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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.

IPR2021-00188
Patent 10,058,107 B2

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

FLAX, *Administrative Patent Judge*.

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

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 10,058,107 B2 ("the '107 patent," Ex. 1001). Paper 1 ("Pet."). Novozymes A/S ("Patent Owner") filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

Under 37 C.F.R. § 42.4(a), we have authority to determine whether to institute trial in an *inter partes* review. We may institute an *inter partes* review if the information presented in the petition filed under 35 U.S.C. § 311, and any preliminary response filed under § 313, shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314.

After reviewing the parties' submissions, we conclude Petitioner demonstrates a reasonable likelihood it would prevail in showing that claims of the '107 patent are unpatentable under the presented ground. Therefore, we institute *inter partes* review of all challenged claims (1, 3–9, and 11–17) under the ground raised in the Petition, pursuant to 35 U.S.C. § 314. *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").

I. INTRODUCTION

A. 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.

B. RELATED MATTERS

Petitioner identifies IPR2021-00189 regarding U.S. Patent 10,555,541 as a related matter. Pet. 4 ("The 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.'"). Patent Owner identifies the same proceeding as a related matter. Paper 6.

C. THE '107 PATENT

The '107 patent is titled "METHOD FOR PRODUCING A DAIRY PRODUCT." Ex. 1001, code (54). The '107 patent issued on August 28, 2018, from U.S. Application 15/433,642 ("the '642 application," *see* Ex. 1011), which was filed on February 15, 2017, and claims priority as a continuation to U.S. Application 12/744,508 ("the '508 application"), which was originally filed on December 2, 2008 as international application PCT/EP2008/066624 ("the '624 PCT application"), and also 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, 2008, and European Application 08156674.7 filed May 21, 2008.[1] Ex. 1001, codes (45), (21), (63), (60), (30), 1:7–17.

[1] Petitioner challenges the '107 patent's claim to priority to any date earlier than the patent's actual filing date of February 15, 2017. Pet. *passim*. Patent Owner identifies the '107 patent's claim to priority to each of the identified preceding filings, but also states that "the challenged claims are entitled to at least the December 2, 2008, filing date of the '624 PCT," and that "[f]or purposes of the IPR and the prior art status of Larsen, it is not necessary to reach the issue of whether the '107 patent claims are entitled to the earlier filing dates of these applications." Prelim. Resp. 3–4, n.2, 19.

The '107 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. The '107 patent further states that "to help dairy maldigesters keep dairy foods in their diet, there is a growing demand for dairy food products that contain no or only low levels of lactose," and "[l]actase is used commercially to break down lactose in milk to produce dairy products which are suitable for people with lactose intolerance and/or have a sweeter taste." *Id.* at 1:34–39. Further, the '107 patent states "[a] lactase from *Bifidobacterium bifidum* has been described having a high transgalactosylating activity, both in the full-length form and especially when truncated from the C-terminal end (*see*, e.g., Jørgensen et al. (2001), *Appl. Microbiol. Biotechnol.*, 57: 647-652 or EP patent 1,283,876)," and "[i]t is an object of the present invention to provide a method for production of dairy products, e.g. fermented dairy products, such as yoghurt, having a low level of lactose by using a lactase," thus "[l]actase to be used according to the invention should hydrolyse lactose efficiently and optimally allow for almost complete lactose hydrolysis. Especially, such lactase should have a high ratio of lactase to transgalactosylase activity." *Id.* at 2:8–26.

Regarding this interplay between lactase hydrolyzing and transgalactosylating functionality, the '107 patent states

> The present inventors have surprisingly found that a C-terminally truncated fragment of the extracellular lactase from *Bifidobacterium bifidum*, which was originally isolated and patented for its ability to make high amounts of galactooligosaccharides from lactose, can be used very successfully for hydrolysis of lactose in milk. When tested in water+100 g/l lactose at 37 °C., the enzyme makes galactooligosaccharides with high efficiency as described in the prior art. However, when tested in milk, the ratio of hydrolytic

> to transgalactosylating activity has changed markedly, resulting in efficient hydrolysis and very low production of galactooligosaccharides.

Id. at 2:32–43. The '107 patent explains that "[a] lactase in the context of the present invention is any glycoside hydrolase having the ability to hydrolyse the disaccharide lactose into constituent galactose and glucose monomers," but that "[a] lactase in the context of the invention may have other activities than the lactose hydrolysing activity, such as for example a transgalactosylating activity." *Id.* at 11:32–41.

The '107 patent identifies many organisms from which a lactase enzyme may be derived, but describes that one preferred enzyme is a lactase from the bacteria species *Bifidobacterium bifidum*

> having a sequence which is at least 50%, such as at least 60%, at least 70%, at least 80%, at least 90%, at least 95% or at least 98% identical to amino acids 28-1931 of SEQ ID NO: 1 or to a lactase active fragment thereof. Such lactase active fragment of SEQ ID NO: 1 may be any fragment of SEQ ID NO: 1 having lactase activity. A lactase active fragment of SEQ ID NO: 1 may be, e.g., amino acids 28-979, amino acids 28-1170, amino acids 28-1323, amino acids 28-1331, or amino acids 28-1600 of SEQ ID NO: 1.

Id. at 11:50–12:25. Other than the claims, this is the only mention in the '107 patent of the amino acid sequence 28–979 of SEQ ID NO: 1 and no smaller fragments of this amino acid sequence are identified. *See generally id.*; *see also id.* at col. 23–33 (SEQ ID NO: 1); *see also* Pet. 19 (citing Ex. 1002 ¶¶ 62–63, and noting this singular disclosure).

The '107 patent describes that in one

> preferred embodiment, the enzyme when hydrolysing the lactose in the milk-based substrate has a ratio of lactase to transgalactosylase activity of more than 1:1, such as more than 2:1 or more than 3:1. In another preferred embodiment, the

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