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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RICHARD J. WURTMAN and INGRID RICHARDSON[1]

Appeal 2016-003785
Application 11/920,915
Technology Center 1600

Before ERIC B. GRIMES, DEBORAH KATZ, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to methods of improving cognitive function or improving intelligence in a subject, which have been rejected for obviousness and obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

STATEMENT OF THE CASE

Claims 74–77, 80, 81, 85–93, 95, and 96 are on appeal. Claim 74 is illustrative and read as follows:

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[1] Appellants identify the Real Parties in Interest as the Massachusetts Institute of Technology and Backbay Scientific. (Br. 1.)

> 74. A method of improving a cognitive function in a subject in need thereof comprising administering to said subject a composition comprising:
>
> (a) an omega-3 fatty acid, an omega-6 fatty acid, or a combination thereof, (b) uridine, an acyl derivative thereof, a uridine phosphate or a CDP-choline, and (c) a choline salt,
>
> wherein the composition has about 200 mg to 800 mg of uridine, an acyl derivative thereof, a uridine phosphate or a CDP-choline and about 200 mg to 800 mg of the choline salt and the composition is administered in a therapeutically effective amount to improve cognitive function in the subject and the subject has no cognitive impairment or memory disorder.

The claims stand rejected as follows:

Claims 74, 75, 81, 85, 87, 88, 91–93, 95, and 96 under 35 U.S.C. § 103(a) as obvious based on Wurtman[2] (Ans. 2);

Claims 76, 77, 80, 86, 89, and 90 under 35 U.S.C. § 103(a) as obvious based on Wurtman and Masor[3] (Ans. 3);

Claims 74–77, 80, 81, 85–93, 95, and 96, provisionally, for obviousness-type double patenting based on claims 1–3, 5, 6, 9–24, 37–39, 41–47, 49–51, 53, 54, 87, and 91 of application 10/941,025 (Ans. 5);

Claims 74–77, 80, 81, 85–93, 95, and 96, provisionally, for obviousness-type double patenting based on claim 1 of application 11/510,737 and Masor (Ans. 6); and

Claims 74–77, 80, 81, 85–93, 95, and 96 for obviousness-type double patenting based on claims 1–14 of U.S. 8,551,452 B2 (Ans. 7).

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[2] Wurtman et al., US 2003/0114415 A1; publ. June 19, 2005.
[3] Masor et al., US 5,492,899; iss. Feb. 20, 1996.

I

The Examiner has rejected claims 74, 75, 81, 85, 87, 88, 91–93, 95, and 96 as obvious based on Wurtman. The Examiner finds that Wurtman teaches "a treatment regimen to prevent or reduce memory impairment and improve cognitive function" by administering effective amounts of choline, cytidine, and uridine, or a pharmaceutically acceptable salt of those compounds. (Ans. 2.) The Examiner finds that Wurtman also teaches linoleic acid or linolenic acid as part of its treatment regimen. (*Id.*)

We agree with the Examiner that the method of claim 74 would have been obvious based on Wurtman, which discloses "compositions and methods for *preventing* and treating memory impairment, particularly memory impairment caused by any of a number of disorders, such as stroke, brain injury, mild cognitive impairment (MCI), Alzheimer's Disease (AD), cerebrovascular disease, and other disorders which cause cognitive disturbances." (Wurtman ¶ 27, emphasis added.)

"The compositions according to this invention include citicoline, or its metabolism products, choline, cytidine, and/or uridine, and optionally one or more fatty acids such as linoleic acid and linolenic acid, and their active metabolites, e.g., arachidonic acid and docosohexenoic acid." (*Id.*) "Citicoline monosodium is an exogenous form of cytidine-5'-diphosphocholine (CDP-choline)." (*Id.* ¶ 24.) Linoleic acid is an omega-6 fatty acid; α-linolenic acid is an omega-3 fatty acid that is metabolized to docosahexaenoic acid. (*See* Spec. ¶¶ 62, 70.) Wurtman states that "where any combination of choline, cytidine, and uridine is used, it is also preferably administered orally as a pharmaceutically-acceptable salt." (*Id.* ¶ 53.)

Wurtman discloses that

> [a] variety of dosage ranges are suitable. The citicoline dosage under the invention may be from about 10 mg to about 1000 mg from one to about 4 times per day. . . . When choline and cytidine and/or uridine are used, the dose is preferably sufficient to provide these compounds in amounts that are commensurate with the amounts of choline, cytidine and/or uridine released when citicoline is metabolized.

(*Id.* ¶ 57.)

Wurtman states that "[t]reatment under the invention is preferably begun prior to the onset of cognitive impairment symptoms, such as memory loss, e.g., in people who have had a stroke or brain injury, or shortly after such symptoms are first exhibited." (*Id.* ¶ 54.) Similarly, Wurtman states that "citicoline, or the choline, cytidine, uridine combinations, may be administered as a preventative measure to patients at risk for developing disorders that cause cognitive impairment. It is beneficial to co-administer these compositions with essential fatty acids . . . such as linoleic acid or linolenic acid." (*Id.* ¶ 56.)

Based on these disclosures, it would have been obvious to administer a composition comprising an omega-3 or omega-6 fatty acid (such as linoleic acid or α-linolenic acid), uridine, and a choline salt in order to improve cognitive function. Wurtman expressly suggests administering its composition to a subject before any symptoms of cognitive impairment, such as memory loss, have been exhibited, and therefore makes obvious practicing its method on a subject with no cognitive impairment or memory disorder.

In addition, Wurtman identifies the dosage of citicoline, or a combination of choline and uridine, as a result-effective variable, and thus

would have made obvious optimizing the amount of choline and uracil in its composition. "[T]he discovery of an optimum value of a variable in a known process is normally obvious," unless the results of optimizing a variable were unexpectedly good or the parameter optimized was not recognized in the prior art as one that would affect the results. *In re Antonie*, 559 F.2d 618, 620 (CCPA 1977).

Appellants argue that Wurtman "continuously focuses the drug administration to the treatment of those who have suffered an injury." (Br. 11.) Appellants argue that "[e]ven preventive administration of the composition is premised on the expectation of the onset of cognitive impairment caused by stroke, brain injury, or 'shortly after' such symptoms." (*Id.*) Appellants argue that "[t]he patient population of the reference is completely opposite that of the claims, injured versus healthy subjects." (*Id.* at 12.) Based on the same reasoning, Appellants argue that Wurtman teaches away from the claimed method. (*Id.* at 13–15.) Similarly, Appellants argue that one of skill in the art would not "abandon the explicit teachings of the '415 publication (to administer a composition to a subject that is cognitively impaired) and, contrary to this, administer the composition to a healthy subject." (*Id.* at 16.)

These arguments are unpersuasive, because claim 74 limits the treated subjects to those "ha[ving] no cognitive impairment or memory disorder." (Claim 74.) The claim language says nothing about injured versus healthy patients; it only distinguishes between those who already have a cognitive impairment or memory disorder, and those who do not. As discussed above, Wurtman states that "[t]reatment under the invention is preferably begun

prior to the onset of cognitive impairment symptoms, such as memory loss, e.g., in people who have had a stroke or brain injury, or shortly after such symptoms are first exhibited." (Wurtman ¶ 54, emphasis added.) Thus, although the patients discussed in Wurtman might be at risk of developing a cognitive impairment, such as memory loss, Wurtman expressly suggests treating patients who do not have a cognitive impairment or memory disorder.

We affirm the rejection of claim 74 under 35 U.S.C. § 103(a) based on Wurtman. Claims 75, 81, 85, 87, 88, 91–93, 95, and 96 have not been argued separately and therefore fall with claim 74. 37 C.F.R. § 41.37(c)(1)(iv).

II

The Examiner has rejected claims 76, 77, 80, 86, 89, and 90 as obvious based on Wurtman and Masor. The Examiner finds that "Wurtman et al. fails to teach the uridine monophosphate and choline chloride, and further administration to an infant," but "Masor et al. teaches a nutritional infant formula comprising uridine monophosphate and choline chloride." (Ans. 4.) The Examiner concludes that it would have been obvious to include uridine monophosphate (UMP) and choline chloride in Wurtman's composition, because "both formulations are supplements." (*Id.*)

Appellants argue, among other things, that Masor does not mention improving cognitive function and, therefore, combining its teachings with Wurtman is merely speculation. (Br. 19.)

We agree with Appellants that the Examiner has not provided an adequate reason for including the UMP and choline chloride of Masor's

infant formula in Wurtman's composition. Masor discloses "infant formulas which contain ribo-nucleotide equivalents." (Masor 1:7–8.) Ribo-nucleotide equivalents include UMP. (*Id.* at 4:26–35.) Masor discloses an exemplary formula containing choline chloride and UMP. (*Id.* at 10:62, 65.)

However, Masor does not disclose that its formula has any effect on improving cognition. It discloses, rather, that its formula "enhanc[es] the immune system of a human," can be "use[d] to treat or prevent diarrheal disease," and provides "a novel antioxidant system." (*Id.* at 5:43–44, 5:58, 6:34.) As discussed above, Wurtman discloses that its composition is used to prevent or treat memory impairment or cognitive impairment such as memory loss. The Examiner has not identified a reason, based on the cited references or the knowledge of those skilled in the art, why a person of ordinary skill in the art would have included components of Masor's infant formula in a composition intended to have a different effect in treated subjects, such as Wurtman's composition.

We therefore reverse the rejection of claims 76, 77, 80, 86, 89, and 90 under 35 U.S.C. § 103(a) based on Wurtman and Masor.

III

The Examiner has provisionally rejected claims 74–77, 80, 81, 85–93, 95, and 96 on the basis that they are not patentably distinct from claims 1–3, 5, 6, 9–24, 37–39, 41–47, 49–51, 53, 54, 87, and 91 of application 10/941,025. (Ans. 5.) At oral argument, Appellants' counsel pointed out all of the cited claims of the '025 application have been cancelled. Thus, the provisional rejection does not identify any claims in the '025 application that define an invention that is not patentably distinct from the claims of the

instant application. We therefore reverse the provisional rejection based on the '025 application.

IV

The Examiner has provisionally rejected claims 74–77, 80, 81, 85–93, 95, and 96 for obviousness-type double patenting based on claim 1 of application 11/510,737 and Masor.[4] The Examiner finds that claim 1 of the '737 application is directed to improving memory or cognition by administering CDP-choline and a polyunsaturated fatty acid, whereas the claims of the instant application are directed to improving cognitive function by administering a uridine compound and a fatty acid. (Ans. 6–7.) The Examiner finds that the method claimed in the '737 application does not include choline salts, but concludes that including them would have been obvious based on Masor. (*Id.*)

Appellants argue that claim 1 of the '737 application "is directed to a different composition and is directed to a patient population explicitly excluded in the present claims." (Br. 7.) That is, "[t]he '737 claim[] explicitly recites a diseased subject. . . . In direct contrast, the present claim recites: 'wherein the subject has no cognitive impairment or memory disorder.' Therefore, . . . the first claim does not overlap with the second claim." (*Id.* at 8.)

We will reverse this provisional rejection. As discussed above, the Examiner has not persuasively shown that it would have been obvious to a

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[4] The Examiner also cites a variety of claims between claim 4 and claim 39 of the '737 application, but as Appellants point out (Br. 6), all of the cited claims except claim 1 have been cancelled.

person of ordinary skill in the art based on Masor's disclosure of infant formula, to include a choline salt in a composition intended to improve memory or cognition.

In addition, we agree with Appellants that the Examiner has not shown that claim 1 of the '737 application and the instantly pending claims are directed to methods that are not patentably distinct. Claim 1 of the '737 application recites improving memory, learning, or cognition in a subject, "wherein the subject has Alzheimer's disease, age-related cognitive disorder, age-associated memory impairment (AAMI), memory decline, Pick's disease, Lewy Body disease or dementia." Claim 74 on appeal, by contrast, recites improving a cognitive function in a "subject [who] has no cognitive impairment or memory disorder."

The Examiner reasons that "a specific symptom, i.e.[,] improving memory, learning, or cognition, in a subject with a condition renders obvious treating that specific symptom without the condition," and gives the example of aspirin being used to treat a headache regardless of whether the headache is due to a migraine or to sensitivity to noise. (Ans. 9.)

Regardless of whether it would be obvious to use an analgesic to treat pain arising from different causes, however, we do not agree that the Examiner's rationale justifies a rejection for obviousness-type double patenting based on the facts here.

> There are two justifications for obviousness-type double patenting. The first is "to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." The second rationale is to prevent multiple infringement suits by different assignees asserting essentially the same patented invention.

In re Hubbell, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (citations omitted).

As discussed above, the claims of the instant application exclude subjects having a memory disorder, while claim 1 of the '737 application requires the treated subject to have "Alzheimer's disease, age-related cognitive disorder, age-associated memory impairment (AAMI), memory decline, Pick's disease, Lewy Body disease or dementia." The Examiner has not shown that the subjects treated in each of the two claimed methods overlap, and therefore has not shown that either application would provide a time-wise extension of a specific right to exclude, or that someone practicing a specific method would be at risk of multiple infringement suits based on the separate patents. The Examiner therefore has not shown that a provisional rejection of the instant claims based on claim 1 of the '737 application is merited.

V

The Examiner has rejected claims 74–77, 80, 81, 85–93, 95, and 96 for obviousness-type double patenting based on claims 1–14 of U.S. 8,551,452 B2. The Examiner concludes that the two sets of claims are not patentably distinct because it would have been obvious, based on the claims of the '452 patent, "to use the omega-3 fatty acid, uridine and choline in treating cognitive function." (Ans. 7–8.)

Appellants argue that

> [t]he '452 patent is directed to a method of evaluating a subject's compliance with taking a uridine dietary supplemental regimen and the present claim is directed to a method of improving cognitive function by administering uridine. Should both claims be allowed, there is no improper patent term extension given the lack of subject matter overlap.

(Br. 9.)

We agree with Appellants. Claim 1 of the '452 patent is directed to a "method of evaluating a subject's compliance with a uridine dietary supplementation regimen" that comprises administering a uridine dietary supplement, then "determining [the] subject's brain cytidine-containing compound level" using a specific in vivo magnetic resonance spectroscopy method, and using the cytidine-containing compound level to evaluate the subject's compliance with the dietary supplementation regimen. ('452 patent, claim 1.)

Claim 74 of the instant application merely requires administering a composition comprising (for example) an omega-3 fatty acid, uridine, and a choline salt. While dependent claims of the '452 patent state that the uridine dietary supplementation regimen can include a uridine source, an omega-3 fatty acid, or a choline salt, the method claimed in the '452 patent still requires the steps of determining the subject's brain cytidine-containing compound level using a specific in vivo magnetic resonance spectroscopy method, and using the cytidine-containing compound level to evaluate the subject's compliance with the dietary supplementation regimen, neither of which are required by the claims of the instant application.

Thus, the Examiner has not established that the instant claims would provide a time-wise extension of the '452 patent's right to exclude, or that someone practicing the instantly claimed method would be at risk of multiple infringement suits based on the '452 patent and a patent to the instant claims. The Examiner therefore has not shown that a provisional

rejection of the instant claims based on the claims of the '452 patent is merited.

SUMMARY

We affirm the rejection of claims 74, 75, 81, 85, 87, 88, 91–93, 95, and 96 under 35 U.S.C. § 103(a) based on Wurtman.

We reverse the rejection of claims 76, 77, 80, 86, 89, and 90 under 35 U.S.C. § 103(a) based on Wurtman and Masor.

We reverse both of the provisional rejections for obviousness-type double patenting.

We reverse the rejection of claims 74–77, 80, 81, 85–93, 95, and 96 for obviousness-type double patenting based on the claims of U.S. 8,551,452 B2.

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).

AFFIRMED-IN-PART