

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN HUMAN MILK
OLIGOSACCHARIDES AND METHODS
OF PRODUCING THE SAME**

Investigation No. 337-TA-1120

LIMITED EXCLUSION ORDER

The United States International Trade Commission (“Commission”) has determined that there is a violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the unlawful importation, sale for importation, or sale within the United States after importation by Jennewein Biotechnologie GmbH (“Jennewein” or “Respondent”) of certain 2’-fucosyllactose oligosaccharides that infringe one or more of claims 1-3, 5, 8, 10, 12, 18, and 24-28 (“the Asserted Claims”) of U.S. Patent No. 9,970,018 (“the ’018 patent”).

Having reviewed the record of this investigation, including the written submissions of the parties, the Commission has made its determination on the issues of remedy, public interest, and bonding. The Commission has determined that the appropriate form of relief includes a limited exclusion order prohibiting the unlicensed entry into the United States of 2’-fucosyllactose oligosaccharides manufactured abroad by or on behalf of, or imported by or on behalf of, Respondent or any of its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns. The exclusion order does not apply to Respondent’s TTFL12 bacterial strain and 2’-fucosyllactose oligosaccharides produced by that strain, which, as the Commission determined, do not infringe the Asserted Claims.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude the issuance of the limited exclusion order, and that the bond

during the period of Presidential review shall be in the amount of five (5) percent of the entered value of the covered articles.

Accordingly, the Commission hereby ORDERS that:

1. 2'-fucosyllactose oligosaccharides that infringe one or more of the Asserted Claims that are manufactured abroad by or on behalf of, or imported by or on behalf of, Respondent, or its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns ("covered articles"), are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining term of the '018 patent, except under license of the patent owner or as provided by law.

2. This Order does not apply to Respondent's TTFL12 bacterial strain and 2'-fucosyllactose oligosaccharides produced by that strain, which, as the Commission determined, do not infringe the Asserted Claims.

3. Notwithstanding paragraph 1 of this Order, covered articles are entitled to entry into the United States for consumption, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, under bond in the amount of five (5) percent of the entered value of the infringing products pursuant to subsection (j) of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337(j)), and the Presidential Memorandum for the United States Trade Representative of July 21, 2005, (70 FR 43251), from the day after this Order is received by the United States Trade Representative, and until such time as the United States Trade representative notifies the Commission that this Order is approved or disapproved but, in any event, not later than sixty (60) days after the date of receipt of this Order. All entries of

covered articles made pursuant to this paragraph are to be reported to U.S. Customs and Border Protection (“CBP”), in advance of the date of the entry, pursuant to procedures CBP establishes.

4. At the discretion of CBP and pursuant to the procedures it establishes, persons seeking to import 2'-fucosyllactose oligosaccharides, that are potentially subject to this Order may be required to certify that they are familiar with the terms of this Order, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under paragraph 1 of this Order. At its discretion, CBP may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate this certification.

5. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to 2'-fucosyllactose oligosaccharides that are imported by or for the use of the United States, or imported for and to be used for, the United States with the authorization or consent of the Government.

6. The Commission may modify this Order in accordance with the procedures described in Rule 210.76 of the Commission’s Rules of Practice and Procedure (19 C.F.R. § 210.76).

7. The Secretary shall serve copies of this Order upon each party of record in this Investigation and upon CBP.

8. Notice of this Order shall be published in the Federal Register.

By order of the Commission.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton', written in a cursive style.

Lisa R. Barton
Secretary to the Commission

Issued: May 19, 2020

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER, COMMISSION** has been served via EDIS upon the Commission Investigative Attorney, **Lisa Murray, Esq.**, and the following parties as indicated, on **May 19, 2020**.



Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainant Glycosyn LLC:

Michael C. Newman, Esq.
MINTZ LEVIN COHN FERRIS GLOVSKY AND POPEO, PC
1 Financial Center
Boston, MA 02111
Email: MCNewman@mintz.com

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: Email Notification of Availability to Download

On Behalf of Respondent Jennewein Biotechnologie GmbH:

Gary M. Hnath
MAYER BROWN LLP
1999 K Street, NW
Washington, DC 20006
Email: ghnath@mayerbrown.com

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: Email Notification of Availability to Download