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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LANNY LEO JOHNSON

Appeal 2019-005344
Application 15/839,491
Technology Center 1600

Before JEFFREY N. FREDMAN, ELIZABETH A. LAVIER, and MICHAEL A. VALEK, *Administrative Patent Judges*.

LAVIER, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1–5, 7–18, and 20. An oral hearing took place on June 2, 2020.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as the inventor of record, Lanny Leo Johnson, M.D. Appeal Br. 1.

[2] A transcript (Tr.) of the oral hearing is of record.

CLAIMED SUBJECT MATTER

The claims are directed to methods for treating osteoarthritis. Claim 1 is illustrative:

> 1. A method of modifying the disease of osteoarthritis in a patient having an osteoarthritic joint, comprising:
>
> orally administering a daily dose of 0.100 to 0.200 mmoles of PCA[3] per kg of body weight of the patient for at least 4 weeks;
>
> wherein the therapeutically effective amount elicits an osteoarthritis disease modifying response comprising:
>
> decreased inflammation and an altered catabolic to anabolic state of the osteoarthritic joint;
>
> improved chondronutrition and chondro-protection of the integrity of articular cartilage of the osteoarthritic joint; and
>
> an increase in one or more synovial joint histological visual scale scores comprising:
>
> i) an increase in a histological visual scale score for the surface of the cartilage;
>
> ii) an increase in a histological visual scale score for subchondral bone; or
>
> iii) an increase in a histological visual scale score for mineralization of the joint.

Appeal Br. 58 (Claims Appendix).

[3] PCA = protocatechuic acid. *See* Spec. ¶ 92.

REFERENCES

The Examiner relies on the following references:

Name	Reference	Date
Kimura et al.	U.S. 4,997,850	March 5, 1991
Sung-Won Min et al., *Anti-inflammatory effects of black rice, cyanidin-3-O-β-D-glycoside, and its metabolites, cyanidin and protocatechuic acid,* 10 INT'L IMMUNOPHARM. 959 (2010).		
ARC Jones et al., *Bioregulation of Lubricin Expression by Growth Factors and Cytokines*, 13 EUROPEAN CELLS & MATERIALS 40 (2007).		
Mukundan Attur et al., *Prostaglandin E_2 Exerts Catabolic Effects in Osteoarthritis Cartilage: Evidence for Signaling via the EP4 Receptor*, 183 J. IMMUNOL. 5082 (2008).		
Donald D. Anderson et al., *Post-Traumatic Osteoarthritis: Improved Understanding and Opportunities for Early Intervention*, 29 J. ORTHOPAEDIC RES. 802 (2011).		
Chia-Yu Lin et al., *Antiglycative Effects of Protocatechuic Acid in the Kidneys of Diabetic Mice*, 29 J. AG. & FOOD CHEM. (2011).		
Maxime Dougados et al., *Evaluation of the Structure-Modifying Effects of Diacerein in Hip Osteoarthritis*, 44 ARTHRITIS & RHEUMATISM 2539 (2001).		

REJECTIONS

1. Claims 1–5, 7, 8, and 10–16 stand rejected under 35 U.S.C. § 103 as unpatentable over Kimura, Min, Jones, and Attur. Non-Final Action 3.[4]
2. Claims 1–5 and 7–17 stand rejected under 35 U.S.C. § 103 as unpatentable over Kimura, Min, Jones, Attur, and Anderson. Non-Final Action 12.
3. Claims 1–5, 7, 8, 10–16, 18, and 20 stand rejected under 35 U.S.C. § 103 as unpatentable over Kimura, Min, Jones, Attur, and Lin. Non-Final Action 13.

[4] Non-Final Office Action dated January 16, 2019.

OPINION

Although there are three rejections on appeal, Appellant does not expressly distinguish among them in its arguments. Instead, Appellant begins by arguing claim 1, and then certain dependent claims. As Kimura, Min, Jones, and Attur are common to all three rejections, and claim 1 is subject to all three rejections, we follow suit and consider the rejections together, focusing largely on claim 1. We address Appellant's major arguments rather than recapitulating the Examiner's rejections in detail. The Non-Final Action and Answer provide a thorough rejection-by-rejection analysis of the claims; we adopt the Examiner's findings as our own.

A. Claim 1

With respect to illustrative claim 1, the Examiner finds that Kimura teaches treatment of osteoarthritis by orally administering PCA[5] in a dosage range of 0.1 to 500 mg/kg/day (0.0006 to 3.2 mmol/kg/day), at 1–4 doses/day, with a disclosed therapeutic mechanism of suppression of production and/or release of IL-1. Non-Final Action 3 (discussing Kimura abstract, 2:23–45, 10:58–60, 11:1–9, claim 9). Kimura provides *in vitro* data showing IL-1α inhibition by PCA. *Id.* (citing Kimura 8:6–11). The dosage range of claim 1 is thus "fully encompassed within that taught by Kimura" (*id.* at 4), such that the Examiner finds that, in the absence of unexpected results, it would have been obvious for the ordinarily skilled artisan to optimize the dosage through routine experimentation (*id.* at 4–5). Further, the Examiner finds that "[i]t would be further within the scope of the artisan to administer the compound for such time to provide adequate treatment to

[5] Kimura refers to 3,4-dihydroxybenzoic acid, and uses the acronym "PAC." Kimura 1:37–38. PCA and PAC are the same compound. *See* Non-Final Action 3. For simplicity, we use "PCA" throughout this Decision.

the patient," and that "[t]here does not appear to be any criticality with any recited dosing protocol." *Id.* at 5.

The Examiner notes that Kimura "is silent regarding the various limitations regarding observed physical outcomes" (*id.* at 3), that is, the "wherein" clause in claim 1 and all its sub-clauses, through the end of the claim. For these, the Examiner cites Min, Jones, and Attur (*see id.* at 3–4), and explains:

> Min, Jones and Attur provide additional information about the anti-inflammatory and anti-catabolic properties of PCA and expected downstream effects, such as enhanced lubricin synthesis. This would lead one of ordinary skill to select this compound in particular for further experimentation and optimization regarding dosage and treatment protocol. Given the known effects of inhibiting inflammatory cytokines, such as IL-1β and TNF-α, one of ordinary skill would further expect a disease modifying effect with beneficial effects to bone and/or cartilage.

Non-Final Action 5.

We have considered all of Appellant's extensive arguments (*see* Appeal Br. 13–45; Reply Br. 2–16), and are not persuaded of any reversible error by the Examiner in rejecting claim 1. As introduced above, Kimura teaches or suggests using PCA, in a dosage range encompassing claim 1, to treat osteoarthritis. Appellant's assertions that Kimura does not disclose the recited dosage emphasize Kimura's lack of exemplary dosage data and *in vivo* testing. *See* Appeal Br. 16–17. But the teachings of a reference are not limited to working examples; rather, a reference is prior art for all that it teaches or suggests. *See In re Mills*, 470 F.2d 649, 651 (CCPA 1972) ("All the disclosures in a reference must be evaluated, including nonpreferred embodiments.") (citations omitted); *see also In re Lemelson*, 397 F.2d 1006,

1009 (CCPA 1968) ("The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain."). Furthermore, "[o]bviousness does not require absolute predictability," but rather "[o]nly a reasonable expectation that the beneficial result will be achieved," *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Thus, in analyzing whether a method of treatment claim is non-obvious, the issue is not whether the cited art provides *in vivo* or *in vitro* data, but what the art, taken as a whole, would have taught or suggested to the ordinarily skilled artisan. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981) ("[T]he test is what the combined teachings of the references would have suggested to those of ordinary skill in the art."); *cf. KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) ("A person of ordinary skill is also a person of ordinary creativity, not an automaton."). In addition, the Examiner relies not only on Kimura, but also on Min, which "establishe[s] that oral administration of PCA suppresses production of IL-1β, as well as COX-2, TNF-α and PGE_2." Ans. 4 (citing Min Abstract, § 3.4, Figs. 6 & 7).

To the extent Appellant argues that Kimura is non-analogous art, or otherwise irrelevant, insofar as "Kimura also used substrates that are not analogous to articular cartilage" (Appeal Br. 18), we are not persuaded. As Kimura is directed to the treatment of osteoarthritis, Kimura is within the same field of endeavor as the present application. Indeed, Kimura treats the same disease with the same medicament as the claims. *See* Non-Final Action 6; *see also In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) ("Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether

the reference still is reasonably pertinent to the particular problem with which the inventor is involved."). Further, Kimura indisputably discloses a method of treating osteoarthritis by administering PCA. *See, e.g.*, Kimura claim 9. Kimura's *in vitro* data, as discussed above, demonstrate an inhibitory effect on IL-1α inhibition by PCA. *See* Kimura 8:6–11, Fig. 1A. As Kimura's choice of substrate is concerned, Kimura chose human synovial cells for the IL-1 assay for good reason: "[t]he synovial cells produce IL-1 but release only a little amount and accordingly are appropriate cells to study an inhibition or an acceleration of IL-1 intracellular production." *Id.* at 7:42–46. While Kimura's data may not be exhaustive, they need not be for purposes of a § 103 rejection. The pertinent issue is what Kimura would have taught or suggested to the ordinarily skilled artisan. Viewed through that lens, Kimura is sufficient.

While Kimura's PCA dosage range is broad, both in absolute terms and relative to Appellant's claimed range, we do not agree with Appellant's assertion that Kimura is "so broad that it gives no meaningful insight" (Appeal Br. 18) regarding dosage. Kimura explains that selecting an appropriate dosage depends on various factors: species, age, individual difference, and stage of the disorder. Kimura 10:64–67. Kimura also notes that due to these considerations, a "dose exceeding the following dose range may sometimes be needed." *Id.* at 10:67–68. Given that variability, Kimura teaches that "generally speaking," a range of 0.1–500 mg/kg body weight/day, and preferably 0.5–200 mg/kg body weight/day can be used in humans. *Id.* at 11:1–4. These considerations are well-reasoned and explain the variability in dosage range to one of ordinary skill in the art. Moreover, as Kimura's dosage range encompasses that of claim 1, the claimed dosage range is *prima facie* obvious over Kimura. *See In re Peterson*, 315 F.3d

1325, 1329 (Fed. Cir. 2003) ("In cases involving overlapping ranges, we and our predecessor court have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness."). As to the duration of treatment, we agree with the Examiner that it would have been reasonably within the skill of the ordinary artisan "to administer the compound for such time to provide adequate treatment to the patient." Non-Final Action 5. Moreover, a skilled artisan would reasonably expect this to be an extended period of time, given the degenerative, persistent nature of osteoarthritis, particularly given Appellant's argument that Kimura was focused on using PCA to treat "the symptoms, not the cause" of osteoarthritis. *See* Tr. 8:1–22.

Appellant's other arguments regarding the individual elements of claim 1 (*see* Appeal Br. 20–27; *see also* Reply Br. 4–9); all pertain to what the Examiner calls "the various limitations regarding observed physical outcomes" (Non-Final Action 3), i.e., the sub-clauses of the "wherein" clause, reciting: decreased inflammation, altered catabolic to anabolic state, improved chondronutrition and protection, and an increase in certain histological visual scale scores (*see* Appeal Br. 58 (Claims Appendix)). We find that these outcomes are inherent results of administering PCA as recited in the claim. "Using the same composition claimed . . . in the same manner claimed . . . naturally results in the same claimed . . . benefits." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1380 (Fed. Cir. 2005). This application of inherency is reasonable because a chemical composition cannot be separated from its properties. *See In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) ("Products of identical chemical composition can not have mutually exclusive properties."); *see also In re Prindle*, 297 F.2d 251, 254 (CCPA 1962) ("Mere recognition of those latent properties does not render the otherwise obvious [claimed subject matter] unobvious and thereby

patentable."). Accordingly, the Examiner need not have gone through the analysis of identifying teachings in the prior art corresponding to these outcomes (*see* Non-Final Action 3–5), and combining them with the other references, in order to reject claim 1.[6]

With respect to the motivation to combine the references, Appellant again urges that Kimura's *in vitro* data are insufficient, and that Kimura's dosage teachings would not have provided the ordinarily skilled artisan with relevant information. *See* Appeal Br. 29–30. For the reasons discussed above, we are not persuaded. Furthermore, we are not persuaded by Appellant's argument (*see* Appeal Br. 31–32) that Kimura's teachings of other compounds in addition to PCA for treating osteoarthritis amount to a teaching away with respect to PCA. But teaching *another* way or additional embodiments is not the same as teaching away from the invention claimed. *See DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) ("A reference does not teach away, however, if it merely expresses a general preference for an alternative invention but does not 'criticize, discredit, or otherwise discourage' investigation into the invention claimed." (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)). This is particularly so here where Appellant's claim 1 does not preclude administration of other compounds in addition to PCA and therefore would seem to encompass the same treatments (i.e., PCA + other compounds) that Appellant characterizes as a teaching away. Moreover, as noted above, Kimura does not "criticize, discredit, or otherwise discourage"

[6] In the alternative, however, we concur with the Examiner's analysis with respect to these properties, for the reasons already of record. *See* Non-Final Action 3–5; Ans. 9.

(*id.*) the administration of PCA to treat osteoarthritis, Kimura *claims* it (*see* Kimura claim 9).

To overcome a *prima facie* case of obviousness, a patent applicant may provide evidence of secondary considerations. Here, Appellant argues that unexpected results, a long felt need in the art, and public policy considerations all weigh in favor of patentability. *See* Appeal Br. 32–45. We address each of these in turn.

For a range that overlaps or is within a prior art range, "the applicant must 'show that the [claimed] range is *critical,* generally by showing that the claimed range achieves unexpected results relative to the prior art range.'" *In re Geisler*, 116 F.3d 1465, 1469–70 (Fed. Cir. 1997) (quoting *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990)). We cannot conclude that Appellant has carried this burden. Appellant attempts to do so by pointing to "the difference in results of the prophylactic and therapeutic groups support[ing] the importance of dosage, interval, and common to drug prescriptions" in the Specification. Appeal Br. 38. In support, Appellant cites data from Figures 5A and 5B[7] of the Specification. *See id.* Figures 5A and 5B of the Specification are bar graphs showing synovial fluid cytokine levels (TNF-α in Figure 5A, and IGF-1 in Figure 5B) as detected by ELISA. With respect to PCA, data are provided in each figure for an untreated control, a "prophylactic" group that received 26.5 mg PCA/kg body weight administered orally 7 times per week for six weeks,[8] and a

[7] Page 38 of the Appeal Brief refers to "Figure 58," rather than Figure 5B. This appears to be a typographical error, as there is no Figure 58, and because the supporting paragraph of the Specification (¶ 53) cited in the Appeal Brief refers to Figure 5B.
[8] The Specification says "42 days" rather than "6 weeks" in paragraph 45. We have converted (6 x 7 = 42) for ease of reference.

"therapeutic" group that received the same dosage at the same frequency, but for four weeks.[9] Spec. ¶¶ 45–46. The Specification (but not the Appeal Brief) acknowledges that for Figure 5A, "the differences seen are not statistically significant." Spec. ¶ 52. And for Figure 5B, the Specification explains that "that IFG-1 levels in the synovial fluid was not significantly changed in all groups." *Id.* at ¶ 53. For both Figures 5A and 5B, the Specification notes that the slight changes that were observed occurred in the prophylactic groups, which received six weeks of treatment, but not the therapeutic groups, which received four weeks of treatment. *See id.* at ¶¶ 52, 53. With respect to Figure 5B, the Specification states that "[t]his may hint that the timing of the treatment may be important." *Id.* at ¶ 53.

At best, the data presented in Figures 5A and 5B of the Specification suggest possible (but not statistically significant, as the Specification acknowledges), minor effects from treating patients for six weeks rather than four weeks, all at a single dosage level of PCA (26.5 mg PCA/kg body weight). These data are insufficient to support Appellant's assertion of criticality of the claimed ranges, for at least three reasons. First, as described above, the improvements shown are minor to the point of being statistically insignificant. The evidence does not clearly "represent a 'difference in kind' that is required to show unexpected results." *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005). Second, whatever improvement (if any) can be discerned from administering PCA daily for six weeks rather than four weeks is not a distinction reflected in claim 1, which, in reciting a treatment period of "at least 4 weeks," encompasses both of the

[9] The therapeutic group appears to have been so named because the subjects in that group were administered PCA from days 42–70 after surgery. Spec. ¶ 45.

tested regimens. Unexpected results must be "commensurate in scope with the degree of protection sought by the claimed subject matter." *Id*. Third, because the Specification tests only a single daily dosage level of PCA, no conclusions can be drawn regarding what dosage *range* is effective.[10] For similar reasons, the data from Figures 5A and 5B of the Specification do not support Appellant's assertion of unexpected results, for want of a nexus with the claimed invention.

Appellant also cites to the declaration of the inventor, Dr. Johnson,[11] in support of the alleged unexpected results. *See* Appeal Br. 18–19 (discussing Johnson Decl. ¶¶ 40–41). Dr. Johnson's declaration provides further explanation and discussion of the Specification data, not additional data. His analysis in support of his conclusion that the results in the Specification are unexpected focuses on the properties or mechanisms of action of PCA in treating osteoarthritis (*see* Johnson Decl. ¶¶ 39–42), emphasizing the "substantial disease modifying effects of PCA" (*id.* ¶ 41) as opposed to prior art teachings regarding symptom management. As discussed above, we are not persuaded by this line of reasoning, because the disease modifying effects are inherent to practicing the method of administering PCA to a patient with osteoarthritis as claimed, and the prior

[10] At the oral hearing, in acknowledging that the Specification only tests a single dosage level of PCA (albeit for different periods of time), counsel for Appellant indicated that additional testing would have been cost-prohibitive. *See* Tr. 6:13–19. While we appreciate this concern, it cannot override the burden of proof, which is on Appellant, to rebut the Examiner's *prima facie* case.

[11] Declaration of Dr. Lanny Johnson under 37 C.F.R. § 1.132, dated May 7, 2018.

art already provides a sufficient rationale (i.e., reducing inflammation) for doing so.

In sum, we agree with the Examiner that "[t]here does not appear to be any criticality with any recited dosing protocol." Non-Final Action 5; *see In re Aller*, 220 F.2d 454, 456–58 (CCPA 1955) ("[W]here 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."); *see also In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). Nor has Appellant proffered sufficient evidence of unexpected results in any other respect. Appellant's arguments regarding long-felt need in the art and public policy (*see* Appeal Br. 32–36, 44–45) are similarly unpersuasive, insofar as they focus on the mechanisms of action of PCA. Treating osteoarthritis with PCA was obvious from the prior art; that Appellant may have discovered additional reasons *why* PCA is an effective osteoarthritis treatment is admirable, but not patentable.

For these reasons and those already of record, and after reviewing all of Appellant's arguments, we are unconvinced that Appellant has shown any reversible error by the Examiner in rejecting claim 1. Accordingly, we affirm the rejections of claim 1. Claims 6, 13, and 18 are not argued separately (*see* Appeal Br. 45), and fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

B. Claims 2–5, 7–12, 14–17, and 20

With respect to claims 2–5, 7–12, 14–17, and 20, the only additional arguments Appellant presents pertain to the additional disease modifying response-related limitations in these claims. *See* Appeal Br. 45–56. For the same reasons as discussed above with respect to the disease modifying response limitations recited in claim 1, we find that these additional limitations in claims 2–5, 14, and 20 are inherent to the administration of PCA to treat osteoarthritis.[12] Accordingly, Appellant has not persuaded us of any reversible error in the Examiner's rejections of claims 2–5, 7–12, 14–17, or 20, and we affirm the rejections thereof.

CONCLUSION

The Examiner's rejections are affirmed.

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[12] The inherency of these limitations likewise subsumes Appellant's new assertion in the Reply Brief that the Examiner's rejections of the dependent claims are arbitrary and capricious, in violation of § 706 of the Administrative Procedure Act (APA), for alleged failure to specifically identify the teachings in the cited references corresponding to the claimed elements. *See* Reply Br. 17. Furthermore, the Examiner makes findings in the Non-Final Action that support the rejection of the dependent claims, even where those claims are not called out by their claim numbers. *See* Non-Final Action 3–5, 13–14. The Examiner's additional discussion of the dependent claims in the Answer, while brief, is responsive to Appellant's arguments. *See* Ans. 14. We also note that the APA argument is new to the Reply Brief (even though it criticizes the Non-Final Action, not only the Answer), without a showing of good cause, and is thus improperly presented as applied to the alleged deficiencies of the Non-Final Action. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015); *see also Ex parte Borden*, 2010 WL 191083 at *2 (BPAI 2010) (informative) ("Any bases for asserting error, whether factual or legal, that are not raised in the principal brief are waived."); *cf. Veterans Contracting Group, Inc. v. United States*, 920 F.3d 801, 806, 808 (Fed. Cir. 2019) (finding APA § 706 challenge to have been waived on appeal for failure to present argument before lower tribunal).

DECISION SUMMARY

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–5, 7, 8, 10–16	103	Kimura, Min, Jones, Attur	1–5, 7, 8, 10–16	
1–5, 7–17	103	Kimura, Min, Jones, Attur, Anderson	1–5, 7–17	
1–5, 7, 8, 10–16, 18, 20	103	Kimura, Min, Jones, Attur, Lin	1–5, 7, 8, 10–16, 18, 20	
Overall Outcome			1–5, 7–18, 20	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED