Trials@uspto.gov
571-272-7822

Paper 10
Date: May 17, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DANISCO US INC. and DUPONT NUTRITION BIOSCIENCES ApS,
Petitioner,

v.

NOVOZYMES A/S,
Patent Owner.

IPR2021-00189
Patent 10,555,541 B2

Before JAMES A. WORTH, ROBERT A. POLLOCK and,
RYAN H. FLAX, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background

Danisco US Inc. and DuPont Nutrition Biosciences ApS (collectively, "Petitioner") filed a Petition for an *inter partes* review of claims 1, 3–9, and 11–17 of U.S. Patent No. 10,555,541 B2 ("the '541 Patent," Ex. 1001). Paper 1 ("Pet."). Novozymes A/S ("Patent Owner") timely filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

B. Summary of the Institution Decision

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least one claim of the '541 Patent is unpatentable, we institute an *inter partes* review of all challenged claims on each of the Grounds raised in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *see also* Guidance on the Impact of *SAS* on AIA Trial Proceedings (April 26, 2018) (available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial) ("Guidance").

C. Real Parties-in-Interest

Petitioner identifies Danisco US Inc., DuPont Nutrition Biosciences ApS, and International Flavors & Fragrances Inc. as real parties-in-interest. Paper 8.

Patent Owner, identifies Novozymes A/S, Novozymes North America Inc. and Chr. Hansen A/S as real parties-in-interest. Paper 6, 1.

D. Related Matters

Petitioner concurrently challenges claims of related patent, US 10,058,107 B2 ("the '107 patent") in IPR2021-00188. *See* Paper 6, 1, Pet. 4, 32 (flowchart illustrating relationship between related patents and patent applications). Petitioner explains that "[t]he claims of the '541 Patent are nearly identical to the claims of the '107 patent, differing only by the added requirement that the claimed polypeptide is "isolated." Pet. 4. Petitioner further notes that the '541 Patent is terminal disclaimed over the earlier-issued '107 patent. *Id.*

E. Asserted Ground of Unpatentability

Petitioner asserts a single ground of unpatentability (Pet. 6):

Claims Challenged	Statutory Basis	Reference(s)
1, 3–9, 11–17	§ 103[1]	Larsen[2]

In support of its patentability challenge, Petitioner relies on, *inter alia*, the Declaration of Douglas S. Clark, Ph.D. Ex. 1002. Based on the preliminary record before us, we determine that Dr. Clark is qualified to offer testimony on the knowledge of one of ordinary skill in the art as of any of the asserted priority dates of the '541 Patent. *See, e.g., id.* ¶¶ 3–38 (Dr. Clark's statements as to his background and qualifications, and

[1] Petitioner asserts that the '541 Patent has a priority date of February 15, 2017, which is after the AIA revisions to 35 U.S.C. § 103 (and § 112) took effect. Patent Owner asserts that the '541 Patent has a priority date at least as early as December 2, 2008, which is before the AIA took effect. Regardless of whether we look to the pre- or post-AIA version of the Patent Act, the same substantive legal requirements apply and no change in the law impacts the outcome of this Decision.

[2] Larsen et al., US 2015/0223481 A1, published Aug. 13, 2015. Ex. 1003.

background on the relevant technology), ¶ 43 (Dr. Clark's opinion regarding the definition of one of ordinary skill in the art), Appendix A (Dr. Clark's curriculum vitae). At this stage of the proceeding, Patent Owner has not submitted, nor was it required to submit, similar testimony evidence.

F. The '541 Patent

The '541 Patent issued to Hendriksen et al., from U.S. Application 16/380,220 (the '220 application), filed April 10, 2019, via a series of continuation applications including U.S. Application 15/433,642, which issued as the '107 Patent, and U.S. Application No. 12/744,508 ("the '508 application), first filed on December 2, 2008, as international application PCT/EP2008/066624 ("the '624 PCT"). Ex. 1001, code (63), 1:7–17; *see also* Pet. 32 (flowchart). Accordingly, the '541 Patent has substantially the same specification as the '107 Patent, the '508 application, and the '624 PCT.

Although not implicated in our decision to institute trial, the '541 Patent further claims priority to U.S. Provisional Application 61/055,164 filed May 22, 2008, U.S. Provisional Application 60/992,783 filed December 6, 2007, European Application 07122110.5 filed December 3, 2007, and European Application 08156674.7 filed May 21, 2008. Ex. 1001, codes (60), (30), 1:6–21; *see also* Prelim. Resp. 3–4, n.2 ("For purposes of the IPR and the prior art status of Larsen, it is not necessary to reach the issue of whether the '541 Patent claims are entitled to the earlier filing dates of these applications.").

1) Background and Specification

The present invention involves enzymes from *Bifidobacterium bifidum* having lactase and transgalactosylase activities. *See, generally,*

Ex. 1001, 2:35–46. With respect to the former, the '541 Patent's Abstract states: "The present invention relates to a method for producing a dairy product using an enzyme having lactase activity." *Id.* at Abstract; *see also id.* at 11:29–41 (defining lactases within the scope of the invention), 11:42–12:10 (biological sources for lactase enzymes). Consistent with the Specification, Dr. Clark explains that lactases, or more specifically, β-galactosidases, "are often used to hydrolyze the sugar lactose naturally present in milk, making low-lactose or lactose-free dairy products suitable for consumption by individuals unable to properly digest dairy products. During lactose hydrolysis, β-galactosidase cleaves lactose into equal amounts of two products, glucose and galactose." Ex. 1002 ¶ 14; *see* Ex. 1001, 1:34–40. According to Dr. Clark:

> Some β-galactosidase enzymes can also convert lactose into galactooligosaccharides through a different reaction known as transgalactosylation. During transgalactosylation, the enzyme breaks lactose into glucose and galactose and transfers galactose to an accepting alcohol group of another carbohydrate (e.g., glucose, galactose, lactose, or galactose-containing oligosaccharides), building carbohydrate chains known as galactooligosaccharides ("GOS").

Id. ¶ 15 (internal citations omitted). These resulting galactooligosaccharides, or GOS, comprise "2 to 20 molecules of galactose and 1 molecule of glucose." Ex. 1007, Abstract. Dr. Clark further explains that "GOS are non-digestible prebiotics that promote proliferation of microorganisms, such as healthy bacteria in yogurt, that can improve digestion and promote growth of

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.