

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HUHTAMAKI FLEXIBLE PACKAGING GERMANY GMBH & CO. KG,
Petitioner,

v.

DANAPAK FLEXIBLES A/S,
Patent Owner.

PGR2023-00008
Patent 11,260,624 B2

Before JO-ANNE M. KOKOSKI, KRISTINA M. KALAN, and
BRIAN D. RANGE, *Administrative Patent Judges*.

KALAN, *Administrative Patent Judge*.

PRELIMINARY GUIDANCE
PATENT OWNER'S MOTION TO AMEND

I. INTRODUCTION

On June 20, 2023, we instituted trial as to claims 1–13 of U.S. Patent No. 11,260,624 B2 (Ex. 1001, “the ’624 patent”). Paper 14. After institution, Patent Owner filed a Motion to Amend that is contingent on the patentability of claims 1, 6–11, and 13.¹ Paper 22 (“Motion” or “Mot.”). Petitioner filed an Opposition (Paper 26 (“Opposition” or “Opp.”)) and submitted a Declaration of Dr. Richard J. Spontak in support of the Opposition (Ex. 1037).

In its Motion, Patent Owner requested that we provide preliminary guidance in accordance with the Board’s pilot program concerning motion to amend practice and procedures. Mot. 2; *see also Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board*, 84 Fed. Reg. 9,497 (Mar. 15, 2019) (providing a patent owner with the option to receive preliminary guidance from the Board on its motion to amend) (“Notice”). We have considered Patent Owner’s Motion and Petitioner’s Opposition.

In this Preliminary Guidance, we provide information indicating our initial, preliminary, non-binding views on whether Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend in a post-grant review and whether Petitioner and the record as a whole establish a reasonable likelihood that the substitute claims are unpatentable. *See* Notice, 84 Fed. Reg. at 9,497 (“The preliminary guidance . . . provides preliminary, non-binding guidance from the Board to the parties about the [motion to amend]”); *see also* 35 U.S.C. § 326(d) (statutory

¹ Patent Owner omitted claim 11 from the listing of claims. Mot. 1. Because Patent Owner provides in the Claims Appendix (“Claims App.”) (Mot. 28) “Proposed substitute claim 20 to replace claim 11” if claim 11 is found unpatentable, we include claim 11.

requirements for a motion to amend); 37 C.F.R. § 42.221 (regulatory requirements and burdens for a motion to amend); *Lectrosonics, Inc. v Zaxcom, Inc.*, IPR2018-01129, Paper 15 (PTAB Feb. 25, 2019) (precedential) (providing information and guidance regarding motions to amend).

For purposes of this Preliminary Guidance, we focus on the proposed substitute claims, and specifically on the amendments proposed in the Motion. *See* Notice, 84 Fed. Reg. at 9,497. We do not address the patentability of the originally challenged claims. *Id.* Moreover, in formulating our preliminary views on the Motion and Opposition, we have not considered the parties' other substantive papers on the underlying merits of Petitioner's challenges. We emphasize that the views expressed in this Preliminary Guidance are subject to change upon consideration of the complete record, including any revision to the Motion filed by Patent Owner. Thus, this Preliminary Guidance is not binding on the Board when rendering a final written decision. *See id.* at 9,500.

II. PRELIMINARY GUIDANCE

A. Statutory and Regulatory Requirements

For the reasons discussed below, at this stage of the proceeding, and based on the current record, it appears that Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend.

1. Reasonable Number of Substitute Claims

Is there a reasonable likelihood that Patent Owner proposes a reasonable number of substitute claims? (35 U.S.C. § 326(d)(1)(B))
Yes. Petitioner challenged claims 1–13 of the '624 patent. Patent Owner moves to: (i) cancel claims 2 and 3 ² and (ii) proposes claims 14–21 as

² The Board interprets PO's motion to amend to be non-contingent with respect to claims 2 and 3 and, therefore, intends to enter adverse judgment against claims 2

potential substitutes for claims 1, 6–11, and 13.³ Mot. 1, Claims App. In other words, Patent Owner proposes to replace two independent claims and six dependent claims with two independent claims and six dependent claims. *See id.* Petitioner does not argue otherwise.

2. Respond to Ground of Unpatentability

Is there a reasonable likelihood that the Motion responds to a ground of unpatentability involved in the trial? (37 C.F.R. § 42.221(a)(2)(i))

Yes. Patent Owner contends that proposed substitute claims 14–21 “are responsive to one or more grounds of unpatentability at issue in this proceeding at least because the amendments enhance clarity of the claims, introduce features that add additional distinguishing features that are not rendered obvious by the asserted references, or both.” Mot. 15; *see id.* at 18–24. Upon review of Patent Owner’s arguments, we agree that proposed substitute independent claims 14 and 21 and proposed substitute dependent claims 15–20 recite new limitations, and new combinations of limitations, that directly respond to the grounds of unpatentability involved in the trial. *See* Mot. 14–15, Claims App. Petitioner does not argue otherwise.

3. Scope of Amended Claims

Is there a reasonable likelihood that the amendment seeks to enlarge the scope of the claims? (35 U.S.C. § 326(d)(3); 37 C.F.R. § 42.221(a)(2)(ii))

No. Patent Owner contends that substitute independent claim 14 “replaces the claim language ‘the base layer comprises aluminum’ with the narrower claim language ‘the base layer consists of aluminum.’” Mot. 12–13; *see id.* at 26. Patent Owner contends that substitute independent claim 14 “clarifies that ‘the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine.’” *Id.* at 12. Patent Owner also contends that substitute independent claim 21

and 3 in the Final Written Decision regardless of the disposition of claims 1–13 or proposed substitute claims 14–21.

³ Patent Owner does not discuss claims 4, 5, and 12. Because Patent Owner’s Motion to Amend does not cancel or propose substitute claims for claims 4, 5, and 12, we understand that these claims are to remain as they are, dependent from claim 1 with no proposed changes or proposed substitute claims.

replaces the claim language “comprising” with the narrower claim language “consisting of,” replaces “the tie layer comprises one or more layers” with the narrower claim language “the tie layer comprises a first layer . . . and a second layer,” and replaces “wherein the tie layer, or the one or more layers of the tie layer, has a loading in the range of 7 to 20 g/m²” with the narrower claim language, “a first layer having a loading . . . and a second layer [each] having a loading in the range of 7 to 18 g/m².” Mot. 14; *see id.* at 29. Proposed substitute claims 15–20 add narrowing features or change the dependency of challenged claims 6–11 of the ’624 patent. Mot. 13; *see* Claims App. Petitioner does not argue otherwise.

4. New Matter

Is there a reasonable likelihood that the amendment seeks to add new subject matter? (35 U.S.C. § 326(d)(3); 37 C.F.R. § 42.221(a)(2)(ii))

No. Patent Owner argues that each limitation of proposed substitute claims 14–21 is disclosed in application 16/835,018 (“the ’018 application”),⁴ from which the ’624 patent issued, and in earlier-filed EP Application No. 15202962.5 (“the ’962 application”), to which the ’624 patent claims priority. Mot. 4. Specifically, Patent Owner identifies corresponding support for each limitation in chart format. *Id.* at 5–12. We address the limitations added in Patent Owner’s Motion to Amend below.

Limitations [14B] and [21B]: “wherein the base layer consists of aluminum”

Patent Owner demonstrates a reasonable likelihood that the limitations of the base layer consisting of aluminum, as recited in proposed substitute claims 14 and 21, do not seek to add new subject matter. *Id.* at 5, 11. Thus, at this stage of the proceeding, on the record before us, Patent Owner has shown a reasonable likelihood that there is adequate written description support in the original disclosure of the ’624 patent for proposed limitations [14B] and [21B].

Limitation [15C] “the method further comprises laminating, after the aggressive chemical-resistant film is formed by coating the coextrusion layer to the base layer consisting of the aluminum, a first outer layer to the

⁴ Patent Owner refers to “U.S. Application No. 16/835,108 (“108 App”) [*sic*].” Mot. 4. We view Patent Owner’s references to the incorrect application number as a clerical error that we correct here.

base layer of the aggressive chemical-resistant film.”

Patent Owner demonstrates a reasonable likelihood that the limitations of an additional lamination step, after formation of the aggressive chemical-resistant film, as recited in proposed substitute claim 15, does not seek to add new subject matter. Mot. 8–9. Thus, at this stage of the proceeding, on the record before us, Patent Owner has shown a reasonable likelihood that there is adequate written description support in the original disclosure of the ’624 patent for proposed limitation [15C].

Limitation [16B] “wherein a loading of a first layer of the tie layer is in the range of 7 to 18 g/m² and a loading of a second layer of the tie layer is in the range of 7 to 18 g/m²”

Limitation [17B] “wherein a loading of a first layer of the plurality of layers is in the range of 7 to 14 g/m² and a loading of a second layer of the plurality of layers is in the range of 7 to 14 g/m². ”

Limitation [21F] “the tie layer comprises a first tie layer having a loading in the range of 7 to 14 g/m² and a second layer having a loading in the range of 7 to 14 g/m²”

Patent Owner cites paragraphs 43 and 147 of the ’018 application for support. Mot. 7–8. Paragraph 43 of the ’018 application discloses that “the tie layer or plurality of tie layers constituting the tie layer, has a loading in the range of 7 to 20 g/m².” *Id.* Paragraph 147 of the ’018 application discloses that “the loading of the tie layers was between 4–18 g/m².”

Regarding the minimum endpoint of 7 g/m² recited in claims 16, 17, and 21, there appears to be support in Paragraph 43 of the ’018 application for the loading of a layer at 7 g/m². With regard to the maximum endpoint of 18 g/m² recited in claim 16, Paragraph 147 of the ’018 appears to support the loading of a layer at 18 g/m². Although we appreciate Petitioner’s point that Laminate 5 appears to be a single tie layer, whereas claim 16 recites two tie layers (Opp. 5), the question is whether there is support for the claimed range in Paragraphs 43 and 147.

For these reasons, we agree with Patent Owner that there is support for the claimed 7 to 18 g/m² layer loading range recited in claim 16. Thus, at this stage of the proceeding, on the record before us, Patent Owner has shown a reasonable likelihood that proposed substitute claim 16 does not introduce new matter.

We disagree with Petitioner that one of ordinary skill in the art would not glean from the two cited paragraphs of the '018 application possession of the maximum endpoint of 14 g/m² recited in claims 17 and 21. We are persuaded by Patent Owner's argument and evidence that a narrower range of 7 to 14 g/m² is not new matter in view of the existing disclosures of a "plurality of tie layers constituting the tie layer," having "a loading in the range of 7 to 20 g/m²" and that "the loading of the tie layers was between 4–18 g/m²." *In re Wertheim*, 541 F.2d 257, 265 (CCPA 1976) ("In the context of *this* invention, in light of the description of the invention as employing solids contents within the range of 25–60% along with specific embodiments of 36% and 50%," finding, as a factual matter, "persons skilled in the art would consider processes employing a 35–60% solids content range to be part of appellants' invention and would be led by the Swiss disclosure so to conclude.").

For these reasons, we agree with Patent Owner that there is support for the claimed 14 g/m² loading range endpoint. Thus, at this stage of the proceeding, on the record before us, Patent Owner has shown a reasonable likelihood that the amended limitations in proposed substitute claims 17 and 21 do not introduce new matter.

As to Petitioner's contention that there is no support for each tie layer having the claimed loading range, we disagree. Paragraph 43 of the '018 application discloses "*the tie layer* or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m²." We understand the disclosed "the tie layer" to apply to each layer.

Limitation [18C] "*the aggressive chemical-resistant film is resistant to the chemical based at least in part on allowing less than 10% of the chemical to migrate into the aggressive chemical-resistant film.*"

Patent Owner demonstrates a reasonable likelihood that the limitations regarding the range of chemical migration, as recited in proposed substitute claim 18, do not seek to add new subject matter. Mot. 9–10. Thus, at this stage of the proceeding, on the record before us, Patent Owner has shown a reasonable likelihood that there is adequate written description support in the original disclosure of the '624 patent for the amended limitation in proposed substitute claim 18.

Limitation [19B] "*performing a coextrusion coating of the coextrusion layer directly to the base layer consisting of the aluminum.*"

Patent Owner demonstrates a reasonable likelihood that the limitations regarding the step of coextruding a coating directly to an aluminum base layer, as recited in proposed substitute claim 19, do not seek to add new subject matter. Mot. 6–7, 10. Thus, at this stage of the proceeding, on the record before us, Patent Owner has shown a reasonable likelihood that there is adequate written description support in the original disclosure of the '624 patent for the amended limitation in proposed substitute claim 18.

Limitation 20D “the chemical is provided in a first patch, and the aggressive chemical-resistant film is resistant to the chemical based at least in part on allowing 90% to 110% of the chemical in the first patch to migrate into a first pouch formed by the aggressive chemical-resistant film relative to an amount of the chemical in a second patch allowed to migrate into a second pouch formed by a second film comprising a contact layer that comprises Barex®.”

Patent Owner demonstrates a reasonable likelihood that the limitations regarding patches, as recited in proposed substitute claim 20, do not seek to add new subject matter. Mot. 10–11. Thus, at this stage of the proceeding, on the record before us, Patent Owner has shown a reasonable likelihood that there is adequate written description support in the original disclosure of the '624 patent for the amended limitation in proposed substitute claim 20.

B. Patentability

For the reasons discussed below, at this stage of the proceeding, and based on the current record,⁵ it appears that Petitioner and the record as a whole establish a reasonable likelihood that proposed substitute claims 14–21 are unpatentable.

⁵ We express no view on the patentability of original claims 1–13 in this Preliminary Guidance. Instead, we focus on limitations added to those claims in the Patent Owner’s Motion to Amend.

Does the record establish a reasonable likelihood that the proposed substitute claims are unpatentable?

Yes, as to claims 14–21. On this record, it appears that Petitioner has shown a reasonable likelihood that claims 14–21 are unpatentable under 35 U.S.C. § 103 based on the following grounds set forth in Petitioner’s Opposition:

1. Claims 14, 15, 19 and 20 would have been obvious over Riis (Ex. 1004), Wypych (Ex. 1005), and Tohara (Ex. 1033)
2. Claims 16, 17, and 21 would have been obvious over Riis, Wypych, Tohara, and Holzmuller (Ex. 1034)
3. Claim 18 would have been obvious over Riis, Wypych, Tohara, and Rivers (1035)

Petitioner also has shown a reasonable likelihood that claim 20 is unpatentable under 35 U.S.C. § 112 as being indefinite.

*Asserted Obviousness of Proposed Substitute Claims 14, 15, 19, and 20⁶
Based on Riis, Wypych, and Tohara*

On the present record, Petitioner has shown a reasonable likelihood that proposed substitute claims 14, 15, 19 and 20 are unpatentable as obvious over Riis, Wypych, and Tohara. *See* Opp. 8–16, 22–24.

Claim 14

wherein the base layer consists of aluminum

Proposed substitute claim 14 is a proposed substitute for claim 1 and the proposed amendment changes “comprises aluminum” to “consists of aluminum” for each of three occurrences of this recitation. Petitioner asserts that “Patent Owner’s interpretation of Riis is limited to Example 5,” but that “interpretation is flawed,” because “Riis teaches ‘a flexible, multilayer packaging film suitable for packaging an article . . . such as transdermal drug delivery patches’ that includes multiple layers, including a barrier layer that is preferably an oxygen and moisture barrier.” Opp. 8–9 (citing Ex. 1004 ¶¶ 12, 58–63). According to Petitioner, “Riis further

⁶ Because claims 15, 19, and 20 depend from claim 14, and Petitioner relies on Tohara for the grounds for claim 14, we understand Tohara to be included in the grounds for claims 15, 19, and 20.

teaches that the barrier layer may be made of ‘any suitable material,’ including aluminum foil.” *Id.* at 9 (citing Ex. 1004 ¶¶ 57–59, 62, 63, 85–87, 157, 174). Petitioner further asserts that “Riis discloses ‘the sealant film was a three-layer coextrusion of EAA, LDPE, and Ethylene-norbornene [cyclic olefin] copolymer (COC) which was extrusion coated *onto the aluminum foil surface* of the multilayer base film.”” *Id.* at 9–10 (citing Ex. 1004 ¶ 174). Petitioner thus asserts, “Patent Owner’s substitute claim 14 limitation requiring ‘coating the coextrusion layer consisting of the tie layer and the COC of the contact layer directly to the base layer consisting of the aluminum,’ is met by Riis.” *Id.* at 10. Petitioner concludes that because Riis does not require any additional layers in that “Riis discloses the optional nature of such layers,” and that the layers need not have “any specific ordering,” the limitations of proposed substitute “claim 14 with respect to a base layer consisting of aluminum foil are rendered obvious.” *Id.* at 10–11.

At this preliminary stage of the proceeding, we agree with Petitioner. Riis discloses that Figure 1 depicts multilayer film 10 that “may have any number of one or more layers and that the six-layered film depicted in FIG. 1 is shown for purposes of example.” Ex. 1004 ¶ 135. As noted by Petitioner’s expert, an ordinary artisan “would understand that Riis discloses the optional nature of the exterior protective layer and associated adhesive layer” and thus “would understand that Riis discloses leaving off the exterior protective layer and second intermediate adhesive layer from the film [], leaving only a film consisting of a barrier layer consisting of aluminum foil and a three-layer coextrusion of LDPE and EAA tie layers and a COC contact layer.” Ex. 1037 ¶¶ 88–89.

wherein the aggressive chemical-resistant film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, and lidocaine

Proposed substitute claim 14 changes “or” to “and” for the list of chemicals to which the film is resistant. Petitioner asserts that this amendment “does not change the scope of the claim” and the “mere change of the disjunctive ‘or’ to the conjunctive ‘and’ does not limit or alter the apparent Markush grouping that requires chemical resistance to only ‘a chemical’ selected from the recited chemicals.” Opp. 11–12. Petitioner asserts, moreover, that even if all the recited chemicals are required, it would have been obvious to modify the method of Riis “with Tohara’s resistance to rivastigmine, because Tohara provides the suitability of using a COC contact layer, like those commercially available

from Topas, to package such products,” consistent with the disclosure of Riis. *Id.* at 14–15 (citing Ex. 1033 ¶¶ 87–89, 94, 95, 102 (disclosing COCs commercially available from Topas); Ex. 1004 ¶¶ 52, 54, 97 (recommending commercially available COCs from Topas)).

At this preliminary stage of the proceeding, we agree with Petitioner. “Treatment of claims reciting alternatives is not governed by the particular format used (e.g., alternatives may be set forth as ‘a material selected from the group consisting of A, B, and C’ or ‘wherein the material is A, B, or C’). MPEP 2117 (citing *Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications*, 76 Fed. Reg. 7162 (February 9, 2011)); *see also* MPEP 2173.05(h). Thus, as noted by Petitioner’s expert, this recitation requires “chemical-specific resistance to only one chemical of the identified chemicals.” Ex. 1037 ¶ 93. Nonetheless, even if all chemicals are required, Tohara discloses “a cyclic polyolefin (hereinafter, also referred to as ‘COC’) film capable of suppressing the adsorption of lidocaine *or* rivastigmine.” Ex. 1033 ¶ 89 (emphasis added); Ex. 1037 ¶ 97. We agree with Petitioner’s expert that because both Riis and Tohara disclose COC for suppressing adsorption of lidocaine and Tohara discloses rivastigmine as an alternative to lidocaine, an ordinary artisan “would reasonably expect that incorporating Tohara’s teachings regarding resistance to rivastigmine into the method of fabricating a laminate of Riis (and Wypych) would be successful.” Ex. 1037 ¶ 99.

Claim 15

Claim 15 depends from claim 14 and is a proposed substitute for claim 10, and the proposed amendment recites “further comprises laminating, after the aggressive chemical-resistant film is formed by coating the coextrusion layer to the base layer consisting of the aluminum, a first outer layer to the base layer of the aggressive chemical-resistant film.” Mot. 27.

Petitioner asserts that “Riis teaches exemplary methods of forming a film, such as coextrusion coating a sealant film (the claimed coextrusion layer) to the aluminum foil surface (barrier/base layer) of a base film that includes outer protective layers,” and explains that the exemplary embodiments “do not require the recited steps to be performed in that order, and, as such, possible alternatives are not expressly precluded.”

Opp. 15 (citing Ex. 1004 ¶¶ 48, 160–174). According to Petitioner, an ordinary artisan “would have been motivated to laminate an outer protective and accompanying adhesive layer to the sealant film of Riis, since Riis does not attribute any particularity to the order disclosed.” *Id.* at 16 (citing Ex. 1037 ¶¶ 107–109).

At this preliminary stage of the proceeding, we agree with Petitioner. As Petitioner’s expert notes, “the ’624 Patent does not attribute any new or unexpected results to the order of laminating the outer protective layers to the film and merely identifies three alternative permutations: ‘the first outer layer and the base layer side may be laminated together before, during, or after the coextrusion layer is applied/coated to the base layer.’” Ex. 1037 ¶ 107 (citing Ex. 1001, 13:51–60). We agree with Petitioner’s expert that because there are a “limited number of possibilities coupled with Riis’s disclosures that the methods of manufacture are not limited in any one order or aspect,” an ordinary artisan “would find it obvious to laminate a first outer layer to the aluminum barrier layer after the three-layer EAA, LDPE, and COC sealant film has been coextrusion coated to the opposite side of the aluminum barrier layer” as a “matter of design choice.” *Id.* ¶ 109; *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.”).

Claim 19

Claim 19 depends from claim 14 and is a proposed substitute for claim 9, and the proposed amendment recites, “wherein coating the coextrusion layer to the base layer comprises performing a coextrusion coating of the coextrusion layer directly to the base layer consisting of the aluminum.” Mot. 28.

Petitioner asserts that because “Riis discloses coextruding a sealant film (EAA, LDPE, COC) onto the surface of the aluminum foil barrier (base) layer,” as recited in claim 14, Riis also “discloses coextruding the coextrusion layer directly to the base layer consisting of aluminum.” Opp. 22 (citing Ex. 1004 ¶¶ 135, 157, 174).

At this preliminary stage of the proceeding, we agree with Petitioner. Riis discloses that “the sealant film was a three-layer coextrusion of EAA, LDPE and Ethylene-norbornene copolymer (COC)

which was extrusion coated onto the aluminum foil surface of the multilayer base film.” Ex. 1004 ¶ 174. Because Riis’s coextrusion layer is “coated *on to* the aluminum foil surface,” we understand the coextrusion layer to be coated “directly to the base layer consisting of the aluminum,” as recited in claim 19. *See* Ex. 1037 ¶ 89.

Claim 20

Claim 20 depends from claim 14 and is a proposed substitute for claim 11, and the proposed amendment recites, “the chemical is provided in a first patch, and the aggressive chemical-resistant film is resistant to the chemical based at least in part on allowing 90% to 110% of the chemical in the first patch to migrate into a first pouch formed by the aggressive chemical-resistant film relative to an amount of the chemical in a second patch allowed to migrate into a second pouch formed by a second film comprising a contact layer that comprises Barex®.”⁷ Mot. 28–29.

Petitioner asserts that Riis discloses the “newly added limitations to substitute claim 20,” because “Riis discloses that the package formed by its inventive film can be used to contain, for example, a transdermal drug delivery patch” and “discloses an aggressive chemical-resistant film that allows 90–110% migration of the chemical when compared with Barex®.” Opp. 23 (citing Ex. 1004 ¶¶ 2, 4, 55, 91–92, 114, 122, 137, 160, 174, 178–181). Specifically, as to the latter limitation, Petitioner asserts, “Riis discloses a range of 0–15% of chemical migration as compared to a similar Barex® product contacting layer,” which meets “the claimed migration of 90–110% when compared to Barex® as an index 100.” *Id.* at 24.

⁷ As discussed *infra*, although we agree that using the trademark Barex® renders claim 20 indefinite, because both Patent Owner and Petitioner (by applying Riis) refer to Barex® as a polyacrylonitrile manufactured by Ineos, for purposes of this preliminary guidance only, we treat these films as being the same film, in order to have a basis to compare claim 20 to Riis. *Compare* Ex. 1001, 1:58–62 (“A known polymer that fulfils the requirements of extreme chemical resistance and inert properties is a polyactyllonitrile [sic] (PAN) based film, which is sold for example as resins under the trademark Barex®, which is manufactured for example by the company Ineos.”) *with* Ex. 1004 ¶ 4 (“A common material employed for transdermal patch package interior surface layers that prevents scalping is polyacrylonitrile which is often sold under the Barex® trademark by Ineos AG).

At this preliminary stage of the proceeding, we agree with Petitioner. Riis discloses: “Typical contents for various embodiments of the inventive container may include, for example, transdermal patches, thin strips of dissolvable material for oral administration, as well as articles for collecting or administering a physiologically active substance e.g. a microdiffusion cassette.” Ex. 1004 ¶ 92. Riis also discloses that a layer is considered effective if “an amount of the active agent migrates into the product contacting layer of the film (the test film) is not more than 15% greater than migrates into a substantially similar film having a Barex® product contacting layer (the reference film) when a product containing the pharmaceutical active agent is positioned relative to the test and reference films.” *Id.* ¶ 129. We credit Petitioner’s expert’s opinion that an ordinary artisan “would understand that 10% difference range disclosed by Riis is equivalent to a range of allowing 90–110% migration as compared to the original amount of chemical present in the contained patch product,” and thus, we agree that “Riis teaches the [claimed] ranges based upon the same comparison [that] allow no more than 10% of chemical migration.” Ex. 1037 ¶ 163 (citing Ex. 1004 ¶ 132).

For these reasons, it appears that Petitioner and the record as a whole establish a reasonable likelihood that proposed substitute claims 14, 15, 19, and 20 would have been obvious over Riis, Wypych, and Tohara.

Asserted Obviousness of Proposed Substitute Claims 16, 17, and 21 Based on Riis, Wypych, Tohara, and Holzmuller

On the present record, Petitioner has shown a reasonable likelihood that proposed substitute claims 16, 17, and 21 are unpatentable as obvious over Riis, Wypych, Tohara, and Holzmuller. *See* Opp. 16–20, 24–25.

Claim 16

Claim 16 depends from claim 14 and is a proposed substitute for claim 6, and the proposed amendment recites, “wherein a loading of a first layer of the tie layer is in the range of 7 to 18 g/m² and a loading of a second layer of the tie layer is in the range of 7 to 18 g/m².” Mot. 27.

Petitioner asserts that Riis discloses one of its “tie layer as falling within the range of 7–18 g/m²” and that it would have been obvious to “optimize the interacting thicknesses of the layers of the tie layer to promote adhesion of layers and to prevent undesirable lamination through routine experimentation.” Opp. 16–17 (citing Ex. 1004 ¶ 20; Ex. 1037

¶¶ 115–117, 126, 127). According to Petitioner, “Holzmuller teaches the need to balance various properties of laminates” and “teaches various ranges of thicknesses for such bonding layers to achieve laminates with improved” properties, including “ranges that encompass the newly claimed ranges.” *Id.* at 17–18 (citing Ex. 1034 ¶¶ 3, 4, 7, 18–20, 23; Ex. 1037 ¶¶ 118–125). Petitioner contends that an ordinary artisan would have been “motivated to optimize Riis’s intermediate tie layers to achieve desired additive effects and would have had a reasonable expectation of success in doing so due to the similarity in structure, function, and polymeric materials considered by both Riis and Holzmuller.” *Id.* at 18–19 (citing Ex. 1037 ¶¶ 115–117, 126, 127). Petitioner contends, moreover, that because “Patent Owner has neither shown evidence nor alleged that the newly claimed range in substitute claim 16 is critical,” the claimed ranges would have been obvious “as a matter of design choice.” *Id.* at 19 (citing *In re Aller*, 220 F.2d 454, 456 (CCPA 1955)); Ex. 1037 ¶¶ 128–130).

At this preliminary stage of the proceeding, we agree with Petitioner. As Petitioner’s expert explains, loading is determined “by multiplying the thickness of the layer by the mass density to yield an area density.” Ex. 1037 ¶ 119 (citing Ex. 1003 ¶ 152). Based on this methodology, we agree with Petitioner’s expert that “Holzmuller’s preferred and especially preferred ranges overlap substantially with the new claimed range recited in Substitute Claim 16.” *Id.* ¶ 125. Our reviewing Court has held that in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *Wertheim*, 541 F.2d at 267. Because the films of Riis and Holzmuller are similar in structure, function, and polymeric materials considered, we agree with Petitioner’s expert that an ordinary artisan “would have a reasonable expectation of success in implementing Holzmuller’s teachings into the method of providing a film with the combination of Riis, Wypych, and Tohara” and “that absent any criticality, the specific dimensional ranges in Substitute Claim 16” would have been obvious. *Id.* ¶¶ 127, 130.

Claim 17

Claim 17 depends from claim 14 and is a proposed substitute for claim 7, and the proposed amendment recites, “wherein a loading of a first layer of the plurality of layers is in the range of 7 to 14 g/m² and a loading

of a second layer of the plurality of layers is in the range of 7 to 14 g/m².” Mot. 27.

Petitioner asserts that claim 17 further narrows the claimed loading ranges, and as discussed for claim 16, “Holzmuller teaches loading ranges that encompass the newly claimed ranges.” Opp. 20.

At this preliminary stage of the proceeding, we agree with Petitioner. As discussed above for claim 16, we agree with the methodology for determining the loading ranges as posited by Petitioner’s expert. *See* Ex. 1037 ¶ 133. Using this methodology, we agree with Petitioner’s expert that Holzmuller’s “ranges overlap substantially with the new claimed range recited in Substitute Claim 17.” Ex. 1037 ¶ 146. Thus, we agree with Petitioner’s expert’s conclusion “that absent any criticality, the specific dimensional ranges in Substitute Claim 17 are obvious,” at least “because such ranges were known in the prior art of Holzmuller.” *Id.* ¶ 149.

Claim 21

Proposed substitute independent claim 21 is a proposed substitute for claim 13. Mot. 29. Patent Owner and Petitioner agree that “Substitute independent claim 21 recites similar features to those discussed above” for claims 14 and 17. Mot. 24; Opp. 25. Specifically, claim 21 requires that the base layer “consists of” aluminum as opposed to the previously recited “comprises,” changes the listing of chemical resistant films to be grouped using “and” instead of “or,” and changes the loading range from “7 to 14 g/m²” from “7 to 20 g/m².” Mot. 29.

Petitioner asserts that because claim 21 includes the same limitations as “discussed above for substitute claims 14 and 17,” the combination of “Riis, Wypych, Tohara, and Holzmuller render this claim obvious” for the same reasons. Opp. 25.

At this preliminary stage of the proceeding, we agree with Petitioner. Because Patent Owner and Petitioner agree that substitute claim 21 recites similar features to those discussed above for claims 14 and 17, Petitioner has shown a reasonable likelihood that proposed substitute claim 21 would have been obvious over Riis, Wypych, Tohara, and Holzmuller for the reasons noted above for claims 14 and 17.

For these reasons, it appears that Petitioner and the record as a whole establish a reasonable likelihood that proposed substitute claims 16,

17, and 21 would have been obvious over Riis, Wypych, Tohara, and Holzmüller.

Asserted Obviousness of Proposed Substitute Claim 18 Based on Riis, Wypych, Tohara, and Rivers

On the present record, Petitioner has shown a reasonable likelihood that proposed substitute claim 18 is unpatentable as obvious over Riis, Wypych, Tohara, and Rivers. *See* Opp. 20–22.

Claim 18 depends from claim 14 and is a proposed substitute for claim 8, and recites “the aggressive chemical-resistant film is resistant to the chemical based at least in part on allowing less than 10% of the chemical to migrate into the aggressive chemical-resistant film.” Mot. 28.

Petitioner asserts that Riis’s COC contact layers “prevent migration of ‘any suitable pharmaceutical active agent,’” but “Riis does not specifically disclose percentages of API migration.” Opp. 20–21 (citing Ex. 1004 ¶¶ 8–9). Nonetheless, Petitioner asserts that “Rivers teaches that packaging films using COCs as product contact layers allow for as little as 1% scalping of a packaged product.” *Id.* at 21 (citing Ex. 1035, 4:13–5:2, 8:32–9:12, 9:31–10:3 (defining scalping), 25:1–31). According to Petitioner, an ordinary artisan “would have had a reasonable expectation of success in looking to Rivers to verify such anti-scalping properties since both Riis and Rivers are similarly directed to multilayer films used to package volatile products susceptible to degradation and adsorption.” *Id.* at 21–22 (citing Ex. 1037 ¶¶ 152–155; Ex. 1004 ¶ 55; Ex. 1035, 25:1–31, 26:16–27:5). Based on this, Petitioner concludes that “substitute claim 18 is rendered obvious by the combination of Riis, Wypych, and Rivers.” *Id.* at 22.

At this preliminary stage of the proceeding, we agree with Petitioner. As Petitioner’s expert notes, Riis and Rivers are each “directed to multilayer films used to package volatile products susceptible to degradation and adsorption, with both Riis and Rivers teaching the use of COC contact layers as advantageous for such purposes.” Ex. 1037 ¶ 155 (citing Ex. 1004 ¶¶ 6, 55; Ex. 1035, 4:13–5:2, 25:1–31, 26:16–27:5). Given these similarities, we agree with Petitioner’s expert that an ordinary artisan would have been motivated to modify “Riis by looking to the teachings of Rivers which express the degree of anti-scalping in absolute terms of allowable percentages of chemical migration,” and “would have [had] a reasonable expectation of success” in doing so. *Id.* at ¶¶ 154–155.

For these reasons, it appears that Petitioner and the record as a whole establish a reasonable likelihood that proposed substitute claim 18 would have been obvious over Riis, Wypych, Tohara, and Rivers.

Asserted Indefiniteness of Proposed Substitute Claims 16, 17, 20, and 21

On the present record, Petitioner has not shown a reasonable likelihood that proposed substitute claims 16, 17, and 21 are unpatentable as indefinite, but has shown a reasonable likelihood that proposed substitute claim 20 is unpatentable as indefinite.

Claims 16, 17, and 21

Petitioner asserts that “Claims 16–17 and 21 are indefinite for all the reasons discussed above regarding the failure of the ’624 Patent’s original disclosures to adequately support the new and more narrow ranges proposed in the substitute claims.” Opp. 6. We disagree.

The Supreme Court interprets the definiteness requirement of 35 U.S.C. § 112(b) “to require that a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014); *see also In re Packard*, 751 F.3d 1307, 1311 (Fed. Cir. 2014) (holding a claim is indefinite when it contains words or phrases whose meaning is “unclear in describing and defining the claimed invention”). “The claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014). That is, “the dispositive question in an indefiniteness inquiry is whether the ‘claims,’ not particular claim terms” satisfy the definiteness standard. *Cox Commc’ns, Inc. v. Sprint Commc’n Co.*, 838 F.3d 1224, 1231 (Fed. Cir. 2016).

Here, claim 16 recites a range of 7 to 18 g/m² and claims 17 and 21 recite a range of 7 to 14 g/m². Mot. 27, 29. Because an ordinary artisan would understand that the lower limit to these claims is 7 g/m² and the upper limit is 18 g/m² for claim 16 and 14 g/m² for claims 17 and 21, the ordinary artisan would know whether the loading of the layer in question is within that range, and thus the claims inform the scope of the invention with reasonable certainty.

Claim 20

Claim 20 is a proposed substitute for claim 11 and the proposed amended limitation recites, “the chemical is provided in a first patch, and the aggressive chemical-resistant film is resistant to the chemical based at least in part on allowing 90% to 110% of the chemical in the first patch to migrate into a first pouch formed by the aggressive chemical-resistant film relative to an amount of the chemical in a second patch allowed to migrate into a second pouch formed by a second film comprising a contact layer that comprises Barex®.” Mot. 28–29.

The MPEP states that if “the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph.” MPEP 2173.05(u) (citing *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982)); *see also Eli Lilly & Co. v. Apotex, Inc.*, 837 Fed. Appx. 780, 784–85 (Fed. Cir. 2020). As discussed above, the ’624 patent discloses the trademark Barex® is a polyacrylonitrile (PAN) based film, which is sold for example as resins manufactured by Ineos. Ex. 1001, 1:58–62. Because Barex® is used to identify a particular product, namely, a specific PAN based film, it does not comply with 35 U.S.C. § 112(b).

Based on the assumptions described above, at this preliminary stage of the proceeding, it appears that Petitioner has shown a reasonable likelihood that proposed substitute claims 14–21 are unpatentable.

III. CONCLUSION

This concludes the Preliminary Guidance, which is Patent Owner’s first option under the Board’s pilot program. Notice, 84 Fed. Reg. at 9,497. Patent Owner has an additional option under the Board’s pilot program to file a revised motion to amend by DUE DATE 3. Paper 15.

In addition to those two options under the Board’s pilot program, Patent Owner is reminded that amendments of the challenged claims may also be pursued in a separate reissue or reexamination proceeding before, during, or after an AIA trial proceeding, including subsequent to the issuance of the Final Written Decision. We draw Patent Owner’s attention to the April 2019 *Notice Regarding*

Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See 37 C.F.R. § 42.8(a)(3), (b)(2).*

PGR2023-00008
Patent 11,260,624 B2

FOR PETITIONER:

Ryan D. Levy
Seth R. Ogden
Mark A. Kilgore
Samuel A. Raque
PATTERSON INTELLECTUAL PROPERTY LAW, P.C.
rdl@iplawgroup.com
sro@iplawgroup.com
mak@iplawgroup.com
sar@iplawgroup.com

FOR PATENT OWNER:

Steven Avena
HOLLAND & HART LLP
saavena@hollandhart.com