, “Supp. Resp.”) and Petitioner filed a Supplemental Reply (Paper 33, “Supp. Reply”). Oral argument was held on July 11, 2018, and a transcript has been entered into the record.³ Paper 42 (“Tr.”). Although the one-year period normally available to issue a Final Written Decision was to expire on July 25, 2018, the Chief Judge determined that good cause existed to extend this deadline by up to six months. Papers 40–41.

This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we conclude that Petitioner has demonstrated, by a preponderance of the evidence, that certain of the challenged claims identified in the Order, i.e., Section V., are unpatentable.

II. BACKGROUND

A. Real Party in Interest

Petitioner identifies Fisher & Paykel Healthcare Limited as the real party in interest. Pet. 11.

B. Related Matters

The parties indicate that the ’061 patent has been asserted in: *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, No. 3:16-cv-02068-DMS-WVG (S.D. Cal.). Pet. 11; Paper 4, 2. Petitioner concurrently filed two other petitions challenging the ’061 patent, IPR2017-00634 and IPR2017-00635, both of which were denied. Pet. 11; Paper 4, 2.

³ Oral argument was rescheduled at the request of the parties to provide time for additional briefing directed to the newly instituted claims. Paper 28.

C. The '061 Patent (Ex. 1001)

The '061 patent, titled “Cushion to Frame Assembly Mechanism,” issued on February 3, 2015, and claims priority from an application filed on January 12, 2006, and two provisional applications filed on October 14 and November 9, 2005, respectively. Ex. 1001, (45), (54), (60), (63). The '061 patent relates to a patient interface for use in treatment of sleep disordered breathing, such as obstructive sleep apnea, and, in particular, to an apparatus for securing a face-contacting portion of a patient interface, such as a cushion, to a frame or shell of the patient interface. *Id.* at 1:17–23.

The patient interface includes mask assembly 210, as illustrated in Figure 3, and is reproduced below. Ex. 1001, 6:53–58.

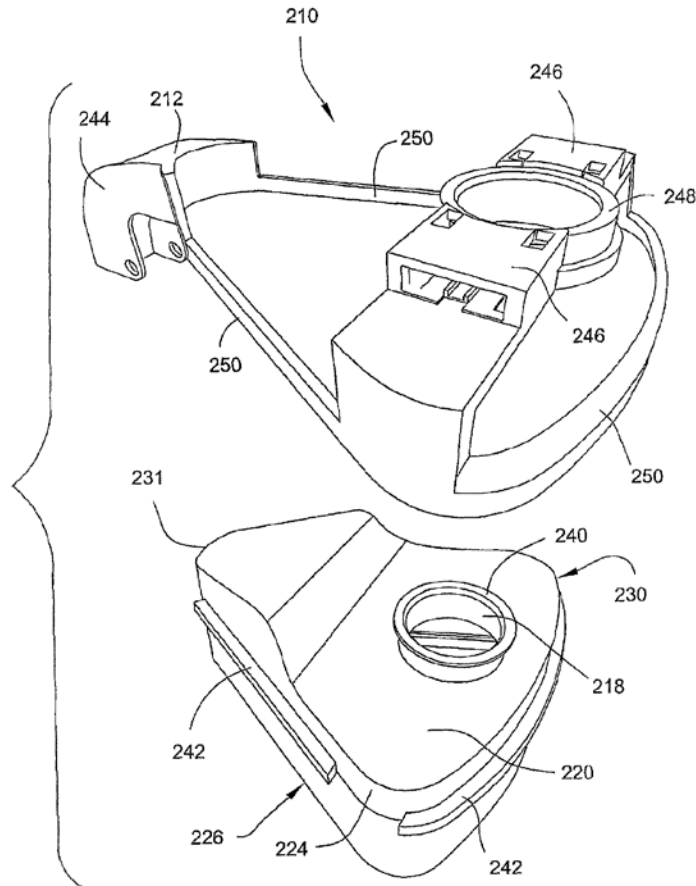


Fig. 3

Figure 3 is an exploded view of the mask assembly. Mask assembly 210 includes skeleton frame 212, which is adapted to interlock removably with cushion/frame sub-assembly 230. *Id.* at 6:56–58. Cushion/frame sub-assembly 230 incorporates an integrally molded one-piece frame and cushion. *Id.* at 6:59–60. Cushion/frame sub-assembly 230 includes upper wall 220, having opening 218 surrounded by annular wall 240, for communicating with an inlet conduit. *Id.* at 6:64–67. Skeleton frame 212 further includes upper support member 244, adapted to support a forehead support, lower headgear clip receptacles 246 that engage a

headgear assembly, and annular connection seal 238 adapted to engage an inlet conduit. *Id.* at 7:11–17.

Figure 4, reproduced below, illustrates engagement of skeleton frame 212 with cushion/frame sub-assembly 230. Ex. 1001, 7:22–23.

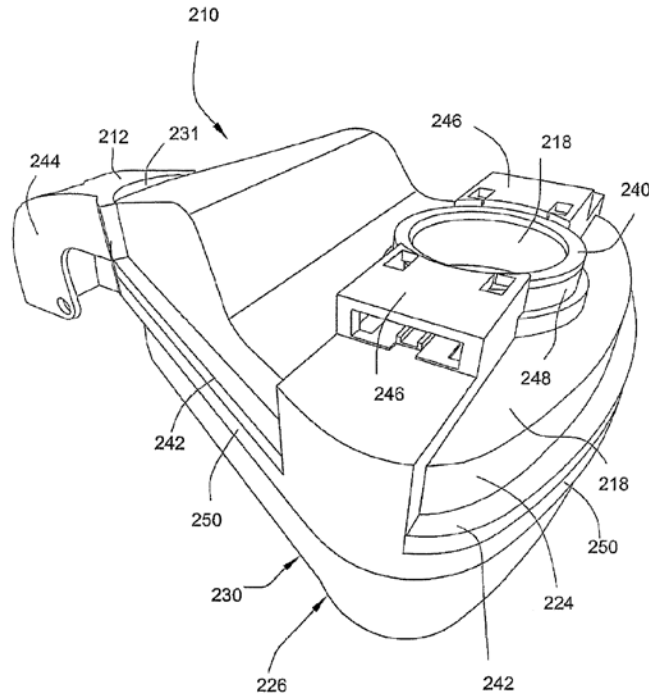


Fig. 4

Figure 4 is a perspective view of the assembled mask assembly. Skeleton frame 212 engages with cushion/frame sub-assembly 230 by interlocking annular elbow connection seal 248 with annular wall 240, interlocking or frictionally engaging upper support member 244 with top portion 231 of cushion/frame sub-assembly 230, and interlocking elongated frame members 250 with corresponding protrusions on cushion/frame sub-assembly 230. Ex. 1001, 7:22–30.

D. Challenged Claims

Of the challenged claims, claims 17, 32, 51, 58, 65, 74, and 81 are independent. Ex. 1001, 20:58–28:34. Each of the independent claims

recites, *inter alia*, a “first frame” or “frame,” a cushion, and a “second frame” or “skeleton frame.” Claims 51, 65, and 81 are illustrative of the claimed subject matter, and are reproduced below:

51. A mask assembly for treatment of sleep disorder breathing by delivering a flow of pressurized gas to a patient, the mask assembly comprising:

- a first frame with a first opening adapted to fluidly communicate an interior of the first frame with an inlet conduit, the first frame being made of a first material;
 - a cushion with a side wall and a face contacting portion extending from the side wall, wherein the cushion is overmolded to the first frame to form a cushion/frame sub-assembly and the cushion is adapted to form a seal around a patient’s nose and mouth, the cushion being made of a second material that is less rigid than the first material; and
 - a second frame adapted to removably interlock with the cushion/frame sub-assembly, the second frame including an upper member configured to provide forehead support; lower portion with a second opening aligned with the first opening so that the inlet conduit fluidly communicates with a breathing chamber formed by the cushion and the first frame, and with headgear attachment structures on opposed lateral sides of the second opening, the headgear attachment structures being adapted to engage with headgear attachments;
 - two elongate frame members that interconnect the upper member and lower portion; and
 - an open space bounded at least in part by the two elongate frame members and the lower portion;
- wherein the first frame protrudes at least partially through the open space.

Id. at 24:1–31.

65. A mask assembly for treatment of sleep disorder breathing by delivering a flow of pressurized gas to a patient, the mask assembly comprising:

- a cushion adapted to form a seal by abutting a patient’s face around the patient’s nose and mouth, the cushion

- comprising a face contacting portion with a sealing portion that contacts the patient's face around the patient's nose and mouth and comprising a first material;
- a frame integrally molded to the cushion, the frame comprising an annular wall surrounding an opening that is adapted to allow fluid communication of the pressurized gas to an interior of the frame and a second wall surrounding the annular wall and connected to the cushion and comprising a second material that is more rigid than the first material;
- an inlet conduit in fluid communication with the frame to communicate the pressurized gas to the interior of the frame; and
- a skeleton frame adapted to be removably engageable with the frame, the skeleton frame comprising an upper support member adapted to receive a forehead contacting portion, a lower frame member comprising attachment locations adapted to engage with clips for straps, two frame members interconnecting the upper support member and the lower frame member and forming an open space between the two frame members and the lower frame member, wherein
- the skeleton frame and the frame are adapted to be releasably engageable to one another at the opening, and
- the frame is at least partially accessible through the open space.

Id. at 25:37–67.

81. A mask assembly for treatment of sleep disorder breathing by delivering a flow of pressurized gas to a patient, the mask assembly comprising:

- a first frame made of first material;
- a cushion connected to the first frame, the cushion being adapted to form a seal around the patient's nose and mouth and being made from a second material that is more flexible than the first material, the first frame and the cushion together forming a breathing chamber; and
- a second frame adapted to constrain the first frame, the second frame comprising an upper member, a lower member with an annular opening adapted to allow an inlet conduit to

provide pressurized gas to the patient, and a separate opening located between the annular opening and the upper member, the separate opening providing access to the first frame when the mask assembly is fully assembled, wherein the first frame and the second frame snap-fit together.

Id. at 27:13–31.

E. Grounds of Unpatentability

Petitioner challenges claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, and 48–91 of the '061 patent on the following grounds (Pet. 15):

References	Basis	Claims Challenged
Berthon-Jones ⁴ and Barnett ⁵	§ 103(a)	81–91
Berthon-Jones, Barnett, and Lithgow ⁶	§ 103(a)	17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 58–73
Berthon-Jones, Barnett, Lithgow, and Burns ⁷	§ 103(a)	51–57 and 74–80

In support of its arguments, Petitioner relies on the declaration of Jason Eaton, P.E. (Ex. 1006) and Patent Owner relies on the declaration of Mr. Alexander Virr (Ex. 2003). The parties rely on other exhibits as discussed below.

III. ANALYSIS

A. Legal Principles

1. Burden of Proving Unpatentability

In an *inter partes* review, the petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never

⁴ WO 2004/041342 A1, pub. May 21, 2004 (Ex. 1002, “Berthon-Jones”).

⁵ US 6,412,488 B1, iss. July 2, 2002 (Ex. 1003, “Barnett”).

⁶ US 2004/0118406 A1, pub. June 24, 2004 (Ex. 1004, “Lithgow”).

⁷ US 5,062,421, iss. Nov. 5, 1991 (Ex. 1005, “Burns”).

shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail in this proceeding, Petitioner must support its challenges by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). Accordingly, all of our findings and conclusions are based on a preponderance of the evidence.

2. Obviousness

A claim is unpatentable under § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). The U.S. Court of Appeals for the Federal Circuit has made clear that a petitioner in an *inter partes* review proceeding cannot “satisfy its burden of proving obviousness” by “employ[ing] mere conclusory statements” and “must instead articulate specific reasoning, based on evidence of record” to support an obviousness determination. *In re Magnum Oil Tools Int'l*, 829 F.3d 1364, 1380–81 (Fed. Cir. 2016).

We analyze the following grounds of unpatentability in accordance with the above-stated principles. Because Patent Owner does not provide evidence regarding secondary considerations, our determination is based on the first three factors. See PO Resp.; Pet. 106; see also *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1373 (Fed. Cir. 2018) (“While [the] burden of

persuasion remains with the challenger, a patentee bears the burden of production with respect to evidence of secondary considerations of nonobviousness.”).

B. Level of Skill in the Art

In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation omitted). In that regard, Petitioner asserts that a person having ordinary skill in the art (“POSITA”) “would have at least a bachelor’s degree in mechanical engineering, biomedical engineering or other similar type of engineering degree combined with at least two years of experience in the field of masks, respiratory therapy, patient interfaces or relevant product design experience.” Pet. 21 (citing Ex. 1006 ¶ 26). Patent Owner does not expressly state its position on the level of ordinary skill in the art in its Patent Owner Response. *See generally* PO Resp. Mr. Virr, Patent Owner’s expert, generally accepts Petitioner’s framework. *See e.g.*, Ex. 2003 ¶ 25 (“My analysis is thus based on the perspective of a POSITA having this level of knowledge and skill.”).

Thus, based on the entire record, we accept Petitioner’s formulation, finding that the POSITA “would have at least a bachelor’s degree in mechanical engineering, biomedical engineering or other similar type of engineering degree combined with at least two years of experience in the field of masks, respiratory therapy, patient interfaces or relevant product design experience.” Ex. 1006 ¶ 26.

C. Claim Construction

The Board interprets claims of an unexpired patent using the broadest reasonable construction in light of the specification of the patent in which they appear.⁸ 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable interpretation standard, and absent any special definitions, claims terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms or phrases must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). In the absence of such a definition, limitations are not to be read from the specification into the claims. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

Petitioner does not propose a specific construction for any claim term in its Petition, applying the “broadest reasonable interpretation in light of the specification of the ’061 patent.” Pet. 16. Patent Owner agrees. PO Resp. 17–18. In our Decision on Institution, we determined that no express construction of any claim term was necessary. Dec. 9–10 (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Now, having considered the entire record, we conclude that our determination regarding the obviousness of the challenged claims does not turn on the interpretation of any of the claim terms, and that no express

⁸ The USPTO revised its rules to harmonize the Board’s claim construction standard with that used in federal district court. 83 Fed. Reg. 51,340 (Nov. 13, 2018). This rule change applies to petitions filed after November 13, 2018, however, and does not apply to this proceeding. *Id.*

construction of any claim term is necessary for purposes of this Final Written Decision.

D. Obviousness Based on Berthon-Jones and Barnett

Petitioner challenges the patentability of claims 81–91 of the '061 patent under 35 U.S.C. § 103 as obvious based on Berthon-Jones and Barnett. In support thereof, Petitioner identifies the disclosures in the cited references alleged to describe the subject matter in the challenged claims, as well as a reason why a POSITA would have modified Berthon-Jones based on the teachings of Barnett. *Id.* at 23–56. Petitioner supports its arguments and evidence with the testimony of its declarant, Mr. Eaton. Ex. 1006.

Patent Owner disputes that Berthon-Jones teaches certain limitations in claims 81–91, and further argues that the proposed combination of Berthon-Jones and Barnett is unavailing for the reasons discussed *infra*. PO Resp. 18–49. Patent Owner supports its arguments and evidence with the testimony of its declarant, Mr. Virr. Ex. 2003.

For the reasons that follow, we conclude that Petitioner has established by a preponderance of the evidence that claims 81, 84, 85, 87, and 88 are unpatentable, but not claims 82, 83, 86, and 89–91. We begin our analysis with a brief summary of the cited references and then address the parties' contentions in turn.

1. Berthon-Jones (Ex. 1002)

Berthon-Jones is a PCT publication titled “Mask and Components Therof” having an international publication date of May 21, 2004. Ex. 1002 (43), (54). Berthon-Jones relates to a “comfortable low-leak mask assembly for use with Non-Invasive Positive Pressure Ventilation (NIPPV).” *Id.* ¶ (57). Figure 51 of Berthon-Jones, reproduced below, is representative.

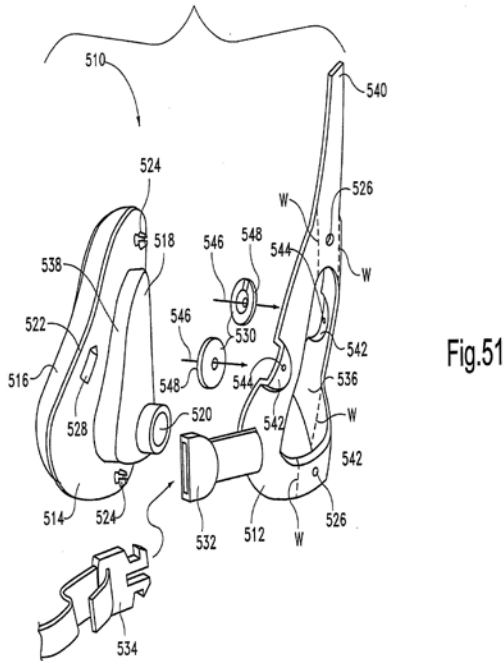


Figure 51 is an exploded perspective view of mask assembly 510.

Mask assembly 510 includes semi-rigid chassis 512 that connects to headgear, and cushion/secondary frame 514 adapted to form a seal with the user's face. *Id.* ¶ 177. Cushion/secondary frame 514 includes fixedly connected cushion portion 516 and secondary frame portion 518. *Id.* ¶ 179. “[S]econdary frame portion 518 maybe be made of a flexible or semi-flexible material, e.g., polypropylene.” *Id.* ¶ 180. Cushion portion 516 is “a generally soft and conforming structure.” *Id.* ¶ 181. Cushion/secondary frame 514 includes connecting members 524, which interface with receiving holes 526 in chassis 512 to provide a snap-fit connection between cushion/secondary frame 514 and chassis 512. *Id.* ¶ 182.

Mask chassis 512 includes central aperture 536 adapted to receive raised, central portion 518 of cushion/secondary frame 514, to provide a conduit for gas delivery through central aperture 536. *Id.* ¶ 184. Adjustment wheel retaining portions 542 are positioned adjacent each side of central aperture 536, and correspond to projections 528 on cushion/secondary frame

514. *Id.* The user turns adjustment wheels 530 to modify the sealing force and/or fit between the user and cushion portion 516. *Id.* ¶ 186.

2. Barnett (Ex. 1003)

Barnett is a U.S. Patent titled “Low-Contact Nasal Mask and System Using Same” having an issue date of July 2, 2002. Ex. 1003, (54), (45). Barnett is directed to a low contact nasal mask having “a one-piece, light weight seal member defining a nose receiving cavity, a collar coupled to the seal member, and a conduit coupling member, and to a system for supplying a flow of gas to a patient that incorporates such a low contact nasal mask.” Ex. 1003, 1:9–13. As shown in Figure 1a, reproduced below, nasal mask assembly 30 includes collar 34 and conduit coupling member 36. *Id.* at 3:48–50.

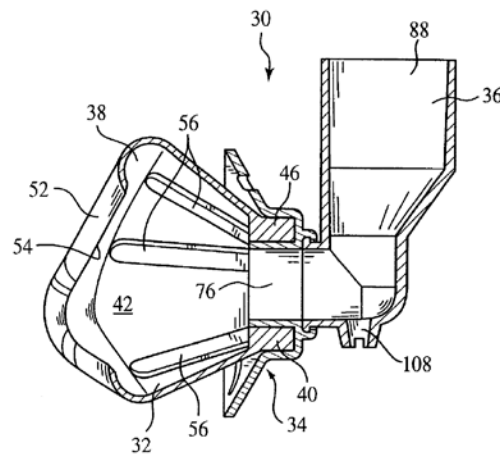


FIG. 1A

Figure 1a is a sectional side view of the nasal mask assembly. Conduit coupling member 36 is rotatably mounted to collar 34 “so that conduit coupling member 36 freely rotates over a range of 360° about a center axis of collar 34.” *Id.* at 3:53–56.

3. Discussion

a. Petitioner’s Challenge to Claim 81

i. Undisputed Limitations of Claim 81

Claim 81 is independent. Petitioner relies on the disclosure in Berthon-Jones for most of the limitations of claim 81, and Barnett for the rest. Pet. 27–46. Petitioner annotated Figure 51 of Berthon-Jones, reproduced below, to illustrate the purported correspondence between Berthon-Jones and claim 81. *Id.* at 28.

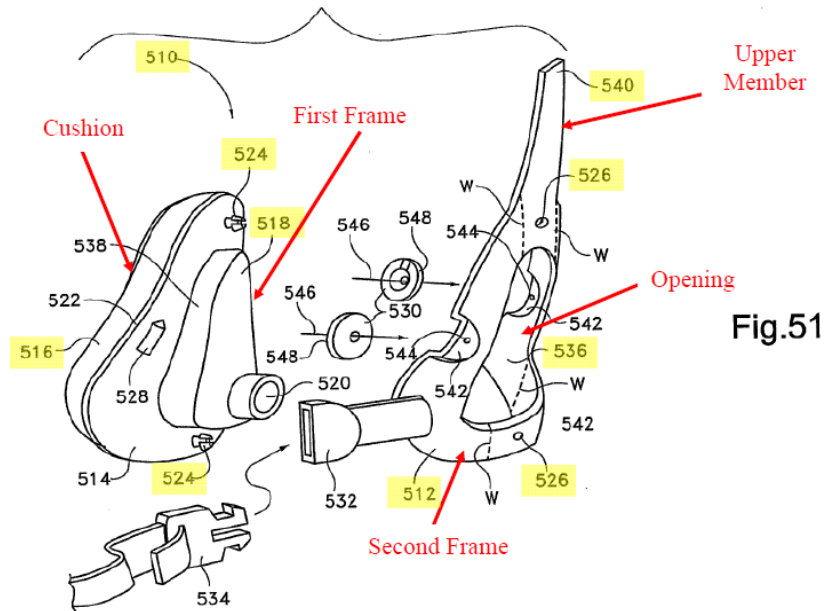


Figure 51 of Berthon-Jones shows an exploded view of mask assembly 510, as annotated by Petitioner.

For example, the preamble of claim 81 is directed to “[a] mask assembly for treatment of sleep disorder breathing by delivering a flow of pressurized gas to a patient” (Ex. 1001, 27:13–14), and Petitioner contends that Berthon-Jones’ mask assembly 510 likewise delivers pressurized gas to a patient to treat sleep disordered breathing (Pet. 30). Claim 81 also requires “a first frame made of a first material.” Ex. 1001, 27:16. Petitioner contends that this limitation is satisfied by the teaching in Berthon-Jones that first frame 518 “may be made of a flexible or semi-flexible material, e.g., polypropylene.” Pet. 31 (citing Ex. 1002 ¶ 180).

Claim 81 also requires “a cushion connected to the first frame, the cushion being adapted to form a seal around a patient’s nose and mouth and being made from a second material that is more flexible than the first material, the first frame and the cushion together forming a breathing chamber.” Ex. 1001, 27:17–21. Petitioner contends that this claim element is satisfied by the disclosure in Berthon-Jones of cushion 516, which is made of a soft material that is more flexible than the semi-soft material of first frame 518, and that when connected, cushion 516 and first frame 518 form a breathing chamber. Pet. 32–33 (citing Ex. 1002 ¶ 179–181; Ex. 1006 ¶¶ 55–57).

Claim 81 additionally recites that “the first frame and second frame snap-fit together.” Ex. 1001, 27:31–32. Petitioner asserts that the disclosure in Berthon-Jones regarding the snap-fit engagement of connecting members 524 on the secondary frame portion into corresponding receiving holes 526 in the mask chassis satisfies this claim limitation. Pet. 46 (citing Ex. 1002 ¶ 182).

Patent Owner does not dispute Petitioner’s contentions with regards to these undisputed claim limitations of claim 81. *See* PO Resp.⁹ Now, in view of the entire record, we adopt as our own Petitioner’s analysis of the

⁹ The scheduling order in this proceeding reminded Patent Owner that “any arguments for patentability not raised in the [Patent Owner Response] will be deemed waived.” Paper 9, 3; *see also In re Nuvasive, Inc.*, 842 F.3d 1376, 1380–81 (Fed. Cir. 2016) (holding that a patentee waived an argument by presenting it only in the preliminary proceeding and not during the trial, despite the Board cautioning the patentee that arguments not briefed in the response would be deemed waived).

undisputed claim limitations as recited in independent claim 81, and find that Berthon-Jones teaches these limitations.

ii. Annular Opening Limitation

We turn next to the disputed limitations of claim 81. Claims 81 also recites a second frame that constrains the first frame, and includes “an upper member, [and] a lower member with an annular opening adapted to allow an inlet conduit to provide pressurized gas to the patient.” Ex. 1001, 27:22–25. Petitioner contends that Berthon-Jones teaches second frame 512 as having upper member 540 and opening 536 that receives and constrains the raised portion of first frame 518. Pet. 34 (citing Ex. 1002 ¶¶ 177, 183–184). Petitioner explains that opening 536 in the lower portion of second frame 512 provides an inlet conduit to provide pressurized gas to the patient, but recognizes that Berthon-Jones does not expressly disclose that opening 536 is annular. *Id.* at 35 (citing Ex. 1002 ¶ 184; Ex. 1006 ¶¶ 59–70). Relying on the testimony of Mr. Eaton, Petitioner contends that “configuring the second frame 512 to directly support the inlet conduit (elbow) at an annular opening that allows pressurized gas to pass from the elbow to the patient was well-known and common in the prior art.” *Id.* (citing Ex. 1006 ¶¶ 59–70). Petitioner relies on Barnett’s teaching regarding “second frame 34 that directly attaches to and supports the inlet conduit 36 at an annular opening 76,” to illustrate that it was known to utilize a frame having an annular opening to receive an inlet conduit. *Id.* at 36 (citing Ex. 1003, 3:52–57, 8:66–9:43). Petitioner also contends that it was known to provide an annular opening in the second frame for directly attaching the inlet conduit with the second frame, as also taught by Barnett. *Id.* at 39 (citing Ex. 1006 ¶ 67; Ex. 1003, 3:52–57, Pet. § I). Petitioner annotated Figure 1A of Barnett,

reproduced below, to illustrate the alleged correspondence between Barnett and claim 81. *Id.* at 36.

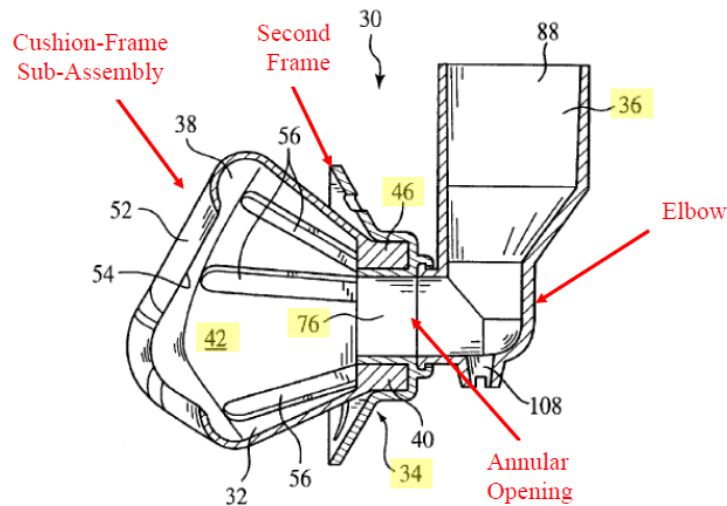


FIG. 1A

Figure 1A of Barnett illustrating a side view of the mask assembly, as annotated by Petitioner.

Petitioner argues that a POSITA “would have viewed these two types of frame-elbow arrangements as two design choices for establishing a seal between an interior of an elbow and a breathing chamber.” Pet. 41 (citing Ex. 1006 ¶¶ 61–70). According to Petitioner, “[a] person of skill in the art would have selected the Barnett configuration as one of a finite number of predictable solutions for providing a connection between the interior of the elbow and the breathing chamber.” *Id.* (citing *KSR*, 550, U.S. at 421). Petitioner contends that the advantages of the proposed Berthon-Jones and Barnett arrangement would have motivated a POSITA to modify Berthon-Jones in view of Barnett. *Id.* Namely, because

Berthon-Jones and Lovell¹⁰ utilize a direct connection between the elbow and the cushion sub-assembly, which requires only a

¹⁰ US 6,631,718 B1, issued Oct. 14, 2003 (Ex. 1012, “Lovell”).

single seal, and Barnett and Gunaratnam¹¹ teach separate sealed connections between: 1) the second frame and the inlet conduit, and 2) the second frame and the cushion-frame sub-assembly. [Ex. 1006] ¶¶ 66–68. Although Barnett and Gunaratnam require two separate seals, directly attaching the inlet conduit to the second frame would make it easier for a patient to detach the cushion-frame sub-assembly from the second frame without affecting the engagement of the inlet conduit with the second frame. *Id.* ¶¶ 62, 69.

Id. Petitioner maintains that the proposed modification would enable the user to remove the cushion-frame sub-assembly without having to disconnect the elbow from the second frame, “making reassembly easier for the user.” *Id.* at 42 (citing Ex. 1006 ¶¶ 62, 69).

Patent Owner does not dispute Petitioner’s assertion that Barnett teaches a second frame that attaches and supports an inlet conduit at an annular opening. Instead, Patent Owner advances arguments and evidence challenging the reasons offered by Petitioner to combine Berthon-Jones and Barnett. For example, Patent Owner argues that Petitioner improperly used hindsight in proposing that a POSITA would have modified Berthon-Jones’ mask to use Barnett’s collar connection. PO Resp. 18–46. We address Patent Owner’s arguments regarding the proposed modification of Berthon-Jones using the teachings of Barnett below.

a) *Whether Petitioner’s Proposed Modification Is Based On Hindsight*

Patent Owner argues that Petitioner’s proposed modification to Berthon-Jones, including “(1) modif[ing] Berthon-Jones’s mask chassis to incorporate Barnett’s collar structure, (2) further modif[ing] the proposed mask chassis/collar structure to include an annular opening that directly

¹¹ US 6,796,308 B2, issued Sept. 28, 2004 (Ex. 1014, “Gunaratnam”).

engages with Barnett's elbow inlet conduit, and (3) includ[ing] a sealed connection between the mask chassis/collar structure and Berthon-Jones's cushion/frame sub-assembly," is based on hindsight. PO Resp. 19. Key to Patent Owner's argument is its contention that a POSITA "would have understood that Petitioner's proposed modifications to the 'Tenth Embodiment' of Berthon-Jones would directly conflict with several critical structures that allow Berthon-Jones's mask assembly to provide Berthon-Jones's stated purpose for a low-leak mask with enhanced/tailored sealing and fit at selected locations on the patient's face." *Id.* at 20–21 (citing Ex. 1002 ¶¶ 11, 182, 185–186; Ex. 2003 ¶¶ 44–49).

We recognize the impropriety of basing a conclusion of obviousness upon facts gleaned only through hindsight. Nonetheless,

[a]ny judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper.

In re McLaughlin, 443 F.2d 1392, 1395 (CCPA 1971); *see also KSR*, 550 U.S. at 421 ("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."). For the reasons discussed below, we do not find that Petitioner's proposed modification to Berthon-Jones using Barnett is based impermissibly on hindsight.

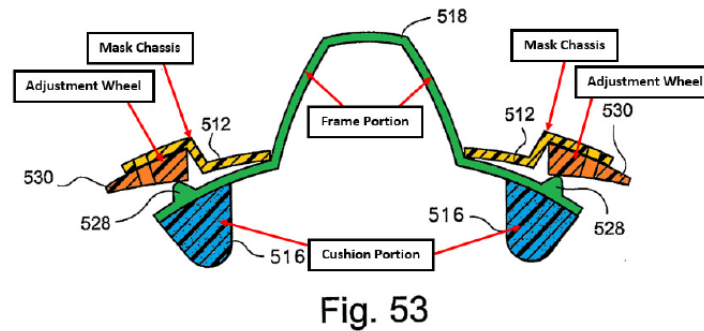
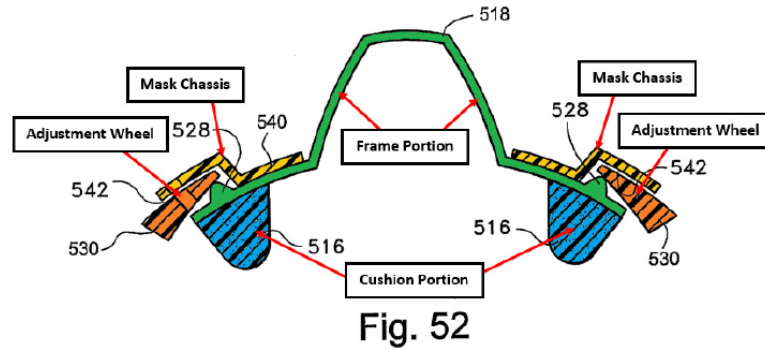
Whether Petitioner's Proposed Modification Deviates from the Intended Purpose and Principle of Operation of Berthon-Jones

Patent Owner first argues that the proposed modification, i.e., incorporating Barnett's rigid collar in Berthon-Jones's mask chassis, is unavailing because operation of Berthon-Jones's adjustment wheels would

compromise the air-tight seal between the mask and the user, thus rendering the resulting mask inoperable for its intended purpose. *Id.* at 22–29.

Referring to the specific embodiment in Berthon-Jones that Petitioner relies on as “the Tenth Embodiment,” Patent Owner argues that the intended purpose of this embodiment “is to provide adjustment wheels that cause its cushion/secondary frame to move or deform relative to its mask chassis so as to provide small adjustments in the fit of the mask assembly to the user’s face.” *Id.* at 22 (citing Ex. 1002 ¶¶ 177, 182, 185–186, Figs. 51–53; Ex. 2003 ¶¶ 30–31). Relying on the testimony of Mr. Virr, Patent Owner argues that the proposed modification “would cause the adjustment wheels to degrade the fit/seal between the patient’s skin and cushion, rather than improve them.” *Id.* (citing Ex. 2003 ¶¶ 44–46). Patent Owner supports its argument by directing us to passages in Berthon-Jones describing how the adjustment wheels operatively “cooperate to cause the cushion/secondary frame 514 to move or deform relative to mask chassis 512 so as to provide small adjustments in the fit of the mask assembly 510 to the user’s face.” *Id.* at 24 (citing Ex. 1002 ¶¶ 177, 182, 185–186, Figs. 51–53; Ex. 2003 ¶¶ 30–31).

To illustrate its understanding of the operation of the adjustment wheels, Patent Owner annotated Figures 52 and 53 of Berthon-Jones, reproduced below. *Id.* at 25 (citing Ex. 1002 ¶¶ 185–186).

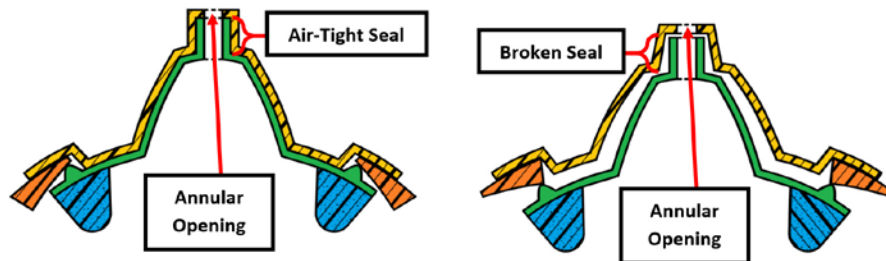


Figures 52 and 53 of Berthon-Jones illustrating operation of the adjustment wheels, as annotated by Petitioner.

Patent Owner explains that Figure 52 shows that “when the thinner portion of an adjustment wheel 530 is between chassis 512 and frame portion 518, the frame portion 518 is fully in contact with the chassis portion 512, and the frame portion 518 has a wider horizontal dimension than in Fig. 53.” *Id.* (citing Ex. 2003 ¶¶ 30–31). Relatedly, Figure 53 illustrates how rotation of the adjustment wheel moves its thicker portion between mask chassis 512 and frame portion 518, deflecting frame portion 518 away from chassis 512 toward the user’s face. *Id.* at 25–26 (citing Ex. 2003 ¶¶ 30–31). Patent Owner argues that “[a] POSITA would consider this a fundamental feature of Berthon-Jones’s Tenth Embodiment because it produces a more effective seal/fit between the cushion portion 516 and a patient’s skin, particularly if

the patient has a smaller or narrower face.” *Id.* at 26 (citing Ex. 2003 ¶¶ 45-46).

Essentially, Patent Owner argues that the proposed modification, involving Barnett’s collar 34 and annular opening for directly attaching with the elbow conduit, “on the mask chassis 512 of Berthon-Jones along with the functionality of the adjustment wheels 530 of Berthon-Jones would cause a failure in the breathing chamber’s air seal.” PO Resp. 26 (citing Ex. 2003 ¶¶ 45). The proposed modification would not have been made, in Patent Owner’s estimation, “because adjustment wheels 530 would force a ‘physical separation’ in Petitioner’s proposed ‘annular opening’ seal between the (semi-rigid) mask chassis 512 and (flexible or semi-flexible) secondary frame portion 518.” *Id.* at 26–27 (citing Ex. 2003 ¶ 45). Patent Owner annotates Figures 52 and 53 of Berthon-Jones, reproduced below, to illustrate this seal failure. *Id.* at 27 (citing Ex. 2003 ¶ 45).



Figures 52 and 53 of Berthon-Jones as annotated by Patent Owner to show the potentially broken seal.

Patent Owner asserts that there is a need for an air tight seal between the mask chassis 512 in gold and air conduit, as well as between the frame portion 518 in green and mask chassis 512 in gold. *Id.* (citing Ex. 2003 ¶ 45). Relying on the testimony of Mr. Virr, Patent Owner explains that rotation of adjustment wheel 530 (in orange) causes a deflection of frame portion 518, allowing air to leak out of the breathing chamber, as shown in

the annotated figure on the right. *Id.* (citing Ex. 2003 ¶ 45; Ex. 1002 ¶¶ 10–11, Abstract). Patent Owner contends that the failure in breathing chamber seal would occur even if mask chassis 512 is attached to the frame portion using connecting members 524 because frame portion 518 would still deflect enough to cause failure of this seal. *Id.* at 28 (citing Ex. 1002, Fig. 51, ¶ 182; Sect. III. A; Ex. 2003 ¶ 45).

Alternatively, Patent Owner takes the position that removal of the adjustment wheels 530 would eliminate the fundamental benefit of Berthon-Jones, i.e. adjustment of the cushion portion 516 fit to provide a seal between the cushion and patient’s skin.¹² *Id.* at 28–29 (citing Ex. 2003 ¶ 46). Absent hindsight, Patent Owner concludes that “nothing in the Petition or Eaton Declaration explains why a POSITA would have started with Berthon-Jones’s repeated mandate that its Tenth Embodiment include key structures—the adjustment wheels—‘to move or deform’ the cushion/secondary frame 14 to the mask chassis 512 ‘so as to provide small adjustments in the fit of the mask assembly 510 to the user’s face’ (Ex. 1002 ¶ 177), and then eliminate this principle of operation from Berthon Jones’s mask assembly.” *Id.* at 29.

In its Reply, Petitioner responds that Patent Owner is narrowly characterizing the intended purpose of Berthon-Jones as directed to the adjustment wheels, rather than the core functionality of supplying breathable pressurized gas to a patient using a mask assembly that offers comfort to

¹² Petitioner confirmed during oral argument that its proposed modification does not modify or remove the adjustment wheels. See TR. 9:12 (“And Fisher & Paykel’s position from the outset has been that those adjustment wheels are not modified. We never proposed that they would be modified or removed.”).

users having a variety of facial shapes and sizes while controlling leaks.

Reply 12 (quoting PO Resp. 24). Berthon-Jones itself generally describes that “[i]t is an aspect of the invention to provide a comfortable low-leak mask for use with Non-Invasive Positive Pressure Ventilation that overcomes the limitations of prior art masks.” Ex. 1002 ¶ 10. Berthon-Jones further describes:

[i]n another aspect, it is desirable to provide a mask system that has one or more of the following features, each of which may assist with improving patient compliance and/or treatment: headgear including straps that are substantially inextensible and/or micro-adjustable; and/or a mask and/or cushion that includes various structures to allow enhanced/tailored sealing and/or fit at selected locations on the patient’s face.

Id. at ¶ 11.

Patent Owner’s arguments, however, are directed to only one of several features discussed in the Tenth Embodiment of Berthon-Jones which seek to provide a comfortable seal between the cushion/secondary frame 514 and the user’s face. Ex. 1002 ¶ 177. For example, Berthon-Jones also describes the Tenth Embodiment, shown in Figures 51–53, as directed to “showing frames/cushions enabling enhanced sealing along the sides of the patient’s nose.” Ex. 1002 ¶ 33. In addition to the adjustment wheels, the Tenth embodiment also describes other features that may provide for a comfortable seal, such as the use of a flexible or semi-flexible material for secondary frame portion 518 (*id.* at ¶ 180); the use of a “generally soft and conforming” structure for cushion portion 516 (*id.* at ¶ 181); or the use of locally weakened portions of mask chassis 512 “in order to allow mask chassis 512 to flex slightly to accommodate various facial shapes” (*id.* at ¶ 187). Based on these passages in Berthon-Jones, we agree with Petitioner that Berthon-Jones describes features in addition to the adjustment wheel for

improving mask fit and function. Reply 13 (citing Ex. 1002 ¶¶ 2–3; *Ultratec, Inc. v. Sorenson Communications*, 2014 WL 4294969 at *5 (W.D. Wis. Aug. 28, 2014) (rejecting “defendants’ attempt to make every element of a patent into a ‘principle of operation’”); *NHK Seating Am., Inc. v. Lear Corp.*, IPR2014-01200, Paper 29 at 18–20 (PTAB Feb. 2, 2016) (rejecting Patentee’s narrow formulation of “intended purpose”).

Moreover, Petitioner argues persuasively that a POSITA “would have understood that the adjustment wheels are not the intended purpose of the Berthon-Jones mask assembly and their function is not the principle of operation.” Reply 13. We credit the testimony of Mr. Eaton, namely that “[e]limination of those adjustment wheels from this embodiment would still allow it to function. . . . it would still work as most any other mask lacking adjustment wheels does.” *Id.* (citing Ex. 2004 at 70:17—71:14).

Central to Patent Owner’s inoperability argument, is its position that the adjustment wheels would force a physical separation at the annular connection between the modified frames and compromise the seal. Reply 14 (citing PO Resp. 26–27). Petitioner disputes this position, instead arguing that adjustment wheels 530 would cause side portions of first frame 518 to flex during adjustment (*id.* (citing Ex. 1002 ¶ 186)) and not cause first frame 518, as a whole, to move away from the second frame 512 (*id.*). We are more persuaded by Petitioner arguments and evidence concerning operation of the adjustment wheels in the mask of Berthon-Jones as modified using the teachings of Barnett. Petitioner supports its understanding of the operation of the adjustment wheels in the modified mask with the cross-examination testimony of Mr. Virr, namely that “Figure 53 doesn’t show separation between the chassis 512 and the frame 518 at the large opening of the chassis” (*id.* (citing Ex. 1018, 125:9–14)); and the “center [of the frame 518]

is stationary with respect to the chassis, and the outer portions, particularly in the area of 528, those must be bending away from the chassis” (*id.* at 14–15 (citing Ex. 1018, 61:4–14)). Mr. Virr also agrees that “Berthon-Jones describes ‘bending of the frame so that some portions of the frame move toward the face and others don’t,’ and that ‘the chassis or frame flexes instead of the entire chassis moving away from the frame.’” *Id.* at 15 (citing Ex. 1018, 123:11–14, 127:20–128:9). Berthon-Jones itself describes the incorporation of features to enhance the flexibility of secondary frame portion 518 (*see e.g.*, Ex. 1002 ¶ 180 (“The secondary frame portion 518 may be made of a flexible or semi-flexible material, e.g., polypropylene.”)); as well as mask chassis 512 (*see e.g.*, *id.* at ¶ 183 (“The mask chassis 512 is a generally triangular contoured plate of semi-rigid material.”)).

Like Petitioner, we question the accuracy of Patent Owner’s annotated Figure 53. Reply 16. As Petitioner points out, Patent Owner “never explains why there would be separation at this central portion of the first frame 518 in the modified mask when there is no such separation in the unmodified mask.” *Id.* at 15–16. We credit the statement of Mr. Virr during cross-examination that “because the annular connection portion of the second frame is a rigid cylinder, it would not deform to the extent shown in his declaration figures and any deformation would not be significant enough to ‘influence the force that’s holding one [frame] to the other.’” *Id.* at 16 (citing Ex. 1018, 136:11–139:14). Also persuasive is Petitioner’s further argument that “Mr. Virr’s depiction of the modified mask showing flexing of the second frame 512 and no flexing of the first frame 518 is inconsistent with Berthon-Jones’s teachings and Mr. Virr’s later admissions.” *Id.* (citing Ex. 1018, 141:8–13 (“Q. Okay. So the frame 51[8] is a more flexible material and would do most of the deforming as the wheels are turned? A.

Relative to the chassis? Q. Yes. A. Yes. For several reasons.”). Based on the present record, we are persuaded by Petitioner’s arguments and evidence that a POSITA “would have known that the adjustment wheels would have caused outer portions of the first frame 518 to flex and would not have separated the central portions of the frames.” *Id.* at 16–17.

Also persuasive is Petitioner’s response to Patent Owner’s arguments concerning potential insufficiency of the friction fit connection at the annular opening as the adjustment wheels are turned. Reply 16–17. As Petitioner points out, there is no dispute that connecting members 524 secure frame 518 of chassis 512 along the center line of the mask (*id.* at 17), and that Mr. Virr agrees that the annular opening/connection of second frame 512 would be along that centerline (*id.* (citing Ex. 1018, 153:24–154:1, 158:10–16)). Petitioner argues persuasively that “Mr. Virr fails to explain how an additional connection, for example a friction fit and/or overlapping cylinders, that was not previously in the Berthon-Jones mask would weaken the connection so that it is pulled apart by the unchanged force of the adjustment wheels.” *Id.* at 17–18. This argument is consistent with Mr. Virr’s later testimony that “there may be regions in the middle of the part where the secondary frame [518] is actually pushed closer to the chassis.” *Id.* at 18 (citing Ex. 1018, 132:3–10)). Also persuasive is Petitioner’s argument that “the Berthon-Jones mask has headgear that holds the mask assembly against the patient’s face and thus pushes the frames together.” *Id.* at 18 (citing Ex. 2004 at 54:11–15, 58:25–59:17).

We are also persuaded by Petitioner’s argument that a POSITA “would have known how to modify the Berthon-Jones mask in a way that maintained a secure annular frame connection.” Reply 18. We credit the cross-examination testimony of Mr. Virr, recognizing that a POSITA “could

have changed various aspects of the mask design to prevent or reduce separation of the frames at the annular connection, including the geometry, flexibility of the first frame 518, force of the headgear straps, and connecting members 524. Reply 18 (citing Ex. 1018, 146:20–147:10, 148:12–154:1).

Thus, considering the evidence and arguments of record, we are persuaded by Petitioner’s contention that its proposed modification does not deviate from the intended purpose and principle of operation of Berthon-Jones.

*Whether the Proposed Modification Would
Impede the Flexibility of the Mask Chassis*

Patent Owner relatedly argues that a POSITA would not have been motivated to combine Berthon-Jones and Barnett as proposed by Petitioner because the proposed modification “would have frustrated the mask chassis’ ability to flex slightly to accommodate various facial shapes.” PO Resp. 30 (citing Ex. 1002 ¶ 187; Ex. 2003 ¶ 47). Patent Owner supports this argument by pointing to the passage in Berthon-Jones discussing the desirability of designing a mask with a flexible chassis in order to accommodate different face shapes. *Id.* (citing Ex. 1002 ¶ 187; Ex. 2003 ¶ 47). Relying on the testimony of Mr. Virr, Patent Owner maintains that “a POSITA would have understood adding a ‘structure . . . similar to the collar 34 taught by Barnett’ would have detrimentally prevented the flexibility of mask chassis 512 expressly sought by Berthon-Jones.” *Id.* at 32 (citing Ex. 2003, ¶ 47). Patent Owner’s position is based on the passage in Barnett describing how the collar “is ‘[p]referably . . . defined by a unitary piece of molded material, such as molded plastic, so that it is relatively rigid.’” *Id.* (citing Ex. 1003, 7:12–14; Ex. 2003 ¶ 47).

Petitioner argues persuasively that the proposed modification to second frame 512 to include an annular opening would not result in an inflexible second frame because the proposed modification does not preclude the inclusion of the locally weakened portions. Reply 19. During cross-examination, Mr. Virr recognizes that “the chassis is generally rigid, it can have these locally weakened areas that allow it to flex” (Reply 19 (citing Ex. 1018 159:11–14; Ex. 1002 ¶ 187); and that “if the chassis were modified to have an annular opening, it could still have these weakened portions that would allow the chassis to flex” (*id.* at 19–20 (citing Ex. 1018, 159:15–19)). Indeed, Mr. Eaton confirms “that aspect of allowing it to flex slightly is a design choice that may or may not be included.” *Id.* (citing Ex. 2004, 55:1–20).

Thus, considering the evidence and arguments of record, we are persuaded by Petitioner’s contention that its proposed modification does not impede the flexibility of the mask chassis.

*Whether the Proposed Modification
Would Result in a Less Reliable Seal*

Relatedly, Patent Owner argues that a POSITA would not have been motivated to combine the sealing mechanism of Berthon-Jones with Barnett because the proposed combination would result in a less reliable seal—namely two air seals versus one. PO Resp. 32–37. Patent Owner contends that a POSITA would not have turned to the sealing mechanism of Barnett to modify the sealing mechanism of Berthon-Jones because the two-frame design of Berthon-Jones solves the problem of an air-tight mask seal in a substantially different way. PO Resp. 32–33 (citing Ex. 2003 ¶ 49). Patent Owner relies on the testimony of Mr. Virr in asserting that, absent hindsight, the seal between the air conduit and breathing chamber would be less

reliable due to the addition of another seal between frame portion 518 and the collar portion of semi-rigid mask 512, rather than connecting the frame portion 518 directly to the air conduit. *Id.* at 33 (citing Ex. 2003 ¶ 48).

Petitioner presents persuasive arguments and evidence that the proposed modification to second frame 512, i.e., to include an annular opening, would not result in a less reliable mask seal. Reply 20–22. We credit the cross-examination testimony of Mr. Virr, agreeing that Berthon-Jones “doesn’t describe how the elbow would be connected” and acknowledging that “it is unclear whether Berthon-Jones provides a stable and secure connection between the two frames.” *Id.* at 20 (citing Ex. 1018, 48:15–49:13, 70:2–14). Petitioner argues persuasively that the proposed “combination of Berthon-Jones’s snap-fit at connecting members 524 and the modified annular connection would provide more security than the snap-fit alone.” *Id.* (citing Ex. 1003, 3:50–52 (“[s]eal member 32 is preferably fixed to a first side of collar 34 so that the seal member does not move relative to the collar”), 7:17–21 (the friction fit “prevent[s] the seal member from being readily pulled off the collar”). We agree with Petitioner that the inclusion of an additional connection, even if a POSITA considers it to be a negative, “must be weighed against the benefits of the proposed modification.” *Id.* at 21 (citing *Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) (“The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another.”))).

In response to Patent Owner’s argument regarding increased difficulty in controlling flow of generators due to variability between masks in the seal between the elbow and rigid second frame 512, Petitioner argues

persuasively that Barnett discloses an elbow that engages a rigid collar, similar to a mask commercialized by Patent Owner. Reply 21 (citing Ex. 1018, 77:7–15). Given the particular level of skill in the art, Petitioner argues persuasively that “a POSITA would have known how to provide an acceptable elbow-to-second frame connection.” *Id.* at 22 (citing Ex. 1018, 84:8—85:2).

Like Petitioner, we agree that Patent Owner does not explain sufficiently why the differences between Barnett’s seal member material and friction fit would have dissuaded a POSITA from combining these teachings. Reply 22 (citing PO Resp. 34–37). As Petitioner notes, there were masks on the market similar to Barnett’s with multiple seals between the frames and elbow. *Id.* (citing Reply II.A.1). Based on the arguments and evidence presented, we are persuaded by Petitioner’s contention that a POSITA would have been capable of designing a seal between two frames. *Id.*

For these reasons, we disagree with Patent Owner’s contention that Petitioner proposed modification is based impermissibly on hindsight.

b) Whether Petitioner’s Articulated Reasoning is “Flawed.”

Next, we consider Patent Owner’s characterization of Petitioner’s articulated reasoning as “flawed.” PO Resp. 37–49. First, Patent Owner argues that “Petitioner wrongly assumes the proposed addition of an annular connection to Berthon-Jones’s mask chassis 512 ‘would provide a more dimensionally stable and secure connection’ between the air conduit and the mask assembly, and that the proposed annular connection would also ‘improve the stability and security of the attachment between the two frames.’” *Id.* at 38–39 (citing Pet. 4, 100–101; Ex. 1006 ¶¶ 68, 130). According to Patent Owner, a POSITA would have considered Berthon-

Jones's mask to be very stable based on its intended use. *Id.* at 39 (citing Ex. 1002, Abstract; Ex. 2003 ¶ 51). Patent Owner further argues that the proposed replacement of the frame conduit connection with a friction seal would not improve the security of Berthon-Jones's connection mechanism. *Id.* (citing Ex. 2003 ¶ 51).

More persuasive, however, is Petitioner's argument and evidence that "just because a reference does not identify deficiencies, does not mean a POSITA would not have been motivated to improve the design." Reply 6 (citing *In re Ethicon, Inc.*, 844 F.3d 1344, 1348–49, 1351 (Fed. Cir. 2017) (affirming obviousness despite patent owner's argument that the primary reference "did not disclose a problem with its polymers" in part because "[t]he normal desire of artisans to improve upon what is already generally known can provide the motivation to optimize variables.")). Petitioner recognizes that its proposed modification would add another connection, but argues persuasively that "a POSITA would have known how to manage potential leaks at multiple connections in the mask assembly." Reply 6–7. Indeed, Patent Owner's expert confirmed during cross-examination the availability of masks in the prior art, including Patent Owner's own masks, with multiple seals and connections. *Id.* at 7 (citing Ex. 1018, 69:8–70:1, 78:14–22, 86:15–87:6, 95:6–13, 98:11–14). As to the use of an elbow arrangement, we credit the cross-examination testimony of Mr. Virr that "[I]n general practice before 2005, no, there was no sealing connection. They were held together, they are mechanically restrained in some way, and then things were done to reduce and to tightly control the leak." *Id.* (citing Ex. 1018, 93:17–94:4).

Second, Patent Owner argues that Petitioner wrongly assumes that the proposed modification, i.e., directly attaching the inlet conduit to the second

frame, would have been advantageous for cleaning and maintenance, or cleaning or replacement of mask components. PO Resp. 40 (citing Pet. 41–42; Ex. 1006 ¶¶ 62, 69). Specifically, Patent Owner argues that Berthon-Jones does not describe a problem with inconvenience during disassembly, reassembly, cleaning, or maintenance. *Id.* (citing Ex. 203 ¶ 52).

Petitioner argues persuasively that *KSR*’s “expansive and flexible approach” does not require that the prior art describe “deficiencies and benefits.” Reply 8 (citing *KSR*, 550 U.S. at 415). Also persuasive is Petitioner’s argument and evidence that “the proposed modification provides at least a suitable option for easy maintenance,” in view of Patent Owner’s acknowledgement that Barnett is not deficient regarding the ease of disassembly, reassembly, cleaning, or maintenance. *Id.* (citing PO Resp. 40).

Third, Patent Owner disputes that the proposed modification would yield predictable results. PO Resp. 40–41. The proposed modification would be unpredictable, in Petitioner’s view, due to the interaction of the adjustment wheels with the modified mask assembly resulting in the breathing chamber’s seal being compromised. *Id.* at 41 (citing Ex. 2003 ¶¶ 44–46, 53).

For the reasons discussed above in connection with Patent Owner’s related argument that the proposed modification would result in a less reliable seal, we disagree with Patent Owner’s argument that the seal of the modified mask would be compromised. Instead, we are persuaded that Petitioner presents sufficient rationale and credible evidence to support its assertion that a POSITA “would have viewed these two types of frame-elbow arrangements as two design choices for establishing a seal between an interior of an elbow and a breathing chamber” (Pet. 41 (citing Ex. 1006 ¶¶

61–70; Pet. § I.)), and that it would have been obvious to a POSITA to “have selected the Barnett configuration as one of a finite number of predictable solutions for providing a connection between the interior of the elbow and the breathing chamber” (*id.* (citing *KSR*, 550, U.S. at 421)). As Petitioner points out, “[t]here is no dispute that there were only a few known options for attaching the elbow.” Reply 4 (citing Ex. 1006 ¶¶ 58–70; Ex. 1018, 43:23–46:21, 78:1–79:12). Petitioner also notes that it describes two commonly known methods for attaching the elbow in a two-frame assembly. Reply 9 (citing Pet. 37–41; Ex. 1006 ¶¶ 60–68). We credit the cross-examination testimony of Mr. Virr, confirming that “prior to 2005, “a [POSITA] would have had some experience hopefully as [sic] designing a connection between the elbow and frame and between a frame and a cushion.” Reply 5 (citing Ex. 1018, 78:20–79:12). Also persuasive is the testimony of Mr. Eaton, explaining that “a POSITA could physically combine the features of Berthon-Jones and Barnett by, for example, ‘fill[ing] in the lower part of opening 536 to define an annular opening similar to that of Barnett,’ or ‘add[ing] a bracket or frame structure to the lower part of the opening 536 with an annular opening like Barnett.’” *Id.* at 9–10 (citing Ex. 1006 ¶¶ 72–78).

Fourth, Patent Owner disputes Petitioner’s position that the proposed modification would have been obvious “because ‘a person of skill in the art would have been motivated to provide cylindrical interfaces to simplify manufacturing and control manufacturing tolerances.’” *Id.* at 42 (citing Pet. 100–101 (citing Ex. 1006 ¶ 130). According to Patent Owner, a POSITA would not have destroyed Berthon-Jones’s intended/purpose and principle of operation and increased the potential for seal problems based on convenience. *Id.* (citing Ex. 2003 ¶ 54). For the reasons discussed above

with respect to Patent Owner’s similar argument, we disagree with Patent Owner’s contention that the proposed modification would destroy Berthon-Jones intended purpose and principle of operation and increase the potential for seal problems.

Patent Owner further argues that Petitioner does not provide underlying facts or data to support its assertion that annular features would have been simpler to manufacture. *Id.* According to Patent Owner, an annular feature and rotatable coupling would require higher tolerances and precision than a snap-fit, resulting in “more complex/costly design, specification, and manufacturing process.” *Id.* at 43 (citing Ex. 2003 ¶ 54). Patent Owner argues that Petitioner does not addresses “why a POSITA would have combined features from two references that plainly describe alternative sealing technologies to arrive at a design that implements neither of those sealing technologies.” *Id.* (citing Ex. 2003 ¶¶ 49, 53; *In re Benno*, 768 F.2d 1340, 1346–47 (Fed. Cir. 1985) (reversing an obviousness rejection where “[n]either reference hints at [the claimed] solution”).

Petitioner counters that the appropriate comparison should be between manufacturing tolerances in Barnett’s elbow connection and Berthon-Jones’s elbow connection, rather than between Barnett’s elbow connection and the snap-fit between Berthon-Jones’s two frames. Reply 10 (citing PO Resp. 43). We agree. As Petitioner points out, neither claim 81 nor Barnett require a rotatable elbow. *Id.* (citing Ex. 1003, 9:1–3). We credit the cross-examination testimony of Mr. Virr concerning the teachings of prior art references regarding elbows with clearance fits, including Barnett and Gunaratnam, explaining the ability of a POSITA to control the leakage through the clearance fit. *Id.* (citing Ex. 1018, 79:25–81:5 (“What it really comes down to is that there is a low clearance joint made between the two,

and what you would have to do in practice is you would have to regulate that fit in production such that it didn't vary too much.”), 80:7–18).

Finally, Patent Owner argues that Petitioner has not demonstrated that a POSITA would have looked to Barnett to modify Berthon-Jones, given that “Berthon-Jones already accomplishes the ability to fine-tune the mask assembly’s seal and fit against the patient’s face, and furthermore provides a robust seal, yet Petitioner proposes modifying the Berthon-Jones anyway by seemingly ‘plucking’ Barnett out of the vast array of prior art.” PO Resp. 46 (citing *WBIP*, 829 F.3d at 1337). We disagree. As the Supreme Court noted in *KSR*, “[t]o determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents.” *KSR*, 550 U.S. at 401. Here, Mr. Eaton explains that both Berthon-Jones and Barnett are interrelated because both are from the same field—CPAP breathing masks used to treat sleep-disordered breathing, and are compatible because both have similar features and construction. Reply 11 (citing Pet. 29; Ex. 1006 ¶ 53). And, Patent Owner’s argument fails to persuade us that Petitioner’s articulated reasoning does not comport with the Federal Circuit’s recognition of “[t]he normal desire of artisans to improve upon what is already generally known” in *Ethicon*.

Thus, upon review of the entirety of the record and for the reasons discussed, we find that the proposed modification of Berthon-Jones, to provide an annular opening in the second frame for directly attaching the inlet conduit with the second frame as taught by Barnett, satisfies the annular opening limitation. We also find that the Petitioner has provided a sufficient rationale, supported by evidence of record, to demonstrate that POSITA would have provided an annular opening in the second frame of Berthon-

Jones for directly attaching the inlet conduit with the second frame, as taught by Barnett. Namely, that “[c]ombining these familiar CPAP mask features according to known methods would have done no more than yield predictable results.” Pet. 29 (citing Ex. 1006 ¶ 53; *KSR*, 550 U.S. at 416).

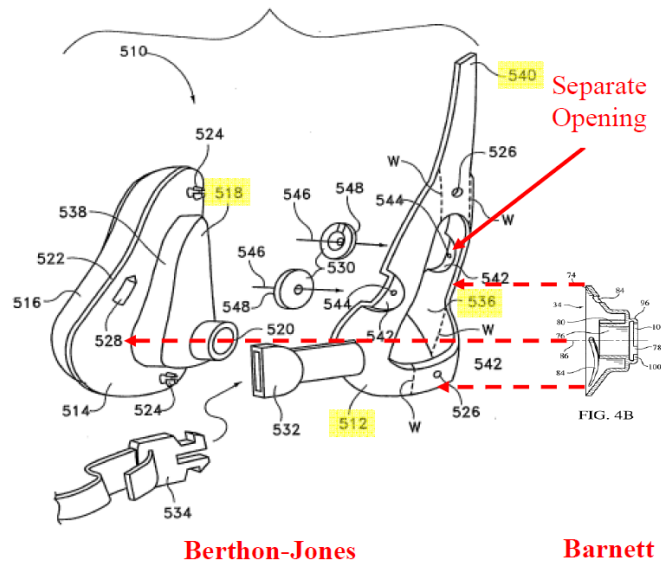
iii. Separate Opening Limitation

Additionally, claim 81 recites “a separate opening located between the annular opening and the upper member, the separate opening providing access to the first frame when the mask assembly is fully assembled.” Ex. 1001, 27:26–29 (“the separate opening limitation”). Petitioner contends that the separate opening limitation is disclosed by the combination of Berthon-Jones and Barnett in two different ways.

a) Whether Petitioner’s First Proposed Modification Satisfies the Separate Opening Limitation

Recognizing that Berthon-Jones’ relatively large opening 536 allows access to first frame 518 when the mask assembly is assembled, but does not disclose that opening 536 is separate and positioned between the annular opening and the upper member, Petitioner first argues that “a person of skill would have known to modify the second frame 512 of Berthon-Jones to directly attach with the elbow at an annular opening that allows pressurized gas to pass to the breathing chamber.” Pet. 42 (citing Pet. § VII (B)(4)(a)(vi)). Relying on the testimony of Mr. Eaton, Petitioner explains that the proposed modification would have involved “providing a bracket or frame structure at the bottom portion of the opening 536 that includes an annular opening and directly attaches with the elbow inlet conduit.” *Id.* (citing Ex. 1006 ¶¶ 72–78). Petitioner annotated

Berthon–Jones and Barnett to illustrate its first proposed modification, reproduced below. *Id.* at 43.



Petitioner's proposed modification to Berthon-Jones' mask, using Barnett's mask, as annotated by Petitioner.

In the first proposed modification, Petitioner contends that the bracket or frame structure, like Barnett’s collar 34, “would define and surround the annular opening of the second frame 512.” *Id.* (citing Ex. 1006 ¶ 73).

Petitioner further states that second frame 512 “would include a separate opening (it would retain the upper part of opening 536) located between the annular opening and the upper member 540, and would provide access to the first frame when the mask assembly is fully assembled.” *Id.* (citing Ex. 1006 ¶ 75). Relying on the testimony of Mr. Eaton, Petitioner argues that a POSITA “would have been motivated to retain the upper part of opening 536 as a separate opening in order to limit or prevent unwanted relative rotation of the frames about the axis of the annular opening.” *Id.* at 44 (citing Ex. 1006 ¶ 75). Petitioner further argues that “[b]y retaining the upper part of the opening 536 in the modified second frame 512 of Berthon-Jones to receive the first frame as described above, the *anti-rotation*

protrusions and channels of Barnett could be eliminated, which would make it a simpler design and easier to establish a reliable sealed connection.” *Id.* (citing Ex. 1006 ¶ 76).

We preliminarily determined in our Decision on Institution that we were not persuaded (1) “that a ‘bracket or frame structure’ would have been a predictable option for incorporating Barnett’s collar 34 into Berthon-Jones’s mask;” and (2) “that Berthon-Jones and Barnett teach retaining the upper portion of opening 536 *as a separate opening* to limit or prevent unwanted rotation.”¹³ Dec. 18. Specifically, we were not persuaded by Petitioner’s reasoning because Berthon-Jones already describes the use of connecting members 524, which fit through opening 526 in order to secure the second frame to the first frame. *Id.* at 18–19 (citing Ex. 1002 ¶ 182, Fig. 51; Prelim. Resp. 22–23).

Now, after further review of the record, we maintain our determination from the Decision on Institution and agree with Patent Owner’s contention that Petitioner’s analysis is conclusory. Supp. Resp. 2–3. Critically, Petitioner’s arguments and evidence do not explain sufficiently why a POSITA would have been motivated to retain the upper portion of Berthon-Jones’s opening 536 as a separate opening to limit or prevent unwanted relative rotation of the frames about the axis of the annular opening (Pet. 43–44 (citing Ex. 1006 ¶ 75)), given that Berthon-Jones already includes structures to limit rotation. That is, why a POSITA would

¹³ Petitioner requested rehearing of this determination, which was denied. Paper 26. After SAS, we modified our Decision on Institution to institute on the non-instituted claims and grounds. Paper 29. The parties requested and were granted additional briefing to address Petitioner’s first proposed modification. Paper 31.

have positioned connecting members 524 at the top and bottom of the secondary frame, “to be inserted into corresponding receiving holes 526 in the mask chassis 512 to secure the cushion/secondary frame 514 to the mask chassis 512.” Ex. 1002 ¶ 182. Neither Petitioner, nor its expert, Mr. Eaton, explain why a POSITA would have considered Berthon-Jones’s existing snap-fit retention structures to be inadequate, and thus “would be motivated to retain this upper part of opening 536 as a separate opening in order to provide a more secure attachment between the frames and to limit or prevent unwanted relative rotation between the frames.” Ex. 1006 ¶ 75.

Nor does Petitioner’s contention, that the first proposed modification would allow for elimination of Barnett’s anti-rotation protrusions and channels in order to provide a simpler design, persuade us that a POSITA would have retained the upper portion of opening 536 of Berthon-Jones as a separate opening. Pet. 44 (citing Ex. 1006 ¶ 76). Namely, because Petitioner’s proposed modification to Berthon-Jones, using Barnett to satisfy the annular opening limitation, does not consider Barnett’s existing anti-rotation protrusions and channels. Rather, Petitioner’s proposed modification to Berthon-Jones only contemplates that Barnett’s second frame 34 would “directly attach[] to and support[] the inlet conduit 36 at an annular opening 76 that allows pressurized gas to pass from the inlet conduit 36 to the breathing chamber 42” and is silent regarding the role of Barnett’s anti-rotation protrusions and channels in the proposed modification. Pet. 36 (citing Ex. 1003, 3:52–57, 8:66–9:43).

Based on the entire record, Petitioner fails to present sufficient arguments and credible evidence to support a finding that the first proposed modification of Berthon-Jones with Barnett, i.e., retaining the upper portion

of opening 536 as a separate opening, teaches the separate opening limitation.

b) Whether Petitioner's Second Proposed Modification Satisfies the Separate Opening Limitation

Alternatively, Petitioner argues that separate opening 526 in second frame 512 satisfies the separate opening limitation, i.e., the second proposed modification. Specifically, Petitioner argues that separate opening 526 in second frame 512 of Berthon-Jones is located between the annular opening and the upper member, and provides access to the first frame 518 when the mask is assembled. Pet. 45 (citing Ex. 1002 ¶ 182). Petitioner reasons that a POSITA would retain connecting members 524 and openings 526 in the modified second frame “to provide a secure connection of the first frame and the second frame in at least an axial direction.” *Id.* (citing Ex. 1006 ¶ 77).

In response, Patent Owner disputes that Berthon-Jones's upper receiving hole 526 in mask chassis 512 is “‘located between the annular opening and the upper member,’ and that it ‘provides access to the first frame 518.’” PO Resp. 48. Patent Owner first argues that because Berthon-Jones' mask chassis 512 does not have an annular opening, “upper receiving hole 526 cannot be between the ‘annular opening’ and any part of the chassis 512.” *Id.* (citing Pet. 35; Ex. 2003 ¶¶ 39, 58). Here, Patent Owner's arguments directed only to Berthon-Jones are not persuasive because Petitioner relies on the proposed modification of Berthon-Jones using the teachings of Barnett to satisfy the annular opening limitation.

Next, Patent Owner argues “a POSITA would have understood the upper receiving hole 526 to be located in the upper member itself, rather than between the upper member and some other portion of the chassis.” *Id.* (citing Ex. 2003 ¶58). More persuasive, however, is Petitioner's annotation

of Figure 51, reproduced below, illustrating how opening 526 would be positioned between the annular opening and upper member 540. Reply 23 (citing Pet. 34).

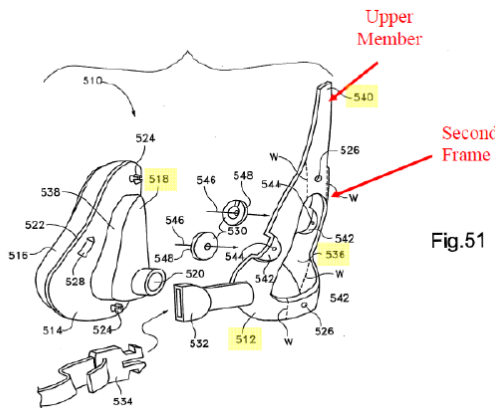


Figure 51 of Berthon-Jones, as annotated by Petitioner, to illustrate positioning of receiving hole 526.

Patent Owner further argues that “Petitioner has failed to show that the receiving hole 526 would ‘provide access to the first frame 518.’” *Id.* at 49 (citing Ex. 2003 ¶ 58; Ex. 1002 ¶ 182). According to Patent Owner, a POSITA “would have recognized the fact that Berthon-Jones’s upper receiving hole 526 is only large enough to admit connecting plug 524, which a POSITA would have understood to be the sole purpose of receiving holes 526.” *Id.* (citing Ex. 2003 ¶ 58; Ex. 2004, 49:10–17).

We disagree. Claim 81 requires that the separate opening “provid[e] access to the first frame when the mask assembly is fully assembled.” Ex. 1001, 27:28–30. Petitioner argues persuasively that “the claim language merely requires that the separate opening provide access to the first frame 518, not any particularly sized portion of the first frame 518.” Reply 23. We credit the testimony of Mr. Eaton and cross-examination testimony of Mr. Virr, in support of Petitioner’s position that upper connecting member

524 is part of first frame 518. *Id.* at 24 (citing Ex. 1002 ¶ 182; Ex. 1018, 162:24–163.1; Ex. 2004, 67:2–68.17).

As Patent Owner points out, Berthon-Jones’s upper receiving hole 526 is large enough to receive connecting member 524. PO Resp. 49. Indeed, both parties describe this connection in Berthon-Jones as a “snap fit.” PO Resp. 28, 35; Reply 24. Berthon-Jones explains that “[c]onnecting members 524 are constructed and arranged to deflect inwardly on insertion into the receiving holes 526 to provide a snap fit between the cushion/secondary frame.” Ex. 1002 ¶ 182. The deflection of the connection member during insertion into the receiving hole would have suggested to a POSITA a correspondence in size between the connecting member 524 and receiving hole 526. In other words, receiving hole 526 would still provide access to first frame 518 after connecting member 524 is inserted into receiving hole 526 because connecting member 524 is part of first frame 518.

Based on the entire record, Petitioner presents sufficient arguments and credible evidence to support a finding that its second proposed modification, involving opening 526 in Berthon-Jones, meets the separate opening limitation.

b. Dependent Claims 82-91

Petitioner provides a detailed mapping of the limitations of each of claims 82–91 onto the combined teachings of Berthon-Jones and Barnett. Pet. 47–56.

i. Claims 82, 83, 89–91

For example, dependent claims 82 and 89 each require that the second frame include the feature of “two elongate frame members connecting the upper member and lower member and at least partially bounding the

separate opening.” Ex. 1001, 27:34–36, 28:20–22 (“the elongate frame members limitation”). Claims 83, and 90–91 depend from claims 82 and 91, respectively. *Id.* at 28:1–4; 31–34. Petitioner relies on the teaching in Berthon-Jones regarding “opening 536 defined by elongate frame members that connect the upper portion and lower portion of the second frame 512” and illustrated this alleged correspondence in annotated Figure 51, reproduced below. Pet. 47 (citing Ex. 1002 ¶ 184).

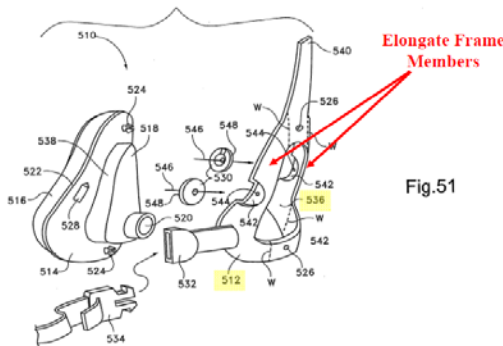


Figure 51 of Berthon-Jones, as annotated by Petitioner, to illustrate the elongate frame members.

We understand Petitioner as relying on its *first* proposed modification to Berthon-Jones using Barnett to satisfy the separate opening limitation (Pet. § VII (B)(4)(a)(vii)), in arguing that “the second frame 512 of Berthon-Jones would still include the elongate frame members at least partially bounding the separate opening.” *Id.* at 48 (citing Ex. 1006 ¶¶ 80–82). As discussed above in Section III.D.3.a(iii)(a), we do not find that Petitioner’s first proposed modification to Berthon-Jones using Barnett meets the separate opening limitation. Nor does Petitioner explain how the elongate frame members limitation would be satisfied in the context of its second proposed modification to Berthon-Jones.

For the same reasons, and based on the entire record, Petitioner does not present sufficient arguments and credible evidence to support a finding

that the combination of Berthon-Jones and Barnett teach the elongate frame members limitation of claims 82, 83, and 89–91, i.e., elongate frame members at least partially bounding the separate opening, based on Petitioner’s second proposed modification.

ii. Claim 86

Dependent claim 86 requires that the separate opening is “substantially triangular.” Ex. 1001, 28:12. Petitioner argues that this limitation is satisfied by the teaching in Berthon-Jones that “first frame 518 is ‘triangularly or pyramidally shaped’ and the second frame 512 is also ‘generally triangular’” (Pet. 51 (citing Ex. 1002 ¶¶ 180, 183)); and further that “Berthon-Jones as modified in view of Barnett would retain a separate opening at the upper part of the central aperture, and this separate opening would still be triangular” (*id.* (citing Pet. § VII (B)(4)(a)(vii))). We understand Petitioner’s argument as relying on its first proposed modification to Berthon-Jones using Barnett to satisfy the separate opening limitation. As discussed above in Section III.D.3.a(iii)(a), we do not find that Petitioner’s first proposed modification meets this limitation. For the same reasons, and based on the entire record, Petitioner does not present sufficient arguments and credible evidence to support a finding that the proposed modification to claims 86, i.e., that the opening is substantially triangular, is shown by the combination of Berthon-Jones and Barnett, based on Petitioner’s second proposed modification.

iii. Claims 84, 85, 87, and 88

Patent Owner does not provide arguments for dependent claims 84, 85, 87, and 88 separate from the arguments discussed above in connection with claim 81. *Id.* at 19–49; Supp. Resp. 2–9. Rather, Patent Owner

disputes that a POSITA would have combined Berthon-Jones with Barnett as proposed by Petitioner, characterizing the proposed modifications to Berthon-Jones as “legally erroneous, factually flawed, and ignore meaningful negative repercussions.” PO Resp. 18–19. We have reviewed Petitioner’s arguments and evidence, and determine that the Petition accounts sufficiently for the undisputed claim elements recited in claims 84, 85, 87, and 88. For the reasons set forth above in Section III.D.3.a., with regard to claim 81, we are likewise persuaded that Petitioner has articulated adequate reasons supported by rational underpinnings to combine Berthon-Jones and Barnett, as well as established sufficiently that the combination of Berthon-Jones and Barnett would have rendered the limitations of claims 84, 85, 87, and 88 as obvious.

Based on the entire record, Petitioner presents sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones and Barnett teaches the limitations of claims 84, 85, 87, and 88.

i. Summary

In view of the forgoing, we conclude that Petitioner has established by a preponderance of the evidence that claims 81, 84, 85, 87, and 88 are unpatentable under 35 U.S.C. § 103(a) as obvious over Berthon-Jones and Barnett, but not as to claims 82, 83, 86, 89–91.

E. Obviousness based on Berthon-Jones, Barnett, and Lithgow

Petitioner challenges the patentability of claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 58–73 of the ’061 patent under 35 U.S.C. § 103 as obvious based on Berthon-Jones, Barnett, and Lithgow. In support thereof, Petitioner identifies the disclosures in the cited references alleged to describe the subject matter in the challenged claims, as well as a reason why

a POSITA would have modified Berthon-Jones based on the teachings of Barnett and Lithgow. *Id.* at 56–90.

Together with the ground based on Berthon-Jones and Barnett, Patent Owner disputes that Berthon-Jones discloses certain limitations, and argues that the proposed combination of Berthon-Jones, Barnett, and Lithgow is unavailing for the reasons discussed above in Section III.D. PO Resp. 18–49. Patent Owner supports its arguments and evidence with the testimony of its declarant, Mr. Virr. Ex. 2003.

After consideration of the arguments and evidence of record, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 17, 18, 20, 21, 23, 28, 29, 32, 33, 35, 36, 38, 43, 44, 46, are unpatentable based on Berthon-Jones and Barnett, but not as to claims 22, 26, 27, 30, 37, 41, 42, 45, 48–50, and 58–73. We begin our analysis with a brief summary of Lithgow and then address the parties’ contentions in turn.

1. Overview of Lithgow (Ex. 1004)

Lithgow is a U.S. Patent Application Publication titled “Cushion for a Respiratory Mask Assembly,” and has a publication date of June 24, 2004. Ex. 1006, (12), (54), (43). Lithgow is directed to

[a] respiratory mask assembly for delivering breathable gas to a patient includes a frame and a cushion. The cushion has a non-face contacting portion structured to be connected to the frame, a face-contacting portion structured to engage the patient’s face, and an intermediate portion that interconnects the non-face contacting portion and the face-contacting portion.
Id. at Abstract.

Respiratory mask assembly 10 includes frame 12 connected to cushion 14, as shown in Figure 1B of Lithgow reproduced below. Ex. 1004 ¶ 111.

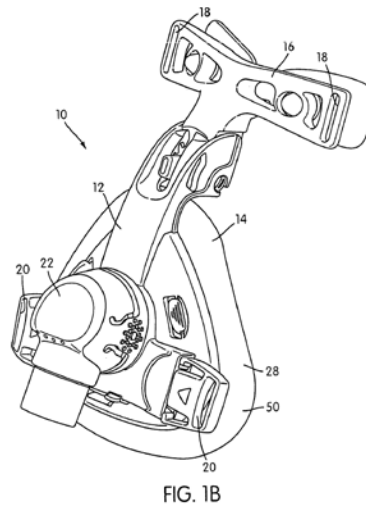


Figure 1b is a perspective view of the mask assembly.

Frame 12 includes a forehead support 16 “movably mounted” to an upper portion of frame 12. *Id.* at ¶ 111. Upper headgear strap connectors 18 removably attach a headgear assembly (not shown). *Id.*

2. Discussion

a. Claim 17

To support its argument that the limitations of claim 17 are found in the proposed combination of Berthon-Jones, Barnett, and Lithgow, Petitioner provides a detailed mapping of each limitation onto the combined teachings of Berthon-Jones, Barnett, and Lithgow, and explains the significance of each passage with respect to the corresponding claim limitation. Pet. 57–62.

For limitations similar to those in claim 81, Petitioner relies on its arguments directed to claim 81. *See e.g.*, Pet. 58 (“As discussed above with respect to Claim 81, Berthon-Jones discloses a first frame made of a first material.”); 59 (“As discussed above with respect to Claim 81 Berthon-Jones discloses a second frame 512 adapted to constrain the first frame 518 and comprising an upper support member 540.”); 61 (“As discussed above with respect to Claims 81 and 91, such configurations in which the second

frame includes an annular connection adapted to engage an elbow were well-known and expressly disclosed by Barnett.”); 62 (“As discussed above with respect to Claim 81, such an opening between the annular connection and the upper support member was well-known and common in CPAP masks, as taught by the combination of Berthon-Jones and Barnett.”).

Similarly, Petitioner relies on its arguments directed to claim 87, in asserting that the disclosure in Berthon-Jones regarding “two headgear clip attachments 532 adapted to engage clips of the mask headgear 534” satisfies the limitation of “two lower headgear clip attachments engaged with clips provided to straps of a headgear assembly.” Pet. 61 (citing Pet § VII(B)(4)(g); Ex. 1002 ¶ 183) (emphasis omitted)).

As discussed above in Section III.D.3.a. and Section III.D.3.b.iii, we adopt as our own Petitioner’s analysis of the undisputed claim limitations as recited in claims 81 and 87, and find that Berthon-Jones teaches these limitations. Moreover, as discussed above in Section III.D.3.a.iii.(a), we do not find that Petitioner’s first proposed modification satisfies the separate opening limitation; however, we do find that Petitioner’s second proposed modification to Berthon-Jones based on Barnett meets the separate opening limitation. Additionally, we do find that Petitioner articulates adequate reasons supported by rational underpinnings for a skilled artisan to combine Berthon-Jones and Barnett, and established by a preponderance of the evidence that the combination of Berthon-Jones and Barnett would have rendered these limitations as obvious.

Petitioner recognizes that Berthon-Jones does not expressly disclose a forehead support, and relies on the teachings of Lithgow for this feature. Pet. 60. That is, the teaching in Lithgow regarding “frame 12 having an upper support member that supports a forehead support 16 that contacts the

face of a patient in use.” *Id.* (citing Ex. 1004 ¶ 111; Figure 1B). Also relying on the testimony of Mr. Eaton, Petitioner reasons that a POSITA “would have been motivated to incorporate a forehead support, as taught by Lithgow, into the mask of Berthon-Jones to provide a more secure fit of the mask to the patient’s face and to stabilize the upper portion of the mask assembly.” *Id.* (citing Ex. 1006 ¶ 104).

Patent Owner contends that Berthon-Jones does not disclose that the second frame includes an “upper support member’ that facilitates the forehead support of the mask assembly”, and that a POSITA “would not have been motivated to modify Berthon-Jones based on Lithgow” to include this feature. PO Resp. 50. Relying on the testimony of Mr. Virr, Patent Owner avers that a POSITA “would have understood that the claimed forehead support includes a component that supports a mask assembly through contact with a user’s forehead (e.g., contacting a user’s forehead with a support member, pad, or other structure attached thereto)” (*id.* (citing Ex. 2003 ¶ 40)), and that Berthon-Jones does not disclose a structure that contacts a patient’s forehead (*id.*). Patent Owner further explains

a POSITA would not have been motivated to modify Berthon-Jones in light of Lithgow to arrive at the claimed ‘upper member’ or ‘upper support member’ limitations of the challenged claims. For example, a POSITA would have recognized the sagittal strap or strap portion of Berthon-Jones to be sufficient to secure the mask to a patient’s face, and thus would not have looked to the forehead support of Lithgow as a reference to increase the security of the mask.

PO Resp. 51 (citing Ex. 2003 ¶ 56).

In Reply, Petitioner argues persuasively that “[t]he experts agree that forehead supports were well-known prior to 2005, and that a POSITA would have included a forehead support to stabilize and secure the mask on the

patient's face.” Reply 24 (citing Ex. 1006 ¶¶ 99–104; Ex. 1018 at 32:2–35:11).

Patent Owner also contends that one of ordinary skill in the art would view Berthon-Jones' “substantially inextensible straps” as reducing movement of the mask on the patient's face, and “would consider this an effective alternative to a forehead support.” PO Resp. 51 (citing Ex. 1002 ¶ 11; Ex. 2003 ¶ 57). We disagree with this contention. As Petitioner points out, Berthon-Jones generally states that “[i]n another aspect, it is desirable to provide a mask system that **has one or more of the following features**, each of which may assist with improving patient compliance and/or treatment: headgear including straps that are substantially inextensible and/or microadjustable” (Reply 25 (citing Ex. 1002 ¶ 11 (emphasis added))); but never “specifies that the sagittal strap or strap portions in the **tenth embodiment** would be substantially inextensible” (*id.*). Moreover, as Petitioner argues, one of ordinary skill in the art “seeking to provide a more secure mask would have looked to prior art references, such as Lithgow, that address this same problem and would apply their teachings together.” *Id.* (citing *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1277 (Fed. Cir. 2004) (“[A] person seeking to solve that exact same problem would consult the references and apply their teachings together.”)). *See also KSR*, 550 U.S. at 417 (“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”).

Patent Owner further asserts that one of ordinary skill in the art would have been discouraged from adding Lithgow's forehead support to Berthon-Jones mask assembly due to increased difficulty in mask assembly and

manufacture. PO Resp. 52 (citing Ex. 2003 ¶ 57). This argument is not convincing because the use of a forehead support was known in the art. Reply 26. We credit the cross-examination testimony of Mr. Virr discounting the alleged difficulty in mask assembly and manufacture, i.e., “I don’t see any reason why a forehead support couldn’t have been added.” *Id.* (citing Ex. 1018 at 168:23–169:11). Moreover, as Petitioner points out, “[e]ven if a POSITA would have considered the forehead support to have some disadvantages, those disadvantages would be outweighed by the improved stability and security described above.” *Id.* (citing *Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) (“The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another.”)).

Patent Owner further contends that “the arguments given in [Patent Owner Response] Section V.A. regarding the intended function and purpose of Berthon-Jones apply equally to the combination of Berthon-Jones and Lithgow as they apply to the combination of Berthon-Jones and Barnett.” PO Resp. 52. For example, that Lithgow’s forehead support would frustrate the ability of the modified Berthon-Jones mask assembly to flex, increase the rigidity of the modified mask assembly, and render the modified mask assembly inoperable for its intended purpose. *Id.* (citing Ex. 2003 ¶ 57).

Petitioner disputes that the addition of a forehead support would frustrate the ability of the modified Berthon-Jones’s mask to “flex slightly to accommodate various facial shapes.” Reply 26 (citing PO Resp. 52). Petitioner has the better argument. As discussed above in Section III.D.3.a., in connection with a similar argument directed to claim 81, Petitioner argues persuasively that the modified mask assembly would retain its locally

weakened portions, thus providing flexibility in the second frame. *Id.* (citing Reply § II.B.2). We credit the cross-examination testimony of Mr. Virr that “if you did design a forehead support in, you would try and show that [the adjustment wheels and weakened zones W] were still functional.” *Id.* (citing Ex. 1018 at 175:23–176:12).

Patent Owner further contends that “for reasons similar to those explained above in [Patent Owner Response] Section V, Petitioner’s analysis again improperly relies upon hindsight.” *Id.* at 53. This contention is not convincing for the reasons discussed above in Section III.D.3.a., in connection with Patent Owner’s arguments directed to the obviousness of claim 81 based on the combination of Berthon-Jones and Barnett.

Based on the entire record, Petitioner presents sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach each of the limitations of claim 17.

b. Independent claim 32

Petitioner contends that independent claim 32 “includes limitations identical to those described above in [Petition] §§ VII(B)(4)(a)(iv), VII(C)(2)(a)(i)–(iii), VII(C)(2)(a)(v) with respect to Claims 17 and 81” and addresses separately any additional limitations. Pet. 62. For example, Petitioner contends that “[a]s discussed above with respect to Claim 17, it was well-known and common in CPAP masks to provide an upper support member adapted to assist with forehead support, as taught by Lithgow.” *Id.* (citing Pet. § VII(C)(2)(a)(iv)). Petitioner also relies on the same arguments provided for the annular opening limitation and separate opening limitations as discussed in connection with claims 17 and 81. *Id.* at 63 (citing Pet. §§ VII(B)(4)(a)(vi), VII(C)(2)(a)(vi), VII(B)(4)(a)(vii), VII(C)(2)(a)(vii)).

As discussed above in Section III.D.3.a., we adopt as our own Petitioner’s analysis of the undisputed claim limitations as recited in independent claim 81, and find that Berthon-Jones teaches these limitations. Moreover, as discussed above in Section III.D.3.a.iii., we do not find that Petitioner’s first proposed modification satisfies the separate opening limitation; however, we do find persuasive Petitioner’s second proposed modification to Berthon-Jones. Additionally, we find that Petitioner articulated adequate reasons supported by rational underpinnings to combine Berthon-Jones and Barnett, as well as established by a preponderance of evidence that the combination of Berthon-Jones and Barnett would have rendered these limitations as obvious.

Patent Owner argues that because Petitioner has not demonstrated that one of ordinary skill in the art would have combined the teachings of Berthon-Jones and Barnett, the proposed combination of Berthon-Jones, Barnett and Lithgow fails for the same reasons. PO Resp. 18–49. Patent Owner further argues that the proposed combination of Berthon-Jones, Barnett, and Lithgow fails for the additional reason that, like with claim 17, one of ordinary skill in the art “would not have been motivated to modify Berthon-Jones in light of Lithgow” to include upper support member feature. PO Resp. 50.

As discussed above in Sections III.D.3.a. and III.E.2.a., we find that Petitioner presents sufficient arguments and credible evidence to support a finding that Berthon-Jones, Barnett, and Lithgow are combinable, and teach or suggest each of the limitations of claims 81 and 17. For the reasons discussed above in connection with our analysis of claims 81 and 17, we determine that Petitioner presents sufficient arguments and credible evidence

to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claim 32.

c. Independent Claim 58

Petitioner contends that independent claim 58 “includes . . . limitation[s] . . . identical to [those] described above in [Petition] § VII(C)(2)(a)(i) with respect to Claim 17” and addresses separately any additional limitations. Pet. 63. For example, Petitioner contends that “[a]s discussed above with respect to Claims 17 and 81, Berthon-Jones discloses a cushion having these features.” *Id.* at 64 (citing Pet. §§ VII(B)(4)(a)(iii), VII(C)(2)(a)(iii)). Petitioner also argues that “[a]s discussed above with respect to Claim 84, Berthon-Jones discloses this feature,” i.e., a frame integrally molded to the cushion. *Id.* (citing Pet. § VII(B)(4)(d) (emphasis omitted)). Petitioner again relies on the same arguments provided for the annular opening limitation, separate opening limitation, upper support member limitation, and headgear attachment location limitation, as discussed in connection with claims 17 and/or 81. *Id.* at 65–69 (internal citations omitted). We agree with Petitioner’s contentions as to these limitations.

Similar to the elongate frame members limitation discussed in connection with claim 82, claim 58 also requires “two frame members interconnecting the upper support member and the lower frame member and forming an open space between the two frame members and the lower frame member.” Ex. 1001, 25:7–10. Petitioner again relies on the second frame of Berthon-Jones as having frame members and an open space as discussed in connection with claim 82, e.g., opening 536 defined by elongate frame members that connect the upper portion and lower portion of the second frame 512 (Pet. 47). *Id.* at 70 (citing Pet. § VII(B)(4)(b)). Again, we

understand Petitioner's arguments as relying on its first proposed modification to satisfy the separate opening limitation, e.g., retaining a portion of opening 536 as a separate opening. As discussed above in Section III.D.3.a.iii.(a), we do not find persuasive Petitioner's arguments directed to its first proposed separate opening modification to Berthon-Jones in view of Barnett. Nor do we find persuasive Petitioner's arguments directed to the elongate frame members limitation of claim 82, namely that the proposed modification to Berthon-Jones in view of Barnett discloses elongate frame members at least partially bounding the separate opening. Critically, Petitioner does not explain how this claim element would be satisfied in the context of its second proposed modification to Berthon-Jones.

For the reasons discussed above in Section III.D.3.b.i., in connection with our analysis of claim 82, we determine that Petitioner fails to present sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claim 58.

d. Independent Claim 65

Petitioner asserts that independent claim 65 "includes limitations identical to those described above in [Petition] §§ VII(C)(2)(a)(i), VII(C)(2)(c)(i)–(ii), VII(C)(2)(c)(v), and VII(C)(2)(c)(viii)–(ix) with respect to Claims 17 and 58" and addresses separately any additional limitations. Pet. 70. For example, Petitioner contends that "[a]s discussed [] with respect to Claims 17 and 81, Berthon-Jones discloses a cushion having these features," i.e., "a face contacting portion with a sealing portion that contacts the patient's face . . . and comprising a first material." *Id.* at 71 (citing Pet. §§ VII(B)(4)(a)(iii), VII(C)(2)(a)(iii) (emphasis omitted)). Petitioner also contends that as discussed with respect to claim 58, Berthon-Jones discloses

a frame having “an annular wall surrounding an opening that is adapted to allow fluid communication of the pressurized gas to an interior of the frame and a second wall surrounding the annular wall and connected to the cushion.” *Id.* (citing Pet. § VII(C)(2)(a)(iii) (emphasis omitted)).

Additionally, Petitioner refers to its arguments directed to claim 58, in contending that Berthon-Jones discloses that the frame comprises “a second material that is more rigid than the first material.” *Id.* (citing Pet. § VII(C)(2)(c)(iv) (emphasis omitted)). Petitioner maintains that the disclosure in Berthon-Jones regarding “[o]n the outward side of the secondary frame portion 518, a connector 520 is provided to connect to a gas supply conduit” satisfies the “inlet conduit in fluid communication with the frame to communicate the pressurized gas to the interior of the frame” limitation. *Id.* at 72 (citing Ex. 1002 ¶ 180 (emphasis omitted)). Petitioner refers to its arguments in connection with claim 58 in asserting that the disclosure in Berthon-Jones regarding skeleton frame 512 being removably connected to frame 518 satisfies the “skeleton frame adapted to be removably engageable with the frame” limitation. *Id.* (citing Pet. § VII(C)(2)(c)(v) (emphasis omitted)). Petitioner refers to its arguments in connection with claim 58 in asserting that the disclosure in Berthon-Jones “regarding lower portion of the frame that includes headgear attachment locations adapted to engage with clips for headgear straps” satisfies the “lower frame member comprising attachment locations adapted to engage with clips for straps” limitation. *Id.* at 73 (citing Pet. § VII(C)(2)(c)(vi) (emphasis omitted)). We agree with Petitioner’s contentions as to these limitations.

As to the limitation reciting “wherein the skeleton frame and the frame are adapted to be releasably engageable to one another at the opening”

(Ex. 1001, 25:64–65), Petitioner points to the teaching in Berthon-Jones concerning opening 536 in skeleton frame 512 that “releasably receives the raised portion of the first frame 518 surrounding the frame opening (bounded by annular wall 520).” *Id.* at 73 (citing Ex. 1002 ¶¶ 177, 184). Petitioner further argues that “to the extent Berthon-Jones provides insufficient teachings for this feature, such an engagement at the opening was well-known and common in CPAP masks” (*id.* at 74 (citing Ex. 1006 ¶¶ 111–115)), and turns to the teaching in Barnett of how skeleton frame 34 “releasably engages the first frame at the opening defined by the neck portion 46 of the first frame” (*id.* (citing Ex. 1003, 7:1–6, 7:28–33, Figure 1)). Petitioner explains that one of ordinary skill in the art “would have been motivated to releasably couple the first frame with the skeleton frame at the opening to reduce the size of the interface between the frame module and the cushion module” (*Id.* at 74 (citing Ex. 1006 ¶¶ 113–115)), and that such person “would have known that a smaller sealing region between the cushion-frame sub-assembly and the second/skeleton frame makes it easier to maintain a sealed connection (*id.* at 74–75 (citing Ex. 1006 ¶ 114)). We agree with Petitioner’s contentions as to this limitation.

Similar to claim 58, however, independent claim 65 requires that the skeleton frame include “two frame members interconnecting the upper support member and the lower frame member and forming an open space between the two frame members and the lower frame member.” Ex. 1001, 25:59–63. Petitioner refers us to its arguments directed to claims 58 and 82 for this limitation. Specifically, Petitioner relies on “opening 536 defined by elongate frame members that connect the upper portion and lower portion of the second frame 512. Pet. 47.

Here, Petitioner's arguments are predicated on its first proposed modification to Berthon-Jones and Barnett to meet the separate opening limitation, as well as its arguments directed to the elongate frame members limitation, which we did not find persuasive. Namely, that the proposed combination of Berthon-Jones and Barnett teach retaining the upper portion of opening 536 as an open space that is bounded by two frame members and a lower frame member. Petitioner's argument is also unavailing because it does not explain how this claim element would be satisfied in the context of its second proposed modification to Berthon-Jones.

For the reasons discussed above in Section III.D.3.a.iii.(a) in connection with our analysis of the first separate opening modification, we determine that Petitioner does not present sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claim 65.

e. Dependent Claims 18, 20–23, 26–30, 33, 35–38, 41–46, 48–50, 59–64, and 66–73

Petitioner provides a detailed mapping of the limitations of each of claims 18, 20–23, 26–30, 33, 35–38, 41–46, 48–50, 58–64, and 66–73 onto the combined teachings of Berthon-Jones, Barnett, and Lithgow. Pet. 75–90.

For dependent claims 18 and 33, which depend from claims 17 and 32, respectively, Petitioner relies on its argument with respect to claim 84 that the “first frame and the cushion are integrally molded in one piece to provide a cushion-frame sub-assembly.” Pet. 75 (citing Pet. § VII(B)(4)(d) (emphasis omitted)). Dependent claims 20 and 35 likewise depend from claims 17 and 32, respectively, and require that the first frame be “contoured to fit over the patient's nose and mouth.” Ex. 1001, 21:15–16, 22:39–40. Petitioner asserts that Berthon-Jones teaches this limitation for the same

reasons as provided for claim 85. *Id.* (citing Pet. § VII(B)(4)(e)). Claims 21 and 36 also depend from claims 17 and 32, and include similar limitations concerning an opening in the first frame “that provides a flow path adapted to communicate with the inlet conduit.” Ex. 1001, 21:19–20, 22:42–43. Petitioner contends that “first frame 518 of Berthon-Jones includes an opening (bounded by annular wall 520) that provides a flow path with the elbow or gas supply conduit.” Pet. 76 (citing Ex. 1002 ¶ 180). We agree with Petitioner’s contentions as to these limitations.

Claims 22 and 37 depend from claims 17 and 32, and similarly describe how “the second frame includes contact points to prevent rotation of the first frame with respect to the second frame.” Ex. 1001, 21:22–23, 22:45–47. Petitioner argues that Berthon-Jones teaches “a second frame 512 with an opening 536 that is sized and shaped to receive the raised portion of the first frame 518.” Pet. 77 (citing Ex. 1002 ¶ 184). Specifically, Petitioner argues that “[t]he walls of the opening 536 contact the first frame and provide contact points that prevent rotation of the raised portion of the first frame 518 relative to the second frame,” as shown in annotated Figure 51, reproduced below. *Id.* (citing Ex. 1006 ¶ 84).

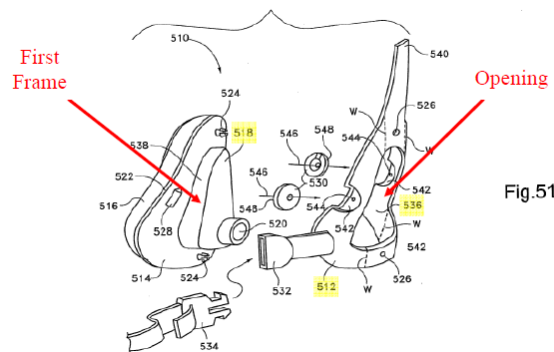


Figure 51 of Berthon-Jones as annotated by Petitioner to show the contact points.

We understand Petitioner’s argument as relying on both Petitioner’s first proposed modification to Berthon-Jones using Barnett to satisfy the separate opening limitation, and the walls in opening 536 as contacting the first frame and providing contact points to prevent rotation of the first frame relative to the second frame (Pet. 77). Because we did not find that Petitioner’s first proposed modification to Berthon-Jones satisfies the separate opening limitation, for the same reasons, we do not find that the “contact point” limitations of claims 22 and 37 are met. Critically, Petitioner does not explain how this claim element would be satisfied in the context of its second proposed modification to Berthon-Jones.

Thus, we determine that Petitioner does not present sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claims 22 and 37.

As to claims 23 and 38, which require that “the first frame and the cushion together form a breathing chamber around the patient’s nose and mouth” (Ex. 1001, 21:25–26, 2249–50), Petitioner relies on its argument from claim 81 that Berthon-Jones teaches a breathing chamber. Pet. 78 (citing Pet. § VII(B)(4)(a)(iv)). For the reasons discussed above in Section III.D.3.a., in connection with claim 81, we determine that Petitioner presents sufficient arguments and credible evidence to support a finding that Berthon-Jones, Barnett, and Lithgow teach the limitations of claims 23 and 38.

Claims 26 and 41 similarly require that the second frame includes “two connecting members that connect a lower portion of the second frame to the upper support member and the opening [or separate opening] is located between the two connecting members.” Ex. 1001, 21:35–38, 22:59–62. Petitioner directs us to its arguments for claim 82, explaining that “[t]he

Berthon-Jones frame 512, as modified in view of Barnett, would still have the connecting members defining a separate opening above the annular opening.” Pet. 79 (citing Pet. § VII(B)(4)(b)). We do not find persuasive Petitioner’s arguments in connection with claim 82 concerning the similar elongate frame members limitation. As with claim 82, we understand Petitioner as relying on its first proposed modification to Berthon-Jones using Barnett, to satisfy the connecting member limitation of claims 26 and 41. For the same reasons, we are likewise not persuaded that the connecting member limitation of claims 26 and 41 are met. Nor does Petitioner explain how this claim element would be satisfied in the context of its second proposed modification to Berthon-Jones.

Thus, we determine that Petitioner does not present sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claims 26 and 41.

Dependent claims 27 and 42 require that the opening or separate opening be “substantially triangular.” Ex. 1001, 21:40, 22:64. Petitioner refers us to its arguments directed to claim 86, namely that Berthon-Jones discloses a triangular opening, which we find unpersuasive. Pet. 79–80 (citing Pet § VII(B)(4)(f)).

Thus for the same reasons as explain above in Section III.D.3.b.ii., in connection with claim 86, Petitioner does not present sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claims 27 and 42.

Dependent claims 28 and 43 each require two lower headgear clip attachments located “adjacent to and on opposite lateral sides of the annular connection (opening).” Ex. 1001, 21:43–44, 22:66–67. Here, Petitioner

relies on its arguments from claim 87, in explaining that Berthon-Jones teaches lower headgear clip attachments. Pet. 80 (citing Pet. § VII(B)(4)(g)). For the reasons discussed above in Section III.D.3.b.iii., in connection with our analysis of claims 87, we determine that Petitioner presents sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claims 28 and 43.

Dependent claims 29 and 44 require that “first frame is releasably secured to the second frame by way of an interlocking and/or frictional fit.” Ex. 1001, Ex. 21:46–47, 23:2–3. Petitioner argues that this limitation is satisfied by the disclosure of holes in second frame 512 that receive connecting members 524 on the first frame, “to secure the first frame 518 to the second frame 512 with an interlocking snap-fit.” Pet. 80–81 (citing Ex. 1002 ¶¶ 177, 182). As discussed above in Section III.D.3.a., in connection with claim 81, we are persuaded by Petitioner’s arguments that a snap-fit is an interlocking or frictional fit. Moreover, we understand Petitioner as relying on its second proposed modification to Berthon-Jones to satisfy both this limitation and the separate opening limitation of the underlying base claim. Patent Owner does not challenge Petitioner’s contentions directed to claims 29 and 44.

Thus for the same reasons as explained above in Section III.D.3.a., in connection with claim 81, Petitioner presents sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claims 29 and 44.

Claim 30 and 45 require that the first frame and second frame “have complimentary shapes.” Ex. 1001, 21:49, 23:5 (“the complimentary shape limitation”). Petitioner argues that Berthon-Jones’ first frame 518 and

second frame 512 “have complementary shapes at the opening 536 and the first frame 518” and that “opening 536 in the second frame 512 is sized and shaped ‘to receive the raised, central portion’ of the first frame 518.” Pet. 81–82 (citing Ex. 1002 ¶ 184). Petitioner annotated Figure 51 of Berthon-Jones, reproduced below, to illustrate this alleged correspondence. *Id.* at 82.

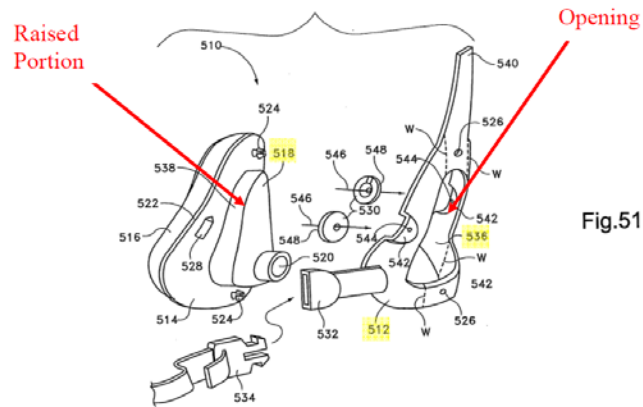


Figure 51 as annotated by Petitioner to show the raise portion and corresponding opening.

As discussed above in Section III.D.3.a.iii.(b) with respect to claim 81, we understand the second proposed separate opening modification as using a bracket or frame structure at the bottom portion of opening 536 that includes an annular opening, and directly attaches to the elbow inlet conduit. Pet. 42 (citing Ex. 1006 ¶¶ 72–78). Petitioner contends that this bracket or frame structure would be similar to collar 34 of Barnett, and that it “would define and surround the annular opening of the second frame.” Pet. 43 (citing Ex. 1006 ¶ 73). To be clear, for the underlying base claim of claims 30 and 45, i.e., claims 17 and 32, we rely on Petitioner’s second proposed modification of Berthon-Jones and Barnett to meet the separate opening limitation. Pet. 45. Specifically, Petitioner’s contention that the separate opening limitation is met by opening 526 in second frame 512. *Id.* Other than asserting that opening 536 would be sized and shaped to receive the

raised portion of first frame 518, Petitioner does not explain how opening 536 would retain its complimentary shape to the raised, central portion of first frame 518 after opening 536 is modified using a bracket or frame structure similar to collar 34 of Barnett. *See* Pet. 81–82.

Thus, Petitioner does not present sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teaches the complimentary shape limitation of claims 30 and 45.

Claim 46 depends from claim 32, and requires that the “annular opening and the elbow are sealingly connected.” Ex. 1001, 23:7. Petitioner directs us to its arguments in connection with claims 81 and 91, namely that “it was well-known and common in CPAP masks to provide an annular opening that directly attaches to the elbow and allows gas to flow to the breathing chamber.” Pet. 82 (citing Pet. §§ VII(B)(4)(a)(vi), VII(B)(4)(j)). Petitioner also contends that “Barnett discloses that the elbow 36 is directly attached to the second frame 34 and a person of skill in the art would have known that this is a sealed connection so that the pressurized gas passes into the breathing chamber and not out of the connection.” *Id.* at 82–83 (citing Ex. 1003, 3:52–57; Ex. 1006 ¶¶ 117–118). Patent Owner counters that Petitioner’s proposed modification would “decrease[] the air seal quality of the Berthon-Jones mask.” PO Resp. 34.

As discussed above in connection with claim 81, we are not persuaded by Patent Owner’s argument concerning air seal quality. For the same reasons provided above in Section III.D.3.a., we are likewise not persuaded by Patent Owner’s similar argument for claim 46.

Thus, Petitioner presents sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claim 46.

Petitioner acknowledges that dependent claim 48 requires limitations similar to those discussed with respect to claim 33, 35–38, 41, 42, 44, and 46. Pet. 83. For example, claim 48 requires that “the cushion comprises a face contacting portion that contacts a patient's face” (Ex. 1001, 23:51–52), and Petitioner argues that “Berthon-Jones discloses a cushion 516 with a face contacting portion that seals against the face of the patient” (Pet. 84 (citing Ex. 1002 ¶ 180)).

At the outset, we note that we are persuaded by Petitioner’s arguments directed to claims 33, 35, 36, 38, and 46, but not as to claims 37, 41, and 42, as discussed above. For these same reasons, Petitioner does not present sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claim 48.

Claim 49 depends from Claim 48, and Petitioner argues that claim 49 “includes each of the limitations of Claims 42 and 45. As discussed above with respect to Claims 42 and 45, Berthon-Jones discloses these features.” Pet 84 (citing Pet. §§ VII(C)(2)(k), VII(C)(2)(n)). For the reasons set forth in the preceding paragraph, Petitioner’s arguments directed to claim 48 fall short. As such, Petitioner does not present sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claim 49.

Claim 50 depends from claim 48, and requires that “the elbow engages the second frame.” Ex. 1001, 23:67. Because we are not persuaded by Petitioner’s arguments in connection with claim 48, for the same reasons

we are not persuaded by its related arguments directed to claim 50, which depends from claim 48. As such, Petitioner does not present sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claim 50.

Claims 59–64 depend from claim 58. Ex. 1001, 25:13–36. Claims 66–73 depend from claim 65. Ex. 1001, 1–28. Because we were not persuaded by Petitioner’s arguments directed to the underlying base claim, i.e., claim 58 and 65, for the same reasons we are not persuaded that Petitioner presents sufficient arguments and credible evidence to support a finding that the combination of Berthon-Jones, Barnett, and Lithgow teach the limitations of claims 59–64 and 66–73.

3. Summary

In view of the forgoing, we conclude that Petitioner has established by a preponderance of the evidence that claims 17, 18, 20, 21, 23, 28, 29, 32, 33, 35, 36, 38, 43, 44, and 46, are unpatentable under 35 U.S.C. § 103(a) as obvious over Berthon-Jones, Barnett, and Lithgow but not as to claims 22, 26, 27, 30, 37, 41, 42, 45, 48–50, and 58–73.

F. Obviousness Based on Berthon-Jones, Barnett, Lithgow, and Burns

Petitioner challenges the patentability of claims 51–57 and 74–80 of the ’061 patent under 35 U.S.C. § 103 as obvious based on Berthon-Jones, Barnett, Lithgow, and Burns. In support thereof, Petitioner identifies the disclosures in the cited references alleged to describe the subject matter in the challenged claims, as well as a reason why a POSITA would have

modified Berthon-Jones based on the teachings of Barnett, Lithgow, and Burns. *Id.* at 91–105.

Patent Owner disputes that the proposed combination of Berthon-Jones and Barnett is unavailing for the reasons discussed in connection with claim 81. Supp. Resp. 2–8. Additionally, Patent Owner challenges whether a POSITA would have modified Berthon-Jones with an over-molded cushion. *Id.* at 10.

We have reviewed each party’s contentions and supporting evidence of record in this trial. As explained below, we conclude that Petitioner has not met its burden of demonstrating by a preponderance of the evidence that claims 51–57, and 74–80 of the ’061 patent would have been obvious. We begin our analysis with a brief summary of Burns and then address the parties’ contentions in turn.

1. Overview of Burns (Ex. 1005)

Burns is a U.S. Patent entitled “Respiratory Mask Having a Soft, Compliant Facepiece and a Thin Rigid Insert and Method of Making” that issued on November 5, 1991. Ex. 1005, (54), (45). Burns is directed to a respiratory mask having “a soft, compliant face-piece to which is permanently sealed a relatively thin, rigid insert.” *Id.* at Abstract.

2. Discussion

a. Claims 51–57

For features of claim 51 that are similar to features recited in other claims, Petitioner refers us to its previously presented arguments. For example, Petitioner argues (1) “mask assemblies that deliver pressurized gas to a patient were well-known and disclosed by Berthon-Jones and Barnett” (Pet. 92 (citing Pet § VII(B)(4)(a)(i))); (2) “[a]s discussed above with respect to claim 21, Berthon-Jones discloses [a first frame]” (*Id.* at 93 (citing

§ VII(C)(2)(g)); (3) “[a]s discussed above with respect to Claim 81, Berthon-Jones discloses [that the cushion forms a seal around the patient’s nose and mouth]” (*id.* at 95 (citing Pet. § VII(B)(4)(a)(iii))); (4) “[a]s discussed above with respect to Claim 29, Berthon-Jones discloses [a second frame]” (*id.* at 96 (citing Pet. § VII(C)(2)(m))); (5) “[a]s discussed above with respect to Claim 17, Berthon-Jones discloses an upper member and it was well-known and common in CPAP masks to provide a forehead support, as disclosed by Lithgow” (*id.* (citing Pet. § VII(C)(2)(a)(iv))); and (6) “[a]s discussed above with respect to Claim 87, Berthon-Jones discloses [headgear attachment structures]” (*id.* at 97 (citing Pet. § VII(B)(4)(g))). For the reasons discussed above in connection with claims 81, 21, 29, 17, and 87, we agree with Petitioner’s contentions as to these limitations.

Additionally, Petitioner relies on its argument discussed in connection with claim 58 to satisfy the limitation that the second frame includes “lower portion with a second opening aligned with the first opening so that the inlet conduit fluidly communicates with a breathing chamber formed by the cushion and the first frame.” Ex. 1001, 24:19–22. Namely, Petitioner argues that “it was well-known and common in CPAP masks to provide an annular opening in the second frame that allows gas to pass to the patient, as taught by the combination of Berthon-Jones and Barnett.” Pet. 96 (citing Pet. § VII(C)(2)(c)(vii)). We agree with Petitioner’s contentions as to this limitation.

Claim 51 also includes the limitation of “a cushion with a side wall and a face contacting portion extending from the side wall, wherein the cushion is over-molded to the first frame to form a cushion/frame sub-assembly.” Ex. 1001, 24:7–10. Petitioner contends that this limitation is taught by Berthon-Jones as modified by Burns. Pet. 93–95. Specifically,

Petitioner argues that “Berthon-Jones also discloses that the cushion 516 may be molded to the first frame 518 to form a cushion-frame sub-assembly 514,” but “does not expressly disclose that the cushion is over-molded to the first frame, but over-molding the cushion to the frame was well-known and common in respiratory masks” as taught by Burns. *Id.* at 94 (citing Ex. 1006 ¶¶ 121–124). Petitioner reasons that a POSITA would have modified Berthon-Jones based on the teachings of Burns because (1) “[s]uch a person would have recognized that an over-molded or integrally molded cushion module would provide an airtight seal between the seal and the cushion and would help prevent unwanted removal of the cushion from the frame”; (2) “the over-molding arrangement would help retain the cushion and the shell in proper attachment by impeding relative axial and rotational movement between the cushion and the shell”; and “an over-molded cushion module would have been simple to manufacture and assemble, and would have facilitated correct alignment.” *Id.* at 95 (citing Ex. 1006 ¶ 124).

Patent Owner counters that Petitioner “failed to show that a POSITA would have modified Berthon-Jones with the claimed ‘over-molded’ cushion attachment where Berthon-Jones already provided an ample solution.” Supp. Resp. 10 (citing Ex. 1002 ¶ 181; Figures 52,53). This argument is not persuasive. Here, Petitioner’s reasoning comports with the Federal Circuit’s recognition in *Ethicon* of “[t]he normal desire of artisans to improve upon what is already generally known.” *See In re Peterson*, 315 F.3d at 1330; *see also KSR*, 550 U.S. at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”). We, therefore, are persuaded by Petitioner’s rationale for the combination of Berthon-Jones with Burns.

Nonetheless, Petitioner relies on its argument that “[a]s discussed above with respect to Claim 82, Berthon-Jones discloses [two elongate

frame members]” (*id.* at 97 (citing Pet. § VII(B)(4)(b))); and related argument that “[a]s discussed above with respect to Claims 81 and 82, a person of skill in the art would have known to provide such an open space, as disclosed by the combination of Berthon-Jones and Barnett” (*id.* (citing Pet. §§ VII(B)(4)(a)(vii), VII(B)(4)(b))); as well as its argument that “[a]s discussed above with respect to Claim 61, Berthon-Jones discloses [the first frame protrudes at least partially through the open space]” (*id.* at 98 (citing Pet. § VII(C)(2)(u))).

Because we were not persuaded by the arguments and evidence Petitioner cites to satisfy these limitations in connection with claims 58, 82, and 61, for the same reasons as discussed above in Sections III.E.2.c., III.D.3.b.i., and III.E.2.e., we likewise do not find that the proposed combination of Berthon-Jones, Barnett, Lithgow, and Burns teach the corresponding limitations recited in claim 51.

For dependent claims 52–57, Petitioner relies on arguments previously discussed in connection with claim 58 (“first opening surrounded by an annular wall”), claim 17 (“headgear attachment”), claim 65 (“first frame and second frame interlock at second opening”), claim 83 (“elongate frame members engage with the cushion/frame sub-assembly”), and claim 88 (“the inlet conduit comprises an inlet elbow”). Pet. 101–104. Petitioner’s arguments directed to dependent claims 52–57, however, do not address the deficiencies in underlying base claim 51.

As such, Petitioner does not provide sufficient arguments or credible evidence to support a finding that the limitations of claims 52–57 are taught by the proposed combination of Berthon-Jones, Barnett, Lithgow, and Burns.

b. Claims 74–80

Petitioner contends that independent claim 74 “includes limitations identical to those described above in §§ VII(D)(2)(a)(i)–(ii), VII(D)(2)(a)(iii)–(iv), and VII(D)(2)(ix) with respect to Claim 51” as well as additional limitations. Pet. 98–101. For example, Petitioner additionally directs us to its arguments for claim 58 (first frame with a first opening); claim 17 (upper member configured to support a forehead contacting portion); claim 81 (second annular opening, accessibility to first frame via open space); and claim 82 (open space bounded by two elongate frame members). *Id.*

We have considered Petitioner’s arguments and evidence in connection with these claim limitations. As discussed above with respect to claim 82 in Section III.D.3.b.i., we do not find that Berthon-Jones teaches an open space bounded by two elongate frame members, i.e., the elongate frame member limitation. Specifically, because Petitioner’s arguments rely on its first proposed modification to Berthon-Jones using Barnett that we find unpersuasive. Nor does Petitioner explain how this claim element would be satisfied in the context of its second proposed modification to Berthon-Jones. For the same reasons, Petitioner does not present sufficient arguments and credible evidence to support a finding that claim 74 would have been obvious based on the proposed combination of Berthon-Jones, Barnett, Lithgow, and Burns.

As to dependent claims 75–80, Petitioner also relies on arguments made in connection with other claims. Nonetheless, Petitioner’s arguments directed to dependent claims 75–80 do not address the deficiencies in underlying base claim 74. As such, Petitioner does not provide sufficient arguments or credible evidence to support a finding that the limitations of

claims 75–80 are taught by the proposed combination of Berthon-Jones, Barnett, Lithgow, and Burns.

c. Summary

In view of the forgoing, we conclude that Petitioner has not established by a preponderance of the evidence that claims 51–57 and 74–80 are unpatentable under 35 U.S.C. § 103(a) as obvious over Berthon-Jones, Barnett, Lithgow, and Burns.

IV. CONCLUSION

For the foregoing reasons, we determine Petitioner has demonstrated that

1. Claims 81, 84, 85, 87, and 88 are unpatentable under 35 U.S.C. § 103(a) as obvious over Berthon-Jones and Barnett, but not as to claims 82, 83, 86, 89–91;
2. Claims 17, 18, 20, 21, 23, 28, 29, 32, 33, 35, 36, 38, 43, 44, 46, are unpatentable under 35 U.S.C. § 103(a) as obvious over Berthon-Jones, Barnett, and Lithgow but not as to claims 22, 26, 27, 30, 37, 41, 42, 45, 48–50, 58–73; and
3. Claims 51–57 and 74–80 are not unpatentable under 35 U.S.C. § 103(a) as obvious over Berthon-Jones, Barnett, Lithgow, and Burns.

V. ORDER

In consideration of the record before us, it is:

ORDERED that claims 17, 18, 20, 21, 23, 28, 29, 32, 33, 35, 36, 38, 43, 44, 46, 81, 84, 85, 87, and 88 are unpatentable under 35 U.S.C. § 103(a) as obvious;

FURTHER ORDERED that claims 22, 26, 27, 30, 37, 41, 42, 45, 48–80, 82, 83, 86, and 89–91 are not shown to be unpatentable; and

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FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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