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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

METRICS, INC., MAYNE PHARMA, and JOHNSON MATTHEY, INC.,
Petitioner,

v.

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB, INC., and
BAUSCH & LOMB PHARMA HOLDINGS CORP.,
Patent Owner.

Case IPR2014-01041
Patent 8,129,431 B2

Before FRANCISCO C. PRATS, ERICA A. FRANKLIN, and
GRACE KARAFFA OBERMANN, *Administrative Patent Judges.*

OBERMANN, *Administrative Patent Judge*.

DECISION
Instituting *Inter Partes* Review
37 C.F.R. § 42.108

I. BACKGROUND

Petitioner requests an *inter partes* review of claims 1–22 of U.S. Patent No. 8,129,431 B2 (Ex. 1001, "the '431 patent"). Paper 9 ("Pet."). Patent Owner filed a Preliminary Response. Paper 13 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter*

partes review may be instituted upon a showing of "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Petitioner makes that showing with respect to claims 1–22; therefore, we institute review as to those claims.

We authorized, and the parties filed, additional briefing on the issue whether the Petition identifies all real parties-in-interest as required by 35 U.S.C. § 312(a)(2). Paper 15 ("Pet. Opp."); Paper 17 ("PO Reply").

Our findings of fact and conclusions of law, including those relating to the Petition's identification of all real parties-in-interest, are based on the record developed thus far, prior to Patent Owner's Response. This is not a final decision as to the patentability of any challenged claim. Our final decision will be based on the full record developed during trial.

A. Related Proceedings

The '431 patent is the subject of two district court actions. *Senju Pharmaceutical Co. v. Lupin, Ltd.*, C.A. No. 1:14-CV-00667-MAS-LHG (D.N.J.); *Senju Pharmaceutical Co. v. Metrics, Inc*, C.A. No. 1:14-cv-03962-JBS-KMW (D.N.J.); *see* Pet. 12.

Concurrently herewith, we issue a decision to institute in IPR2014-01043, involving the same parties and directed to U.S. Patent No. 8,669,290 B2, which claims priority to the '431 patent.

B. The '431 Patent

The '431 patent relates to an aqueous liquid preparation consisting essentially of two components: (1) bromfenac (or its salts and hydrates); and (2) tyloxapol. Ex. 1001, 11:66–12:10 (independent claim 1). Bromfenac is a non-steroidal anti-inflammatory drug ("NSAID") and tyloxapol serves as a non-ionic surfactant, or stabilizer, in the preparation

recited in the challenged claims. *Id*. at 1:24–47, 2:34–49, 4:37–41. The '431 patent discloses a preparation useful for ophthalmic administration, such as an eye drop to treat blepharitis, conjunctivitis, scleritis, and postoperative inflammation. Ex. 1001, Abstract. The '431 patent discloses that the preparation also is useful as a nasal drop for treatment of allergic rhinitis and inflammatory rhinitis. *Id*.

According to the '431 patent, an object of the invention is to provide an aqueous liquid preparation of bromfenac that "is stable within a pH range giving no irritation to eyes" when preserved with a quaternary ammonium compound, such as benzalkonium chloride ("BAC"). *Id*. at 2:14–22. Petitioner contends, and Patent Owner does not contest at this stage of the proceeding, that NSAIDs were known to interact with BAC to form insoluble complexes, which reduce the stability of the ophthalmic preparation, by rendering the preservative (BAC) less available to serve its function. Pet. 23 (citing Ex. 1003 ¶ 31). The inventors claim to have discovered that addition of an alkyl aryl polyether alcohol type polymer, such as tyloxapol, provides the sought-after stability, giving no irritation to the eyes. Ex. 1001, 2:35–49.

C. Illustrative Claim

Petitioner seeks *inter partes* review of claims 1–22 of the '431 patent. Independent claim 1 is illustrative of the subject matter and is reproduced below.

> 1. An aqueous liquid preparation consisting essentially of the following two components, wherein the first component is 2-amino-3-(4-bromobenzoyl)-phenylaceticacid or a pharmacologically acceptable salt thereof or a hydrate thereof, wherein the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate, and 3/2

> hydrate and the second component is tyloxapol, wherein said liquid preparation is formulated for ophthalmic administration, and wherein when a quaternary ammonium compound is included in said liquid preparation, the quaternary ammonium compound is benzalkonium chloride.

Ex. 1001, 11:66–12:10.

D. Prior Art Relied Upon

Petitioner relies upon the following prior art references:

Owaga, U.S. Patent No. 4,910,225, issued Mar. 20, 1990 (Ex. 1004) ("Owaga").

Sallmann *et al.*, U.S. Patent No. 6,107,343, issued Aug. 22, 2000 (Ex. 1009) ("Sallmann").

Fu, AU-B-22042/88, issued Mar. 16, 1989 (Ex. 1011 ("Fu").

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–22 of the '431patent on the grounds set forth in the chart below. *See* Pet. 18–19, 43–46.[1] Petitioner also relies on a declaration of Dr. Uday B. Kompella. Ex. 1003.[2]

[1] Petitioner's identification of challenged claims in its chart of grounds (Pet. 18–19) differs from the arguments presented in support of the challenges (*see* Pet. 43–46). We identify the challenged claims based on the arguments presented in the Petition.

[2] Dr. Kompella has a Ph.D. in Pharmaceutical Sciences and has significant experience, as a tenured professor, researcher, and author, in the field of ophthalmology and ophthalmic preparations. Ex. 1003 ¶¶ 12–17. He appears on this record to have the requisite familiarity with ophthalmic preparations to opine on the views of a hypothetical person of ordinary skill

References	Basis	Claims Challenged
Owaga and Sallmann	§ 103	1–5, 7–14, and 18–19
Owaga, Sallmann, and Fu	§ 103	6, 15–17, and 20–22

II. ANALYSIS

A. Threshold Issues Under 35 U.S.C. §§ 312 (a)(2), 315(a)(1)

We first address two threshold issues raised by Patent Owner: (1) whether the Petition identifies all real parties-in-interest, as required under 35 U.S.C. § 312(a)(2); and (2) whether Petitioner is barred from pursuing an *inter partes* review under 35 U.S.C. § 315(a)(1).

i. Real Parties-in-Interest under 35 U.S.C. § 312(a)(2)

Patent Owner contends that the filing date of the Petition should be vacated because the Petition does not identify all real parties-in-interest, as required by 35 U.S.C. § 312(a)(2). Prelim. Resp. 14–20. The gravity of that contention, and its potential ramifications, prompted us to authorize further briefing on the issue. We may consider a petition for *inter partes* review only if it identifies all real parties-in-interest. 35 U.S.C. § 312(a)(2).

Patent Owner argues that Coastal Pharmaceuticals, Inc. ("Coastal") is an unidentified real party-in-interest in this proceeding. Prelim. Resp. 1. On that point, Patent Owner contends that Coastal filed, "on [Petitioner's] behalf," a certification with the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"). *Id*. Patent Owner states that Petitioner's "arguments in the

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in the art at the time of the invention. *See id*. At this stage of the proceeding, we find his testimony credible and persuasive.

[P]etition are copies of those in Coastal's Paragraph IV Notice Letter," which "issued [on] the same day by the same counsel" as the Petition. *Id*. at 2; *see id*. at 15–16 (citing Ex. 2001) (comparing pages A-2–A-30 in that letter with pages 1–55 in the Petition). Patent Owner also argues that Petitioner "conceded in district court that [Petitioner] and Coastal are in privity and that any judgment reaching one would reach the other." *Id*. at 2; *see id*. at 16–17 (citing Ex. 2003, 4–5; Ex. 2004, 30–31).

Petitioner responds that Coastal is no more than "a business name" for Petitioner. Pet. Opp. 1. Petitioner argues that its "assumed name" is not a juridical entity apart from Petitioner; therefore, Coastal cannot be considered a separate real party-in-interest. *Id*. at 5 (citing Ex. 1054, "Corporate Certificate of Assumed Name"). In fact, Petitioner comes forward with persuasive evidence that, prior to the filing of the Preliminary Response in this proceeding, counsel for Patent Owner admitted in district court that Coastal and Petitioner are "one and the same" juridical party. *Id*. at 5–6 (citing Ex. 1056, 30:2-23) (transcript of proceeding in New Jersey action).

Petitioner argues, persuasively, "that it would be 'nonsensical' to maintain an action against both a legal entity and its assumed name." Pet. Opp. 8 (citing *Pinkerton's, Inc. v. Superior Court*, 57 Cal. Rptr.2d 356, 360 n.1 (Cal. Ct. App. 1996)). As Petitioner points out, where Samuel Clemens is dismissed from a case, a plaintiff cannot continue to pursue the action against Mark Twain. *Id*. (quoting *Pinkerton's, Inc*., 57 Cal. Rptr.2d at 357). In fact, because a business name is not a separate juridical entity, the district court in the related New Jersey action "dismissed and terminated the case against Coastal as a d/b/a." *Id*. at 4. "[I]n an effort to promptly resolve this issue," however, Petitioner is amenable to identifying itself as

"Metrics, Inc. d/b/a Coastal Pharmaceuticals" in this proceeding, provided that the Petition retains its original filing date. *Id*.

The evidence of record persuades us that the Petition and the Paragraph IV certification were filed by the same party (namely, Petitioner) on the same day, by the same counsel, and with what appear to be essentially the same arguments—yet Petitioner did not identify the Paragraph IV certification in the Petition. PO Reply 1–2. Although that action, on Petitioner's part, falls short of a model of candor, we are not persuaded that Petitioner was required to identify Coastal as a real party-in-interest in the Petition, based on the evidence presented at this stage of the proceeding.

Petitioner's counsel represents that Coastal is an "assumed name" of Petitioner. Pet. Opp. 5. Petitioner also comes forward with a copy of "a sworn affidavit," which was filed in the related district court litigation, wherein "Stefan Cross, President of Metrics," attests "that Coastal is not a recognized separate entity and is used in the marketplace to distinguish Metrics' contract services business segment from its pharmaceutical products business." Ex. 1055 ¶¶ 12–13; *see* Pet. Opp. 5–6 (quoting Ex. 1056, 30:2–23) (counsel for Petitioner, affirming in district court that Coastal "is not a juridical party, it's not anything other than a trade name").

We agree with Petitioner that "a corporate entity using a business name, or a d/b/a ('doing business as') name, does not create a legal entity in the name" that is "separate from the underlying corporate entity." Pet. Opp. 2; *see id*. at 8 (citing *Snowden v. CheckPoint Check Cashing*, 290 F.3d 631, 634–35 n.2 (4th Cir. 2002); *Pinkerton's, Inc.*, 57 Cal. Rptr.2d at 360 (citing consistent treatment of business names from different jurisdictions)). "The business name is a fiction, and so too is any implication that the business is a

legal entity separate from its owner." *Pinkerton's, Inc.*, 57 Cal. Rptr.2d at 360 (quotations omitted). Accordingly, based on the record developed thus far, we determine that Coastal is not a separate juridical entity or, therefore, a separate real party-in-interest in this proceeding.

Any collateral estoppel effect that arises from our Final Written Decision will bind Petitioner, whether operating as Metrics or under its business name, Coastal. Petitioner, therefore, is not required to file an updated mandatory notice, correcting the real party-in-interest. Based on the information presented thus far, we decline to vacate the filing date accorded the Petition.

ii. Paragraph IV Certification as an "Effective" Declaratory Judgment Action under 35 U.S.C. § 315(a)(1)

Petitioner filed the Paragraph IV certification and, thereby, challenged the validity of the '431 patent prior to the filing of the instant Petition. Prelim. Resp. 12. Patent Owner argues that the filing of that Paragraph IV certification was "the full functional equivalent of initiating a declaratory judgment action and should be viewed as foreclosing" Petitioner's access to an *inter partes* review. Prelim. Resp. 12 (citing 35 U.S.C. § 315(a)(1)). We disagree. Our governing statute states, in relevant part:

> (1) INTER PARTES REVIEW BARRED BY CIVIL ACTION.—An inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

35 U.S.C. § 315(a)(1).

When the statute refers to filing a civil action, it refers to filing a complaint with a court to commence a civil action. *See, e.g., Baldwin Cnty. Welcome Ctr. v. Brown*, 466 U.S. 147, 149 (1984) (a civil action is brought

upon filing a complaint with a court); *Ariosa Diagnostics v. Isis Innovation Ltd.*, Case IPR2012-00022, slip op. at 4–5 (PTAB Feb. 12, 2013)(Paper 20) (citing *Baldwin*, 466 U.S. at 149). Petitioner's act of initiating a challenge to patent validity, by filing of a Paragraph IV certification with the FDA, did not involve filing of a complaint with a court. A Paragraph IV certification may represent an out-of-court challenge to patent validity, but it does not constitute "a civil action challenging the validity of" any patent claim. 35 U.S.C. § 315(a). Thus, Petitioner's action of filing a Paragraph IV certification does not bar institution of the present Petition under 35 U.S.C. § 315(a). We have considered, but find unpersuasive, Patent Owner's arguments that a perceived conflict between the America Invents Act and the Hatch-Waxman Act compels a different result. Prelim. Resp. 4–14.

On this record, we determine that the Petition is not time-barred under 35 U.S.C. § 315(a)(1).

B. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Claim terms are given their ordinary and customary meaning, as 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). If an inventor acts as his or her own lexicographer, the definition must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). The construction that stays

true to the claim language, and most naturally aligns with the inventor's description, is likely the correct interpretation. *Id.* at 1250.

At this stage of the proceeding, we determine that the claim terms are clear on their face, and none is specially defined in the written description of the '431 patent. No claim term requires express construction for the purposes of this decision. We observe, however, that, notwithstanding Patent Owner's arguments to the contrary, both parties acknowledge that the phrase "consisting essentially of," which appears, for example, in claim 1, has a well-defined meaning in patent law; and that the transitional phrase excludes unrecited ingredients that materially affect the composition. *See, e.g.*, Pet. 3, 14 (correctly stating that definition); Prelim. Resp. 3 (arguing that "the petition misstates or ignores" that transitional phrase); *PPG Indus. Inc. v. Guardian Indus. Corp*, 156 F.3d 1351, 1354 (Fed. Cir. 1998) ("By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.").

C. The Applied Prior Art

We next turn to the prior art references raised in the Petition and, in particular, to our analysis of what those references convey about the state of the art at the time of the invention of the '431 patent.[3] We discuss facts as

[3] Patent Owner argues that the Petition fails to include "[a] full statement of the reasons for the relief requested," because the Petition advances additional prior art references, outside of those identified in the stated grounds of unpatentability. Prelim. Resp. 37 (quoting 37 C.F.R. § 42.22 (a)(2)); *see id*. at 26 n.4 (citing 37 C.F.R. §§ 42.104(b)(2), (b)(4)). We limit our analysis to "patents or printed publications" identified in the Petition

presented thus far in the record. Any inferences or conclusions drawn from those facts are neither final nor dispositive of any issue.

i. Owaga and Sallmann

Petitioner shows sufficiently that Owaga's Example 6 discloses an aqueous liquid preparation consisting essentially of bromfenac (an NSAID), polysorbate 80 (a non-ionic surfactant), and BAC (a preservative)—and that the liquid preparation is formulated for ophthalmic administration. Pet. 21–22 (claim chart for claim 1); Ex 1004, 10:5–18 (for aqueous liquid preparation), 10:5–9 (for bromfenac and polysorbate 80).

Petitioner also shows sufficiently that Sallmann's Example 2 discloses an aqueous liquid preparation consisting essentially of diclofenac (an NSAID), tyloxapol (a non-ionic surfactant), and BAC (a preservative)—and that the liquid preparation is formulated for ophthalmic administration. Pet. 21–22 (claim chart for claim 1); Ex 1009, 8:1–15 (for aqueous liquid preparation), 8:1–10 (for diclofenac and tyloxapol); Ex. 1003 ¶ 54.

We are persuaded, based on the information presented, that Owaga discloses every element of claim 1, but for the use of tyloxapol as the non-ionic surfactant—Owaga discloses polysorbate 80 for that function. Sallmann, by contrast, discloses every element of claim 1, but for the use of bromfenac as the NSAID—Sallmann discloses diclofenac for that function.

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with particularity for each ground; here, that is a first ground based on Owaga and Sallmann, and a second ground based on Owaga, Sallmann, and Fu. 37 C.F.R. § 42.104(b)(2); *see* 35 U.S. C. § 312 (a petition must identify "with particularity . . . the grounds on which the challenge to each claim is based").

That sets up the central dispute, at this early stage of the proceeding, which is whether Petitioner shows sufficiently that a person of ordinary skill in the art would have been prompted to (1) modify the ophthalmic preparation of Owaga's Example 6, by replacing polysorbate 80 with tyloxapol; or, alternatively, (2) modify the ophthalmic preparation of Sallmann's Example 2, by replacing diclofenac with bromfenac. Either substitution results in a preparation that satisfies every limitation of claim 1.

ii. Fu

The second ground asserted in the Petition relies on Owaga and Sallmann in combination with Fu. Pet. 19, 43–46. Petitioner shows sufficiently that Fu discloses that ophthalmic preparations of NSAIDs and BAC, which contain octylphenols (the class to which tyloxapol belongs) as the non-ionic surfactants, are more stable than those containing polysorbate 80 as the non-ionic surfactant. Ex. 1011, Example 5; Ex. 1003 ¶¶ 33, 64. Fu discloses that the non-ionic surfactant will stabilize an ophthalmic preparation of an NSAID and BAC, when included in a weight-volume percent of 0.02. Ex. 1011, 18:5–28, Example 2, Example 5; Ex. 1003 ¶¶ 75, 93. That disclosure bears upon the dependent claims, which require that "the concentration of the tyloxapol is about 0.02 w/v %." *See, e.g.*, Ex. 1001, 12:33–34 (claim 6), 13:23 (claim 15).

D. Analysis of Grounds of Unpatentability

We next turn to the two asserted grounds of unpatentability, which are based on obviousness over Owaga and Sallmann alone (for claims 1–5, 7–14 and 18–19) and in combination with Fu (for claims 6, 15–17, and 20–22). Pet. 19. Our inferences and conclusions are based on the information presented thus far, and are neither final nor dispositive of any issue. Based

on the information presented in the Petition and the Preliminary Response, we determine that Petitioner is reasonably likely to prevail in showing that (1) claims 1–5, 7–14 and 18–19 are unpatentable over Owaga and Sallmann under 35 U.S.C. § 103; and (2) claims 6, 15–17, and 20–22 are unpatentable over Owaga, Sallmann, and Fu under 35 U.S.C. § 103.

i. Claims 1–5, 7–14 and 18–19 over Owaga and Sallman

Petitioner shows sufficiently that Owaga's Example 6 discloses each element of claim 1, except that Owaga discloses polysorbate 80 as the non-ionic surfactant, whereas claim 1 recites tyloxapol for that function. Pet. 21–22 (claim chart for claim 1, and citations to record therein). Petitioner also shows sufficiently that an ordinary artisan, equipped with the disclosures of Owaga and Sallmann, would have recognized that tyloxapol and polysorbate 80 serve a common function in the art; both are useful as non-ionic surfactants for stabilizing an ophthalmic preparation of an NSAID and BAC. *See* Ex. 1003 ¶¶ 55–58.

In that regard, Sallmann discloses tyloxapol as a preferred non-ionic surfactant in an aqueous ophthalmic preparation of an NSAID and BAC. Ex. 1009, 4:62. Based on the record developed thus far, we are persuaded that, taken together, the disclosures of Owaga and Sallmann would have suggested to an ordinary artisan that either tyloxapol or polysorbate 80 would work to stabilize an ophthalmic preparation of an NSAID and BAC, by preventing the formation of the insoluble complexes that destabilize the preparation. *See* Ex. 1003 ¶¶ 31, 55–58.

A claim likely is obvious if it is no "more than the predictable use of prior art elements according to their established functions," even without an express suggestion to combine. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398,

417 (2007). Where two known alternatives are interchangeable for a desired function, an express suggestion to substitute one for the other is not needed to render a substitution obvious. *In re Fout*, 675 F.2d 297, 301 (CCPA 1982); *In re Siebentritt*, 372 F.2d 566, 568 (CCPA 1967). On this record, Petitioner shows sufficiently that a person of ordinary skill in the art would have expected that substituting tyloxapol, in place of polysorbate 80 in Owaga's Example 6, predictably would result in a stable ophthalmic preparation of bromfenac and BAC.

Patent Owner argues that test results presented in the '290 patent show that polysorbate 80 and tyloxapol, although useful for the common function of stabilizing BAC in a NSAID-containing ophthalmic preparation, nonetheless "were not interchangeable and [] the skilled person would not have substituted one for the other." Prelim. Resp. 28. In that regard, Patent Owner points out that, during patent prosecution, the Office was persuaded that information reflected in Table 1 of the '290 patent establishes "that tyloxapol has an unexpected property in stabilizing an aqueous solution of bromfenac in comparison with polysorbate 80." *Id*. (quoting Ex. 2005, 3–4) (emphasis omitted).

We are not persuaded, however, at this preliminary stage of the proceeding, that Table 1 is probative of secondary considerations of nonobviousness, that is, unexpected results. Ex. 1001, 7:40–55. On this record, the information in Table 1 is insufficient to establish unexpected results, because no comparison is made between the subject matter of the claimed invention and the closest prior art, that is, Owaga or Sallmann. *See* Pet. 51; Ex. 1003 ¶¶ 95–99. A comparison of the information in Table 1 with that in Table 2, moreover, suggests that another factor—a change in pH

from 7.0 in Table 1 to over 8.0 in Table 2—may influence stability. Ex. 1001, 7:40–55 (Table 1, reporting a stability for tyloxapol-containing preparation of 73.8% at pH of 7), 8:16–32 (Table 2, reporting a stability for tyloxapol-containing preparation of over 90% at pH of slightly over 8). Other evidence of record—specifically, Table 11 of Owaga—suggests that the information in Table 1 of the '431 patent, which persuaded the Examiner, is not reliable to establish unexpected results when tyloxapol is selected over polysorbate 80 in a preparation that contains the other elements of claim 1. *See* Ex. 1004, 10:49–52, Table 11 (reporting a stability of 100% for Owaga's Example 6 preparation, formulated with polysorbate 80).

In the alternative, we are persuaded that Petitioner is reasonably likely to prevail in showing that an ordinary artisan would have been led to substitute bromfenac for the diclofenac in the ophthalmic preparation of Sallmann's Example 2. Pet. 26–27 (citing Ex. 1003 ¶ 53); Ex. 1009, 8:1–15 (Sallmann's Example 2, disclosing an ophthalmic preparation that meets every limitation of claim 1, except that Sallmann uses diclofenac and not bromfenac as the NSAID). Sallmann in Example 2 discloses that diclofenac is suitable for use as the NSAID in an ophthalmic preparation of an NSAID and BAC. Ex. 1009, 8:1–15. Owaga in Example 6 discloses that bromfenac is suitable for use as the NSAID in an ophthalmic preparation of an NSAID and BAC. Ex. 1004, 10:5–9. At the time of the invention, bromfenac and diclofenac were known to share several structural features. Pet. 27; Ex. 1003 ¶¶ 24, 27.

Petitioner shows sufficiently that an ordinary artisan, equipped with the disclosures of Sallmann and Owaga, would have expected that diclofenac and bromfenac would work interchangeably in an ophthalmic

preparation of an NSAID and BAC. At this stage of the proceeding, we are persuaded that those disclosures would have led one to modify the preparation of Sallmann's Example 2, by using bromfenac as an interchangeable alternative to diclofenac, because both were known to serve the same function in an ophthalmic preparation. *See KSR Int'l Co.*, 550 U.S. at 417 (a claim likely is obvious if it is no "more than the predictable use of prior art elements according to their established functions").

On this record, Petitioner establishes also a reasonable likelihood of showing that the subject matter of claims 2–5, 7–14 and 18–19 would have been obvious over Owaga and Sallmann. Pet. 31–43, 47–50. Claim 18 is the only independent claim, other than claim 1. Ex. 1001, 13:16–14:9 (claim 18). Petitioner comes forward with evidence adequate to establish that the subject matter of claim 18 would have been obvious over Owaga and Sallmann, for the same reasons discussed above in connection with claim 1. Pet. 31–35. Petitioner also shows sufficiently that the dependent claims "merely recite concentrations or ranges of specific ingredients" that "the '431 patent characterizes as 'conventional.'" Pet. 35 (citing Ex. 1001, 6:11–31). Petitioner advances evidence adequate to establish that the additional features recited in the dependent claims add nothing of patentable consequence. Pet. 36–43, 47–50.

Accordingly, based on the information presented at this preliminary stage of the proceeding, Petitioner is reasonably likely to prevail in showing that claims 1–5, 7–14 and 18–19 are unpatentable over Owaga and Sallmann. Our findings and conclusions are not final and may change upon consideration of the whole record developed during trial.

ii. Claims 6, 15–17, and 20–22 over Owaga, Sallmann, and Fu

Petitioner is reasonably likely to prevail in showing that claims 6, 15–17, and 20–22 are unpatentable over Owaga, Sallmann, and Fu under 35 U.S.C. § 103. Those claims require a concentration of tyloxapol that "is about 0.02 w/v %." *See, e.g.*, Ex. 1001, 12:55 (claim 6); 13:2–3 (claim 15). Based on the record developed at this preliminary stage of the proceeding, we are persuaded the Petitioner comes forward with evidence sufficient to establish that a person of ordinary skill in the art would have been prompted by Fu to include tyloxapol, in a concentration of "about 0.02 w/v %," *id.*, in the modified composition of Owaga or Sallmann. Pet. 44–46.

Specifically, Petitioner shows sufficiently that Fu would have suggested to an ordinary artisan "that ophthalmic formulations of NSAIDs and BAC containing ethyoxylated octylphenols (the class that includes tyloxapol) as the non-ionic surfactant are more stable than those containing polysorbate 80 as the non-ionic surfactant." Pet. 46 (citing Ex. 1011, Example 5; Ex. 1003 ¶¶ 34–35, 75–76); Ex. 1011, 4. Furthermore, Fu suggests using that class of non-ionic surfactants in a concentration of 0.02 w/v % in the modified ophthalmic formulation" suggested by Owaga and Sallmann. *Id*. (citing Ex. 1011, 18:5–28, Example 2, Example 5; Ex. 1003 ¶¶ 75–76).

Moreover, it appears to us, at this stage of the proceeding, that it would have been within the grasp of an ordinary artisan to manipulate the concentration of tyloxapol in the modified preparation of Owaga or Sallmann "to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456–57 (CCPA 1955) ("where the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation").

Here again, our findings and conclusions are not final and may change upon consideration of the whole record developed during trial. Based on the information presented at this early stage of the proceeding, however, we are persuaded that Petitioner is reasonably likely to prevail in showing that claims 6, 15–17, and 20–22 are unpatentable over Owaga, Sallmann, and Fu.

E. Patent Owner's Other Arguments

We have considered each counterargument presented in Patent Owner's Preliminary Response. At this early stage of the proceeding, however, none persuades us to deny the Petition. We discuss some of those arguments below, observing that our factual findings and conclusions of law are not final at this preliminary stage of the proceeding.

i. Multiple Proceedings under 35 U.S.C. § 325(d)

We have considered Patent Owner's suggestion that we should exercise our discretion to deny the Petition because it raises substantially the same arguments or prior art that were raised during patent prosecution. Prelim. Resp. 25–37. Patent Owner's arguments and evidence do not persuade us that the Office previously considered or resolved the arguments as to Owaga and Sallmann that are raised in the Petition. *Id*.; Ex. 2005 (evidence of patent prosecution file history). Accordingly, we decline to exercise our discretion to deny the Petition under 35. U.S.C. § 325(d).

ii. Presentation of Alternative Arguments

Patent Owner also contends that the Petition is defective because, for example, as to the ground based on Owaga and Sallmann, the Petition "switches Owaga's order of application, making it a secondary reference to

Sallmann and creating an entirely different alleged ground of unpatentability." Prelim. Resp. 40. We find that argument unpersuasive, where Patent Owner does not show sufficiently any tangible prejudice resulting from what, in our view, amounts to Petitioner's proper presentation of alternative arguments. *See In re Bush*, 296 F.2d 491, 496 (CCPA 1961) ("[T]o term one reference primary and the other secondary" is a distinction "of little consequence, and [] basing arguments on" such distinctions is an attempt 'to make a mountain out of a mole-hill.'") (quotation omitted).

iii. Request to Expunge Hara

Patent Owner objects to Exhibit 1002, which Petitioner advances as an English translation of Hara,[4] on the grounds that Petitioner provides no "affidavit attesting to the accuracy of the translation." Prelim. Resp. 34 (quoting 37 C.F.R. § 42.63(b)). Specifically, Patent Owner requests that we expunge Exhibit 1002 from the record, and reject Petitioner's reliance upon it, for failure to comply with the Board's Rule 42.63(b). *Id*.

We do not consider Hara in our analysis, because it is not identified with particularity as providing a basis for unpatentability in any ground. *See supra* n.3. In any event, based on the record developed thus far, we determine that Patent Owner's request for relief is premature. Within ten (10) business days of the institution of trial, Patent Owner may serve on Petitioner an objection to Exhibit 1002. 37 C.F.R. § 42.64(b)(1). Petitioner may respond to the objection by timely serving supplemental evidence (for example, an affidavit attesting to the accuracy of the translation). *Id*. § 42.64(b)(2). Should a disagreement persist regarding the admissibility of

[4] Yoshiyuki Hara, "Bromfenac sodium hydrate," *Clinics & Drug Therapy* 2000, Vol. 19, No. 10, 19:1014-1015 (2002).

Exhibit 1002, Patent Owner may raise its objections in a timely-filed motion to exclude evidence, which we shall resolve in our Final Written Decision.

III. CONCLUSION

Based on the information presented in the Petition, as well as the arguments and evidence presented in the Preliminary Response, we conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 1–22 of the '431 patent are unpatentable. We institute trial based on each ground of unpatentability stated in the Petition. At this preliminary stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim.

IV. ORDER

It is:

ORDERED that an *inter partes* review is instituted, as to claims 1–22 of the '431 patent, on the following grounds:

A. Claims 1–5, 7–14, and 18–19 as unpatentable over Owaga and Sallmann under 35 U.S.C. § 103;

B. Claims 6, 15–17, and 20–22 as obvious over Owaga, Sallmann, and Fu;

FURTHER ORDERED that no other ground of unpatentability is authorized; and

FURTHER ORDERED that notice is hereby given of the institution of a trial commencing on the entry date of this decision. 35 U.S.C. § 314(c); 37 C.F.R. §42.4.

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