

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.

PGR2021-00004
Patent 10,533,183 B2

Before ULRIKE W. JENKS, JO-ANNE M. KOKOSKI, and
ROBERT A. POLLOCK, *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 1–9 (“the challenged claims”) of U.S. Patent No. 10,533,183 B2 (Ex. 1001, “the ’183 patent”). Paper 1 (“Pet.”). BASF Plant Science GmbH (“Patent Owner”) did not file a Preliminary Response.

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 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 1–9 of the ’183 patent.

A. Real Parties in Interest

Each party identifies itself as the real party-in-interest. Pet. 4; Paper 5, 1.

B. Related Matters

The parties identify as a related matter pending U.S. Patent Application No. 16/371,696, which, like the application from which the ’183 patent issued, is a continuation of U.S. Patent Application No. 15/256,914 (“the ’914 application,” issued as U.S. Patent No. 10,141,638 B2). Pet. 6; Paper 5, 1.

C. The '183 Patent

The '183 patent, titled “Oils, Lipids and Fatty Acids Produced in Transgenic *Brassica* Plant,” issued on January 14, 2020 from U.S. Application No. 16/371,837 (“the '837 application”), filed on April 1, 2019. Ex. 1001, codes (21), (22), (45), (54). The '837 application is a continuation of the '914 application, which is a continuation of U.S. Application No. 12/280,090 (“the '090 application”), which in turn was filed as Application No. PCT/EP2007/051675 on February 21, 2007. *Id.* at code (63).

The '183 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, code (54), 1:29–31, 2:3–5. 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 6:5–9. 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 $\Delta 5$ -elongase sequence in transgenic plants.” *Id.* at 6:15–19.

The process described in the '183 patent includes providing to a plant nucleic acid sequences that code for each of a polypeptide having (1) $\Delta 6$ -desaturase activity; (2) $\Delta 6$ -elongase activity; (3) $\Delta 5$ -desaturase activity; and (4) $\Delta 5$ -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 a $\Delta 4$ -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, 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 and 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 1–9 (“the challenged claims”) of the ’183 patent. Claim 1 is the only independent claim, and is reproduced below:

1. Oils, lipids and/or fatty acids produced by a transgenic *Brassica* plant, wherein said oils, lipids and/or fatty acids comprise in the sn-2 position^[1] 25% to 40% by weight of eicosapentaenoic (EPA) based on the total EPA.

Ex. 1001, 61:33–36.

E. Asserted Grounds

Petitioner asserts that the challenged claims are unpatentable on the following twenty grounds. Pet. 26–29.

¹ Petitioner’s expert explains that “sn position” refers to “stereospecifically numbered” positions on a glycerol molecule to which fatty acids are attached. Ex. 1002 ¶ 46.

| Claim(s) Challenged | 35 U.S.C. § | Reference(s)/Basis |
|---------------------|-------------|-------------------------------|
| 1-9 | 112(a) | Written description |
| 2 | 112(a) | Written description |
| 3 | 112(a) | Written description |
| 4 | 112(a) | Written description |
| 5 | 112(a) | Written description |
| 6 | 112(a) | Written description |
| 7 | 112(a) | Written description |
| 8 | 112(a) | Written description |
| 1-9 | 112(a) | Enablement |
| 2 | 112(a) | Enablement |
| 3 | 112(a) | Enablement |
| 4 | 112(a) | Enablement |
| 5 | 112(a) | Enablement |
| 6 | 112(a) | Enablement |
| 7 | 112(a) | Enablement |
| 8 | 112(a) | Enablement |
| 1-3, 5-9 | 102(a) | Wu ² |
| 1-9 | 102(a)/103 | '093 publication ³ |
| 1-9 | 103 | Wu, '093 publication |
| 1-9 | 103 | '387 publication ⁴ |

Petitioner relies on the Declaration of Narendra Yadav, Ph.D. (Ex. 1002) in support of its arguments.

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art (“POSITA”) as of the date of the invention “would have had at least a Ph.D. in molecular biology, molecular genetics, biochemistry, or a related field and at least 3–5

² G. Wu et al., *Stepwise engineering to produce high yields of very long-chain polyunsaturated fatty acids in plants*, 23 NATURE BIOLOGY 8, 1013–17 (August 2005) (Ex. 1008).

³ Published PCT Application No. WO 2005/083093 A2 (Ex. 1006).

⁴ Published PCT Application No. WO 2007/096387 A1 (Ex. 1003).

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