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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WILLIAM L. PRIDGEN

Appeal 2018-002182
Application 13/761,079[1]
Technology Center 1600

Before RICHARD M. LEBOVITZ, CHRISTOPHER G. PAULRAJ, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method to treat a subject afflicted with one or more functional somatic syndrome conditions. The Examiner rejected the claims on appeal as obvious under 35 U.S.C. § 103(a). We affirm-in-part.

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. According to Appellant, the real party in interest is Innovative Med. Concepts, Inc. App. Br. 3.

STATEMENT OF THE CASE

The Specification states that "[t]he present invention relates to pharmaceutical compositions and methods of treating functional somatic syndromes using combination therapies." Spec. ¶ 2.

Claims 19–28 are on appeal. Claims 19, 22, and 23 are representative and read as follows:

> 19. A method to treat a subject afflicted with one or more functional somatic syndrome conditions, the method comprising
>
> administering to the subject in need thereof a therapeutically-effective combination of famciclovir and meloxicam,
>
> wherein the amount of famciclovir is administered in a total daily dose range from about 250 mg to about 2000 mg,
>
> wherein the amount of meloxicam is administered in a total daily dose range from about 7.5 mg to about 30 mg, and
>
> wherein the one or more functional somatic syndrome conditions is selected from the group consisting of fibromyalgia, chronic fatigue syndrome, irritable bowel syndrome, chronic depression, chronic clinical anxiety disorder and chronic interstitial cystitis.
>
> 22. A method to treat a subject afflicted with irritable bowel syndrome, the method comprising
>
> administering to the subject in need thereof a therapeutically-effective combination of famciclovir and meloxicam,
>
> wherein the amount of famciclovir is administered in a total daily dose range from about 250 mg to about 2000 mg, and
>
> wherein the amount of meloxicam is administered in a total daily dose range from about 7.5 mg to about 30 mg.
>
> 23. A method to treat a subject afflicted with a combination of fibromyalgia, chronic fatigue syndrome and irritable bowel syndrome, coexistent in the subject, the method comprising
>
> administering to the subject a therapeutically-effective combination of famciclovir and meloxicam,
>
> wherein the amount of famciclovir is administered in a total daily dose range from about 250 mg to about 2000 mg, and

> wherein the amount of meloxicam is administered in a total daily dose range from about 7.5 mg to about 30 mg.

App. Br. 16–17.

The claims stand rejected as follows.

Claims 19–21, and 24–28 were rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Maziasz[2] and Payne.[3]

Claims 22 and 23 were rejected under 35 U.S.C. § 112 for failure to comply with the enablement requirement.

ENABLEMENT

In rejecting claims 22 and 23 for failure to comply with the enablement requirement, the Examiner reviewed the factors delineated in *In re Wands* USPQ 2d 1400 (CAFC 1988). In particular, the Examiner found that the art with respect to irritable bowel syndrome ("IBS") was "unpredictable because there are no known structural abnormalities, specific laboratory tests, and/or biological markers for the condition/disease." Ans. 9 (addressing claim 22), 12 (addressing claim 23). According to the Examiner, IBS is diagnosed solely based on symptoms and thus "it would be difficult to determine the therapeutic effectiveness of the . . . combination of famciclovir and meloxicam . . . and/or their specific claimed *'dose range'* for the condition/disease of irritable bowel syndrome (IBS)." *Id.* The Examiner also found that the only treatment exemplified and the only guidance provided in the Specification was for treating patients with fibromyalgia. *Id*. Accordingly, the Examiner concluded that "the quantity

[2] Maziasz, US Patent Publication No. 2004/0157848 A1, published Aug. 12, 2004 ("Maziasz").
[3] Payne, *A New Fibromyalgia Remedy: Antiviral Drugs,* U.S. News & World Report, published April 11, 2008 ("Payne").

of experimentation needed to make and or use the invention would be great." *Id.* at 10, 13. We are not persuaded.

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

> The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. The scope of the claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation.

National Recovery Techs. Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195–96 (Fed Cir. 1999).

The Examiner bears the burden of explaining why the scope of protection claimed is not adequately enabled by the description of the invention provided in the specification including, "providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." *In re Wright*, 999 F.2d 1557, 1561–62 (Fed. Cir. 1993). Appellant has persuaded us that the Examiner has not carried this burden.

The Specification discloses a method of treating functional somatic syndrome conditions including irritable bowel syndrome by "administering to the subject a therapeutically-effective combination of famciclovir and meloxicam." Spec. ¶ 32. Famciclovir is an antiviral compound. Id. ¶ 13. The Specification also discloses dosage ranges for the antiviral compound (Spec ¶¶ 104–106) and for meloxicam. *Id.* ¶ 122; *see also, id.* ¶¶ 115–117. The Examiner asserts that "there are no known structural abnormalities,

specific laboratory tests, and/or biological markers for [IBS].” Ans. 9, 14. Appellant disputes this (App. Br. 7), but we need not determine whether the Examiner is correct because the Examiner’s assertion does not provide “sufficient reasons for doubting” the assertion in the Specification that irritable bowel syndrome can be treated by administering a combination of famciclovir and meloxicam. *In re Wright*, 999 F.2d at 1561–62. Appellant claims a method of treatment, not a method of diagnosis. As Appellant points out, “[a] patient seeking treatment does not particularly care about biomarker levels and merely wants the *symptoms* to resolve.” App. Br. 7. Because the Examiner’s assertion does not provide a sufficient evidentiary basis on which to doubt that the *symptoms* of IBS can be treated by administering a combination of famciclovir and meloxicam as claimed, we reverse the Examiner’s rejection of claims 22 and 23 for failure to comply with the enablement requirement.

OBVIOUSNESS

Appellant argues claims 19–21 and 24–28 together. We designate claim 19 as representative.

Maziasz discloses “a method and a composition for the treatment of a herpes virus infection as well as associated diseases and related disorders” by “administering to the subject a cyclooxygenase-2 selective inhibitor . . . and an anti-herpes virus agent.” Maziasz ¶ 10. More specifically, Maziasz discloses that the combination of a cyclooxygenase-2 selective inhibitor and an anti-herpes virus agent may be used to treat the herpes virus known as cytomegalovirus (“CMV”). *Id.* ¶¶ 3, 453. In Table C3, Maziasz discloses 120 “suitable combinations” of cyclooxygenase-2 inhibitors and anti-herpes

virus agents including the claimed combination of meloxicam and famciclovir. *Id.* ¶ 448.

Payne provides a review of the book *The New Fibromyalgia Remedy: Stop Pain Now with an Anti-Viral Drug Regimen*, by Daniel C. Dantini. It discloses that Dantini "believes that fibromyalgia is caused by the Epstein-Barr virus, cytomegalovirus, herpesvirus 6, or parvirus." Payne. Payne quotes Dantini as teaching that fibromyalgia can be treated by "[c]ontrol[ing] the viruses using the antiviral drugs famciclovir (brand name Famvir) or valacyclovir (Valtrex)." *Id.*

In finding claim 19 obvious, the Examiner concluded that it would have been obvious to treat fibromyalgia by treating cytomegalovirus, one of the viral illnesses that Payne teaches is "linked to the condition of fibromyalgia," using the combination of meloxicam and famciclovir as taught by Maziasz. Ans. 6. The Examiner finds that an ordinary artisan's reasonable expectation that such treatment would be successful would have been furthered by Maziasz's teaching that the patients to be treated may have an autoimmune disease. *Id.* (citing Maziasz ¶¶ 457–458 (which disclose "the subject may have a depressed immune response, such as . . . a subject with an autoimmune disease" and that a further aspect of Maziasz's invention involves "treat[ing] herpes related disorders" including "myalgia.") .

With respect to the claimed dosages, the Examiner found that Maziasz disclosed a famciclovir dosage range falling within that recited in claim 19 and a cyclooxygenase 2-selective inhibitor dosage range that "substantially overlap[s] the . . . claimed range." Ans. 4–5.

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Ans. 3–7; Final Act.[4] 2–7) and agree that claims 19–21 and 24–28 would have been obvious over the combination of Maziasz and Payne. We address Appellant's arguments below.

Appellant argues that "[t]he Examiner bears the burden of showing that the Claim 19 combination [of famciclovir and meloxicam] is no different than any other combination in Maziasz." App. Br. 10. Appellant contends that the Examiner's rejection cannot stand on the premise that it would have been obvious to select one from among the many combinations disclosed in Maziasz to treat fibromyalgia when there is no teaching that any of those combinations can be used to treat fibromyalgia. *Id.* We are not persuaded.

Maziasz discloses a number of combinations of compounds that are useful for treating cytomegalovirus. Maziasz ¶¶ 448, 453. It would have been obvious to select any one of the combinations of compounds disclosed for the purpose of treating cytomegalovirus. *Sinclair & Carroll Co. v. Interchemical Corp.* 325 U.S. 327, 335 (1945) ("Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put into the last opening in a jig-saw puzzle."). There was no need for the Examiner to find a teaching in Maziasz that its combinations of compounds can be used to treat fibromyalgia because Payne discloses that fibromyalgia is caused by cytomegalovirus and may be treated by controlling the virus with antiviral drugs. *See generally* Payne. Given Payne's teaching linking fibromyalgia to cytomegalovirus, we agree with the Examiner that it would have been obvious to select one of the combinations

[4] Office Action mailed February 10, 2017 ("Final Act.").

of compounds disclosed in Maziasz as useful for treating cytomegalovirus to treat fibromyalgia.

Appellant argues that the ordinary artisan would have expected different combinations of compounds disclosed in Maziasz's Table C3 to behave differently with respect to CMV. App. Br. 10. Appellant relies on the following passage from Maziasz:

> Typically when the subject is a human, the composition is employed to treat or prevent herpes simplex virus type 1 (HSV-1), herpes simplex virus type 2 (HSV-2), cytomegalovirus (CMV), and varicella zoster virus (VZV) infections. Even more typically when the subject is a human, the composition is utilized to treat or prevent either a HSV-1 or a HSV-2 infection.

Maziasz ¶ 453. Based on this passage, Appellant argues that "the particular focus on HSV-1/2," which Payne does not teach as being relevant to fibromyalgia, "suggests that some of the combo-treatments work better against HSV-1/2 than against CMV." App. Br. 10. Appellant thus argues that "one of ordinary skill would not expect, based on the combined teachings of Maziasz and Payne, that all drug combinations listed in Maziasz would be effective for treating functional somatic syndrome disorders." *Id.* at 10–11. We are not persuaded because we do not interpret the disclosure in Maziasz that its compositions are "more typically" used to treat HSV-1 and HSV-2 as teaching or suggesting that any of its compositions are not useful for treating CMV. Moreover, even if some of Mazaisz's compositions were better at treating CMV than others—a proposition not supported by persuasive evidence—that does not render the choice of any one of the compositions non-obvious. *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012) ("[J]ust because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes.").

Appellant argues that the use of meloxicam to "block[] viral replication by simultaneous inhibition of COX-1 and COX-2" is critical to the claimed method. App. Br. 11. Appellant then argues that Maziasz does not provide any motivation to select balanced COX-enzyme dual-inhibition as would be provided by a combination treatment including meloxicam. *Id.* We are not persuaded because Maziasz expressly discloses the combination of meloxicam and famciclovir. Maziasz ¶ 448.

Appellant argues that Dantini's book, which Payne reviews, "explicitly prescribes cessation of pain medicines," which would include meloxicam, for treating fibromyalgia patients. App. Br. 13. Appellant argues that this strongly teaches away from the claimed method. *Id.* We are not persuaded.

As an initial matter, Appellant does not provide any citation to any specific passage in Dantini's book,[5] leaving us to speculate about which passage(s) Appellant contends teach away from the claimed method. Regardless, we are not persuaded that Dantini teaches away from the claimed method.

Dantini discloses that many fibromyalgia patients are "taking other medications – antidepressants, pain medicines, or other prescriptions – for their fibromyalgia symptoms when we begin the antiviral protocol" and further teaches "withdraw[ing] those medications slowly *during the course of treatment*." Dantini 89 (emphasis added). Dantini thus expressly contemplates that treatment with a pain medication may continue during

[5] References to Dantini are to the reference provided with the Information Disclosure Statement, filed on January 6, 2015. The copy provided was not a complete copy. We did not consider any portions of Dantini that were not of record.

antiviral treatment. *See also, id.* ("I don't advise individuals to go cold turkey with any medication, but suggest they withdraw from it gradually"). In addition, Dantini expressly teaches that "NSAIDs are fine for minor temporary relief but the pain in fibromyalgia returns." Dantini 69. Finally, Appellant's argument assumes that the only effect of meloxicam is to treat pain. However, Mazaisz suggests that COX-2 inhibitors, like meloxicam, are not just pain medications, but can have antiviral effects. *See* Mazaisz ¶ 7 ("Treatment of the cytomegalovirus infected fibroblasts with a cyclooxygenase-2 selective inhibitor, however, reduced the yield of virus in the cells by a factor of about 100.")

Appellant argues that claim 19 recites a meloxicam dosage in milligrams per day while the Examiner's Answer "cites a disclosure of **cyclooxygenase-2-selective inhibitor** dosage presented in terms of **milligrams per kilogram body weight per day."** Reply. Br. 2. Appellant further argues that even if the cited doses are translated to a daily dose in milligrams by using an average U.S. body mass of 70 kg^2, the resulting ranges are "so absurdly broad as to be of no use at all to a skilled person for purposes of dosing meloxicam." *Id.* at 3 (calculating ranges of "70 mg to 1400 mg per day," "700 μg to 7 kg per day," and "between about 7 mg and about 3.5 kg per day"). We are not persuaded.

While the Examiner's Answer quotes dosages that are provided in mg/kg, the Examiner cites to paragraph 412 of Maziasz. Ans. 15. Paragraph 412 of Mazaisz states:

> The amount of active ingredient that can be combined with the carrier materials to produce a single dosage of the cyclooxygenase-2 selective inhibitor will vary depending upon the patient and the particular mode of administration. In general, ***the pharmaceutical compositions may contain a***

> ***cyclooxygenase-2 selective inhibitor in the range of about 0.1 to 2000 mg, more typically, in the range of about 0.5 to 500 mg and still more typically, between about 1 and 200 mg***. A daily dose of about 0.01 to 100 mg/kg body weight, or more typically, between about 0.1 and about 50 mg/kg body weight and even more typically, from about 1 to 20 mg/kg body weight, may be appropriate. The daily dose is generally administered in one to about four doses per day.

Maziasz ¶ 412 (emphasis added). As is readily apparent, the cited paragraph provides doses in both mg and in mg/kg. The doses provided in mgs overlap with those recited in claim 19. As Appellant has not provided evidence demonstrating that the claimed range is critical, we agree with the Examiner that the claimed range would have been obvious based on the disclosure of Maziasz. *See In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Accordingly, we affirm the Examiner's rejection of claims 19. Because they were not argued separately, we also affirm the Examiner's rejection of claims 20, 21, and 24–28.

SUMMARY

In summary:

Claims Rejected	**35 U.S.C. §**	**Basis**	**Affirmed**	**Reversed**
22, 23		Enablement		22, 23
19–21, 24–28	103(a)	Maziasz, Payne	19–21, 24–28	
Overall Outcome			19–21, 24–28	22, 23

AFFIRMED-IN-PART