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Paper 9
Entered: June 15, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VDF FUTURCEUTICALS, INC.,
Petitioner,

v.

HANIF KAZEROONI, BAHRAM NASERNEJAD, ABBAS ABDOLMALAKI, AND AKBAR ZARE,
Patent Owner.

Case IPR2017-00547
Patent 9,327,025 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and ROBERT A. POLLOCK, *Administrative Patent Judges.*

POLLOCK, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

VDF Futurceuticals, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–9 of U.S. Patent No. 9,327,025 B2 (Ex. 1001, "the '025 patent"). Paper 1 ("Pet."). Patent Owner did not elect to file a Preliminary Response to the Petition.

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see* 37 C.F.R. §§ 42.4, 42.108. Upon considering the Petition, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. Accordingly, we institute an *inter partes* review of claims 1–9 of the '025 patent.

A. Related Proceedings

According to Petitioner, there are no other judicial or administrative matters that would affect, or be affected by, a decision in this proceeding. Pet. iv; *see* Paper 5, 2.

B. The '025 Patent and Relevant Background

The '025 Patent issued to Hanif Kazerooni, Bahram Nasernejad, Abbas Abdolmalaki, and Akbar Zare from U.S. Application No. 13/726,500, which was filed on December 24, 2012. The '025 Patent does not, on its face, claim benefit of priority to any other applications.

The '025 patent relates to the synthesis of ^{10}boron-enriched calcium fructoborate (E^{10}BCFB) and its use in Boron Neutron Capture Therapy (BNCT) radio-chemotherapy. Ex. 1001, Abstract. The treatment of cancers

with BNCT was well known in the art. *See*, *e.g.*, Ex. 1001, 1:22–2:67, Figs. 1, 2. According to the Specification, the therapy begins with preferential delivery of a ^{10}B-enriched drug into tumor cells. *Id.* When the concentration of ^{10}B reaches 20–35 μm per gram of tumor tissue, the tumor is bombarded with low energy (slow) neutrons, causing the ^{10}B to emit gamma radiation and high energy alpha particles (^{4}He and ^{7}Li). *Id.* Because the ^{4}He and ^{7}Li alpha particles have a relatively short range, they preferentially damage only the cancerous cells, largely sparing surrounding healthy tissue. *Id.*

Calcium fructoborate is a naturally occurring compound found in some vegetables. *Id.* at Abstract. As found in nature, however, such boron-containing molecules contain only about 20% of the ^{10}B isotope, with the balance being ^{11}B. *Id.* at 3:2–3. The low level of ^{10}B in naturally occurring boron compounds renders them unsuitable for use in BNCT. *Id.* at 4:4–7. Drugs for BNCT therapy are, therefore, synthesized using ^{10}B-enriched reactants such as commercially available ^{10}B-enriched boric acid. *Id.* at 3:3–9. Consistent with the teaching, the prior art of record states that "[a]ll [BNCT] agents which enter clinical trials must be boron-10 enriched (>95%)" and "regardless of the agent type . . . agent syntheses rest upon the availability of boron-10 enriched inorganic precursors." Ex. 1024,[1] 40–41.

The '025 patent discloses a method for making a genus of ^{10}B-enriched sugar complexes using ^{10}B-enriched boric acid, most

[1] Hawthorne and Lee, "*A critical assessment of boron target compounds for boron neutron capture therapy*," 62 J. Neuro-Oncology 33–45 (2003).

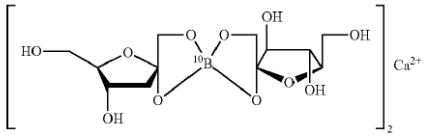
particularly, the E^{10}BCFB isomers of Formula A and Formula B. *See* Ex. 1001, 14:46–16:6. Drugs containing these ^{10}B-enriched sugar complexes may be administered by IP, IV, or oral routes for BNCT therapy. *Id.* at 13:22–48.

C. Challenged Claims

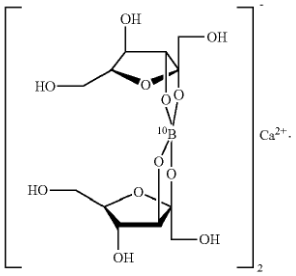
The independent claims at issue are directed to a drug containing certain E^{10}BCFB isomers (claim 1); a method of synthesizing E^{10}BCFB and related compounds (claim 2); and a method of treating cancer using E^{10}BCFB (claim 7).

Claim 1 recites:

> 1. A novel drug containing enriched 10-Boron for cancer cell treatment in Boron Neutron Capture Therapy (BNCT) comprising an Enriched 10-Boron Calcium Fructo Borate (E^{10}BCFB) having a Formula A or a Formula B, wherein the Formula A is represented by:



and wherein the Formula B is represented by:



Claim 2 recites:

> 2. A method of synthesizing an enriched 10-Boron complex for Boron Neutron Capture Therapy (BNCT) comprising:

dissolving a monosaccharide in a solvent at room temperature while stirring, wherein the solvent is water or alcohol, and wherein the monosaccharide is selected from a group consisting of a glucose and a fructose;

adding a solution of an enriched ^{10}B boric acid with maximum content of ^{10}B to form a mixture;

adjusting a pH of the mixture, wherein the pH of the mixture is adjusted to be equal to 3–4;

adding a solution of a carbonate salt of calcium to the mixture while continuously stirring, wherein the solution of the carbonate salt of calcium is added after a produced carbon dioxide gas is completely removed from the mixture;

forming a bi-phase solution, wherein the bi-phase solution comprises a lower phase and an upper phase, wherein the lower phase is a boron complex and wherein the upper phase is an oily liquid;

separating the lower phase by scratching the lower phase using a glass bar;

collecting the lower phase; and

grinding the lower phase to obtain an enriched 10-Boron complex or a composition.

Depending from claim 2, claim 3 recites that "the enriched 10-Boron complex is Enriched 10-Boron Calcium FructoBorate ($E^{10}BCFB$)"; claim 4 further limits the enriched 10-boron complex to Formula A or Formula B as set forth in claim 1; and claims 5 and 6, respectively, specify molar concentrations of monosaccharide and ^{10}B-enriched boric acid used in the reaction.

Claim 7 recites:

7. A method of treating cancer using Boron Neutron Capture Therapy (BNCT) comprising steps of:

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