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Paper 11
Date: September 10, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION,
Petitioner,

v.

BASF PLANT SCIENCE GMBH,
Patent Owner.

PGR2020-00033
Patent 10,301,638 B2

Before ULRIKE W. JENKS, JO-ANNE M. KOKOSKI, and JEFFREY W. ABRAHAM, *Administrative Patent Judges.*

KOKOSKI, *Administrative Patent Judge*.

DECISION
Granting Institution of Post-Grant Review
35 U.S.C. § 324(a)

I. INTRODUCTION

Commonwealth Scientific and Industrial Research Organisation ("Petitioner") filed a Petition requesting post-grant review of claims 1–23 ("the challenged claims") of U.S. Patent No. 10,301,638 B2 ("the '638 patent," Ex. 1001). Paper 2 ("Pet."). BASF Plant Science GmbH ("Patent Owner") filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

Under 35 U.S.C. § 324(a), a post-grant review may be instituted only if "the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." Post-grant review is available for patents that issue from applications that at one point contained at least one claim with an effective filing date on or after March 16, 2013. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), §§ 3(n)(1), 6(f)(2)(A). Upon consideration of the Petition, the Preliminary Response, and the evidence of record, we determine that the evidence and arguments presented in the Petition are sufficient to establish that it is more likely than not that at least one of the challenged claims is unpatentable. Accordingly, for the reasons that follow, we institute a post-grant review of claims 1–23 of the '638 patent.

A. Real Parties-in-Interest

Petitioner identifies Commonwealth Scientific and Industrial Research Organisation as the real party-in-interest. Pet. 4. Patent Owner identifies BASF Plant Sciences GmbH as the real party-in-interest. Paper 8, 1.

B. Related Matters

The parties identify as related matters several U.S. patent applications that claim the benefit of priority to the application that issued as the '638 patent. Pet. 5–6; Paper 8, 1.

C. The '638 Patent

The '638 patent, titled "Oils, Lipids and Fatty Acids Produced in Transgenic *Brassica* Plant," issued on May 28, 2019 from U.S. Application No. 15/256,914 ("the '914 application"), filed on September 6, 2016. Ex. 1001, codes (21), (22), (45), (54). The '914 application is a continuation of U.S. Application No. 12/280,090 ("the '090 application"), which was filed as Application No. PCT/EP2007/051675 ("the '675 PCT") on Feb. 21, 2007.

The '638 patent relates to a process for the production of eicosapentaenoic acid ("EPA"), docosapentaenoic acid ("DPA"), and/or docosahexaenoic acid ("DHA") in transgenic plants, and to "oils, lipids, and/or fatty acids which have been produced by the process." Ex. 1001, 1:25–27, 2:1–3. The Specification explains that there is "a great need for a simple, inexpensive process for the production of polyunsaturated, long-chain fatty acids, specifically in plant systems" for use in fortifying food and animal feed. *Id.* at 6:4–8. To that end, the Specification teaches that the yield of long-chain polyunsaturated fatty acids ("LCPUFAs"), particularly EPA, DPA, and/or DHA "can be increased by expressing an optimized Δ5-elongase sequence in transgenic plants." *Id.* at 6:15–19.

The process described in the '638 patent includes providing to a plant nucleic acid sequences that code for each of a polypeptide having (1) Δ6-desaturase activity; (2) Δ6-elongase activity; (3) Δ5-desaturase activity; and (4) Δ5-elongase activity. *Id.* at 6:27–42. "To produce DHA it is additionally necessary to provide at least one nucleic acid sequence which codes for a polypeptide having Δ4-desaturase activity in the plant." *Id.* at 6:42–45. The Specification teaches that the fatty acids EPA, DPA, and/or DHA produced by the process are "present with a content of in each case at

least 5% by weight, preferably of in each case at least 6, 7, 8 or 9% by weight, particularly preferably of in each case at least 10, 11, or 12% by weight, and most preferably of in each case at least 13, 14, 15, 16, 17, 18, 19, or 20% by weight based on the total fatty acids in the transgenic plant." *Id*. at 15:29–36.

The Specification further teaches that useful plants that are suitable for the process include "plants which serve to produce foods for humans or animals, to produce other consumables, fibers and pharmaceuticals," such as cereals, tubers, sugar plants, and oil and fat crops. *Id*. at 16:61–17:4. Several plant families are identified as being "advantageous," including the *Brassicaceae* family. *Id*. at 17:4–16; *see id*. at 23:38–52.

D. Challenged Claims

Petitioner challenges claims 1–23 ("the challenged claims") of the '638 patent. Claims 1 and 9 are the only independent claims, and are reproduced below:

> 1. Oils, lipids and/or fatty acids produced by a transgenic *Brassica* plant, wherein said oils, lipids, and/or fatty acids comprise 60 to 85% by weight of polyunsaturated fatty acids based on the total fatty acids in the transgenic plant, wherein said polyunsaturated fatty acids comprise at least 20% by weight of eicosapentaenoic acid (EPA), at least 2% by weight of docosapentaenoic acid (DPA), and at least 4% by weight of docosahexaenoic acid (DHA) based on the total fatty acids in the transgenic plant in the form of triacylglycerides.

Ex. 1001, 61:36–45.

> 9. Oils, lipids and/or fatty acids produced by a transgenic *Brassica* plant, wherein said oils, lipids and/or fatty acids comprise a total amount of at least 54% by weight of polyunsaturated ω3-fatty acids based on the total fatty acids in the transgenic plant.

Id. at 62:63–67.

E. Asserted Grounds

Petitioner asserts that claims 1–23 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–23	112(a)	Lack of written description support[1]
1–23	112(a)	Lack of enablement[2]
9	102(a)	Published PCT Application No. WO 99/64614 ("the '614 publication," Ex. 1012)
9, 10, 12, 13, 14, 16	102(a)	Published PCT Application No. WO 2015/196250 A1 ("the '250 publication," Ex. 1014)
1–23	102(a) or 103	Published PCT Application No. WO 2005/083093 A2 ("the '093 publication," Ex. 1006)

Pet. 33–36. Petitioner relies on the Declaration of Narendra Yadav, Ph.D., (Ex. 1002, "the Yadav Declaration") to support its contentions.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner contends that a person having ordinary skill in the art "would have had at least a Ph.D. in molecular biology, molecular genetics, biochemistry, or a related field and at least 3–5 years of experience in molecular genetics or biology, plant genetics, or recombinant DNA techniques," but that "[a]n individual need not have every qualification enumerated above and more experience, such as research work on plant lipids, can compensate for less formal education." Pet. 38 (citing Ex. 1002

[1] Grounds 1–11 challenge subsets of claims 1–23 for lack of written description support based on different claim limitations.
[2] Grounds 12–22 challenge subsets of claims 1–23 for lack of enablement of different claim limitations.

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