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Paper 28
Date: October 23, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW U LIFE CORPORATION,
Petitioner,

v.

AXCESS GLOBAL SCIENCES, LLC,
Patent Owner.

IPR2019-01141
Patent 6,613,356 B1

Before GEORGIANNA W. BRADEN, JENNIFER MEYER CHAGNON, and MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

New U Life Corporation ("Petitioner") filed a Petition (Paper 1 ("Pet.")) seeking an *inter partes* review of claims 1–19 of U.S. Patent No. 6,613,356 B1 ("the '356 patent," Ex. 1001). We instituted trial to review the challenged claims. Paper 8 ("Dec."). Thereafter, Axcess Global Sciences, LLC[1] ("Patent Owner") filed a Response to the Petition (Paper 11, "PO Resp."), Petitioner filed a Reply (Paper 15, "Reply"), and Patent Owner filed a Sur-Reply (Paper 17, "Sur-Reply"). Patent Owner also filed a contingent Motion to Amend the challenged claims in the event any of the challenged claims were determined unpatentable (Paper 12, "MTA"), Petitioner filed an Opposition to Patent Owner's MTA (Paper 14), and we provided Preliminary Guidance on the MTA (Paper 16). Patent Owner subsequently withdrew its MTA (Paper 18). Thus, there is no pending motion to amend and only the challenged claims are at issue in this proceeding. We held an oral hearing on September 1, 2020. A transcript of that hearing is of record (Paper 26, "Tr.").

We issue this final written decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons explained below, we conclude Petitioner has shown by a preponderance of evidence that claims 1, 2, 5, 8, 11, 14, and 17 of the '356 patent are unpatentable, but has failed to show by a preponderance of evidence that claims 3, 4, 6, 7, 9, 10, 12, 13, 15, 16, 18, and 19 are unpatentable on any ground raised in the Petition.

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[1] The Petition identifies VND Butyrate, LLC as the Patent Owner. In its mandatory notice, Patent Owner represents that the "entire right, title and interest in and to" the '356 patent was assigned to Axcess Global Sciences, LLC "on or about November 20, 2018." Paper 5, 2.

A. Related Proceedings

Patent Owner informs us that the following actions involve the '356 patent: *RK Solutions v. Equinox Nutraceuticals*, No. 2:18-cv-00797-RJS-EJF (D. Utah) and *RK Solutions, LLC v. Vitajoy USA Inc.*, No. 2:18-cv-06608-CAS-E (C.D. Cal.). Paper 5, 2.

In addition, *inter partes* review of claims 1 and 2 of the '356 patent was previously instituted based on a petition from a different petitioner in IPR2015-01798. That case was terminated pursuant to joint motion of the parties prior to the filing of a response by Patent Owner and before any final decision from the Board. *See* IPR2015-01798, Paper 16.

B. Background of Technology and the '356 Patent

The '356 patent relates to "a medication for weight loss by means of appetite suppression and a method for administering this medication" to humans. Ex. 1001, Abstr. This medication "comprises potassium butyrate and closely related chemical compounds, which reduce appetite in mammals when administered orally." *Id.* at 2:18–22. According to the Specification, "[t]he anorexic effect of the butyrate ion is thought to be due to the fact that its presence is a signal to the stomach receptors that there are bacteria in the stomach contents," which indicates the stomach is full or "stagnant." *Id.* at 3:11–25. Thus, consuming butyrate ion before each meal makes the stomach feel as if more was eaten than was actually eaten, thereby suppressing the appetite. *Id.* at 3:35–37.

C. Illustrative Claims

Claims 1, 14, and 17 are independent claims. Claims 1–13 are method claims, and claims 14–19 are composition claims. Claim 1 is illustrative of the method claims and is reproduced below.

> 1. A process for causing weight loss, or avoidance of weight gain, in mammals, comprising oral administration to said mammals of butyric acid or one or more pharmaceutically effective and acceptable salts or derivatives of butyric acid selected from the group consisting of/butyric acid, sodium butyrate, calcium butyrate, potassium butyrate, magnesium butyrate, alphahydroxybutyric acid, sodium alphahydroxybutyrate, calcium alphahydroxybutyrate, potassium alphahydroxybutyrate, magnesium alphahydroxybutyrate, betahydroxybutyric acid, sodium betahydroxybutyrate, calcium betahydroxybutyrate, potassium betahydroxybutyrate, magnesium betahydroxybutyrate, isobutyric acid, sodium isobutyrate, calcium isobutyrate, potassium isobutyrate, and magnesium isobutyrate.

Ex. 1001, 8:65–9:12. As shown above, claim 1 recites the oral administration of butyric acid as well as certain salts and derivatives of butyric acid specified in a Markush group. Adopting the parties' nomenclature, we refer to these compounds collectively as the "Markush Compounds."

Claims 14 and 17 are composition claims directed to a "capsule" and "tablet," respectively, comprising one or more of the Markush Compounds in "an amount effective for weight loss or avoidance of weight gain." Claim 14 is illustrative of the composition claims and is reproduced below.

> 14. A composition of matter comprising a capsule capable of dissolving in the stomach of a mammal, wherein said capsule contains, in an amount effective for weight loss or avoidance of weight gain in said mammal, one or more of the compounds selected from the group consisting of/butyric acid, sodium butyrate, calcium butyrate, potassium butyrate, magnesium butyrate, alphahydroxybutyric acid, sodium alphahydroxybutyrate, calcium alphahydroxybutyrate, potassium alphahydroxybutyrate, magnesium alphahydroxybutyrate, betahydroxybutyric acid, sodium betahydroxybutyrate, calcium betahydroxybutyrate, potassium

betahydroxybutyrate, magnesium betahydroxybutyrate, isobutyric acid, sodium isobutyrate, calcium isobutyrate, potassium isobutyrate, and magnesium isobutyrate.

Ex. 1001, 10:7–22.

D. Asserted Challenges to Patentability

Petitioner asserts the following challenges to patentability: [2]

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1, 2, 5–14, 17	102	Pawan[3]
1	103	Pawan
2, 5–14, 17	103	Pawan, Neesby,[4] Moran[5]
3, 4, 15, 16, 18, 19	103	Pawan, Neesby, Moran, Strachan[6]
1, 2, 5–14, 17	102	Martin[7]
1	103	Martin
2, 5–14, 17	103	Martin, Neesby, Moran
3, 4, 15, 16, 18, 19	103	Martin, Neesby, Moran, Strachan

[2] In addition, the Petition presents alternative challenges asserting that Neesby and Moran anticipate claim 1 "[i]f . . . the Board construes claim 1 so as to consider the preamble *not* limiting." Pet. 59–60, 67. As explained below, we determine the preamble is limiting and, therefore, do not address these alternative challenges further.

[3] Pawan et al., Effect of 3-Hydroxybutyrate in Obese Subjects on Very-Low-Energy Diets and During Therapeutic Starvation, The Lancet 15–17 (1983) (Ex. 1010) ("Pawan").

[4] Neesby, U.S. Patent No. 4,721,716, issued Jan. 26, 1988 (Ex. 1014) ("Neesby").

[5] Moran et al., U.S. Patent No. 5,962,523, issued Oct. 5, 1999 (Ex. 1015) ("Moran").

[6] Christine Elizabeth Strachan, *The Formulation Technology of Dispersible Tablets* (Feb. 2000) (Ph.D. thesis, Liverpool John Moores University) (Ex. 1012) ("Strachan").

[7] Martin et al., U.S. Patent No. 6,380,244 B2, filed July 22, 1999, issued Apr. 30, 2002 (Ex. 1017) ("Martin").

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