

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WASHINGTON UNIVERSITY,
APPELLANT

Appeal 2007-3558

Reexamination Control 90/005,368¹
U.S. Patent 5,550,166²
Technology Center 1600

November 09, 2007

Before TEDDY S. GRON, CAROL A. SPIEGEL, and MARK NAGUMO,
Administrative Patent Judges.

NAGUMO, *Administrative Patent Judge.*

DECISION ON APPEAL

¹ Request for Reexamination filed 24 May 1999, by a third party requester.

² "166 Patent," issued to Richard E. Ostlund and William R. Sherman on 27 August 1996, based on application 08/407,430, filed 17 March 1995. The real party in interest is listed as Washington University; Humanetics Corp. is said to be a licensee. (Appeal Brief filed 16 January 2001 ("Br."), at 1.)

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A. Introduction

Appellant ("Washington") appeals under 35 U.S.C. § 134 from the final rejection of claims 1–23 in the Reexamination, which are all of the pending claims. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

The subject matter on appeal relates to a composition for treating insulin resistance in a mammal and a method of treating insulin resistance comprising administering an effective amount of the composition to an insulin-resistant mammal.

Claims 1 and 15 are the independent claims and are representative of the subject matter on appeal.

Claim 1

A composition useful in treating conditions of insulin resistance, hyperlipidemia or dyslipidemia in a mammal comprising
an effective amount of pinitol or a derivative or metabolite thereof.

(Br. App. A at 1; indentation and subparagraphing added.)

Claim 15

A method of treating conditions of insulin resistance in a mammal comprising
administering an effective amount of pinitol or a derivative or metabolite thereof.

(Br. App. A at 3; indentation and subparagraphing added.)

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The Examiner has maintained the following rejections:

- (1) Claims 1–14 are rejected under 35 U.S.C. § 103(a) in view of Narayanan³.
- (2) Claims 1–23 are rejected under 35 U.S.C. § 103(a) in view of the combined teachings of Larner⁴ and Narayanan.

B. Findings of Fact (FF)

The following findings of fact and any set out in the Discussion are supported by a preponderance of the evidence of record.

Diabetes mellitus and insulin resistance

1. "Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both." (Br. App. C⁵ at 54, cols. 2–3.)
2. Resistance to insulin action is characterized by "diminished tissue responses to insulin at one or more points in the complex pathways of hormone action." (Br. App. C at 54, col. 3.)
3. Hyperglycemia (excess blood sugar) is said to be associated with "long-term damage, dysfunction, and failure of various organs, especially

³ C.R. Narayanan et al., *Pinitol—A New Anti-Diabetic Compound From the Leaves of Bougainvillea spectabilis*, 56 *Current Science*, 139 (1987).

⁴ Joseph Larner et al., *Method of Treating Defective Glucose Metabolism Using Synthetic Insulin Substances*, U.S. Patent 5,652,221, issued 29 July 1997, from application 08/335,015, filed 7 November 1994.

⁵ *Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus*, 23 *Diabetes Care*, Supplement 1, 54 (2000)

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the eyes, kidneys, nerves, heart, and blood vessels." (Br. App. C at 54, cols. 2–3.)

The 166 Patent Disclosure

1. According to the 166 Patent, "[t]he invention relates to pinitol and derivatives and metabolites thereof, and compositions containing same for treating conditions associated with insulin resistance." (166 Patent at 1:11-13.)
2. According to the 166 Patent, insulin-resistance in a subject may result in elevated levels of insulin in the bloodstream, leading to a host of harmful effects. (166 Patent at 1:58-65.)
3. The prior art is said to have discovered that the action of insulin may be mediated by inositol phosphoglycan molecules, and that "[a]ugmenting the release of these molecules is one way to improve insulin sensitivity." (166 Patent at 2:3–7.)
4. The sole or predominant hydrolysis product of certain inositol phosphoglycans is said to be D-chiro-inositol, which was found to be lower in diabetic tissues and fluids than in their normal counterparts. (166 Patent at 2:12-20.)
5. These results are said to have been the basis for the treatment of insulin resistant patients with D-chiro-inositol proposed in U.S. Patent 5,124,360 [to Larner and Kennington]. (166 Patent at 2:20–24.)
6. The 166 Patent states that "Pinitol is a methyl ether of D-chiro-inositol and is readily hydrolyzed to D-chiro-inositol." (166 Patent at 2:37–38.)

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7. Pinitol and its derivatives or metabolites are said to be available from a number of natural sources, including soy beans, pine needles, and *Bougainvillea* leaves. (166 Patent at 4:5–9.)

8. Derivatives and metabolites of pinitol are said to include pinitol glycosides. (166 Patent at 4:1–2.)

Narayanan

9. According to Narayanan, an alcoholic extract of *Bougainvillea spectabilis* was found to have significant hypoglycemic effects on normal and alloxan-induced diabetic mice. (Narayanan at 139, col. 1, 1st para.)

10. The extract, purified by chromatography and recrystallization, is said to have been characterized as D-chiro(+)o-methyl inositol (pinitol) by its melting point, optical rotation, NMR, IR, and mass spectral properties. (Narayanan at 139, col. 1, 2d and 3d para.)

11. The compound was administered orally to induced-diabetic mice at 0.01 g/kg body weight over a period of 76 hours and the blood sugar level monitored. (Narayanan at 139, col. 2, 2d full para.; and at 140, Table 2.)

12. Narayanan reports that, "[i]n alloxan-induced diabetic mice, on chronic treatment of pinitol for 72 hr (5 doses), a significant fall in BSL [blood sugar level] was observed. . . All these results show that pinitol has significant hypoglycemic and anti-diabetic action." (Narayanan at 139, col. 2; and at 140, Table 3.)

Larner

13. Larner reports that certain small synthetic amines of disaccharides mimic the action of insulin, acting to reduce elevated blood glucose levels. (Larner at 1:50–52.)
14. In particular, beta-glycosides of certain amino sugars with pinitol are said to be preferred. (Larner at 2:21-44.)
15. The compounds are said to be "useful in the treatment of defects in glucose metabolism such as impaired glucose tolerance insulin resistance, or the elevated blood sugar associated with type II diabetes." (Larner at 5:33-36.)
16. Larner reports that type II diabetic model hyperglycemic rats were injected with solutions of the compounds, resulting in decreases of 30% (± 9.5) of blood glucose concentrations compared to saline-injected controls (decrease of 2.5% (± 2.6)). (Larner at 5:52–54.)
17. According to Larner, preferred doses are in the range of 0.1 to 10 mg/kg [of body weight], 1.0 to 2.0 mg/kg being most preferred. (Larner at 5:57–59.)
18. Larner does not disclose oral administration of the compounds.

C. Discussion

Claims under reexamination shall be given their "broadest reasonable interpretation consistent with the specification, and limitations appearing in the specification are not to be read into the claims." *In re Yamamoto*, 740 F.2d 1569, 1571, 222 USPQ 934, 936 (Fed. Cir. 1984). Claimed

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subject matter is shown to be obvious when it is shown that the differences between the claimed invention and the prior art are such that the claimed subject matter would have been obvious to one of ordinary skill in the art.

35 U.S.C. § 103(a). The "recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not distinguish a claim drawn to those things from the prior art." *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

Narayanan

The Examiner found that Narayanan describes doses of pinitol, D-chiro(+)-o-methyl inositol, consistent with the limitation that the dose be an effective amount of pinitol as disclosed by the 166 Patent. (Ans. at 2, incorporating by reference the Office Action mailed 23 March 2000 (Paper 10), at 2, and the final Office Action mailed 16 August 2000 (Paper 13), at 2–3.) The Examiner maintained that the intended utility (treatment of insulin resistance) could not make an old composition patentable, and rejected claims 1–14 as unpatentable under 35 U.S.C. § 103(a) in view of Narayanan. (*Id.*)

Appellant does not argue the separate patentability of any of claims 1–14 with respect to Narayanan. Accordingly, claims 1–14 stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

Appellant argues that because Narayanan provides no teaching or motivation to treat insulin resistance, hyperlipidemia, or dyslipidemia, one skilled in the art could not determine what is an effective amount of pinitol for these treatments. (App. Br. at 6.) Appellant argues further that the Examiner erred in assuming that Narayanan in fact discloses pinitol (*id.*), and that the Narayanan material was not likely to have been pure (*id.* at 7).

These arguments are without merit. Claim 1 is drawn to a composition of matter comprising an effective amount of pinitol. Narayanan states that the material was characterized by a number of techniques, including its melting point, specific rotation, NMR, IR, and mass spectra, and also of its derivatives, citing an article published in the Journal of the American Chemical Society. (FF 10; Narayanan at 139, col. 1.) Appellant has not, in its brief or in Ostlund's declaration⁶, identified any definite reason to doubt the accuracy of Narayanan's identification of the material said to be pinitol. As for the alleged impurity of the Narayanan pinitol, the claims are open to additional materials due to the transitional phrase "comprising." In this regard, Appellant has not identified any factors indicating that whatever additional materials were present would have rendered the pinitol ineffective for the treatment of insulin resistance. Finally, to the extent that the "effective amount" limitation is meaningful, Narayanan discloses that amounts of 0.01 g (10 mg) pinitol per kilogram of mouse body weight were found to be effective at reducing blood sugar levels. Thus, Narayanan describes individual doses of pinitol well within the range disclosed and

⁶ Declaration by Richard E. Ostlund ("Dr. Ostlund") filed 19 May 2000, during prosecution of the Reexamination application.

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claimed by Appellant (0.1 mg to 1.0 g pinitol per kg body weight of a mammal, per day). It is hornbook patent law that identification of a new use for an old material does not make the old material patentable. *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (1974).

As anticipation is the epitome of obviousness, we AFFIRM the rejection of claims 1–14 under 35 U.S.C. § 103(a) in view of Narayanan.

Larner and Narayanan

The Examiner found that Larner discloses derivatives of pinitol and their use for treating insulin resistance in amounts (2 mg/kg body weight exemplified, 0.1 mg to 10.0 mg/kg preferred: Larner at 5:55–59) within the scope of independent claims 1 and 15. The Examiner argued that the disclosure of oral administration of pinitol for periods up to three days by Narayanan would have rendered the oral administration, for comparable times, of the pinitol glycosides taught by Larner, obvious to a person having ordinary skill in the art. (Paper 13 at 4.)

Appellant does not argue for the separate patentability of any claims other than claim 19 (oral administration of the drug), claim 22 (administration of the drug for a day or longer), and claim 23 (administration of the drug for three days or longer). Accordingly, we limit our discussion to claims 1, 15 and claims 19, 22, and 23, which depend from claim 15.

Initially, we note that all the claims are limited to "pinitol, or a derivative or metabolite thereof" or to processes of using these compounds. Appellant has not directed our attention to any express definition of the terms "derivative" or "metabolite" in the supporting specification. We note,

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however, that the 166 Patent describes "[s]uitable derivatives and metabolites of pinitol" as including "pinitol glycosides." (166 Patent at 4:1-4.) Larner describes its invention as "beta-glycosides of 2-deoxy-2-amino sugars with derivatives of inositol" (Larner at 2:35–36), with pinitol being an especially preferred derivative of inositol (*id.* at 2:26-28). We thus find that the amino-disaccharides, such as 2-deoxy-2-amino-galactopyranosyl pinitol, disclosed by Larner are "derivatives" of pinitol within the scope of claims 1 and 15. Moreover, Larner discloses the use of these compounds for the "treatment of defects in glucose metabolism such as impaired glucose tolerance insulin resistance, or the elevated blood sugar associated with type II diabetes" (FF 15; Larner at 5:33–36) in a rat model for type II diabetes. The dosages, as noted *supra*, are within the range disclosed to be useful for the treatment of insulin resistance.

We thus find that Larner anticipates the subject matter of claims 1 and 15. We therefore AFFIRM the rejection of claims 1–18, 20, and 21 under 35 U.S.C. § 103(a) in view of the combined teachings of Larner and Narayanan.

Turning to the remaining claims, we have found that Larner discloses administration of the pinitol derivatives by injection. (FF 16; Larner at 5:41–43.) Narayanan teaches the effective oral administration of pinitol, a methyl ether of a sugar, for use as a blood-stream delivered treatment of hyperglycemia in a model for type I diabetes. This teaching provides the suggestion that the oral administration of a sugar derivative would likely be effective as a mode of drug delivery. Accordingly, we have no difficulty concluding that the Examiner has established a *prima facie* case of

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obviousness of the oral administration of effective amounts of pinitol derivatives as required by claim 19.

Narayanan also describes the administration of pinitol over periods of up to 76 hours for the treatment of hyperglycemia. (FF 11; Narayanan at 139, col. 2; at 140, Table 2.) As diabetes types I and II are well known, even by lay persons, to be chronic conditions that can require a daily regimen of treatment, we have no difficulty finding that Narayanan supports the Examiner's rejections. We also find that that Narayanan would have suggested to those skilled in the art that administration of Larner's pinitol derivatives would be useful for the treatment of insulin resistance over periods of one day or three days or longer as required by claims 22 and 23, respectively.

On the record before us, we AFFIRM the rejection of claims 19, 22, and 23 under § 103(a) in view of the combined teachings of Larner and Narayanan.

D. Summary

In view of the record and the foregoing considerations, it is ORDERED that the rejection of claims 1–14 under 35 U.S.C. § 103(a) in view of Narayanan is AFFIRMED; FURTHER ORDERED that the rejection of claims 1–23 under 35 U.S.C. § 103(a) in view of the combined teachings of Larner and Narayanan is AFFIRMED; and

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FURTHER ORDERED that 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

MAT

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