

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

**NOTICE OF COMMISSION FINAL DETERMINATION FINDING
A VIOLATION OF SECTION 337; ISSUANCE OF A LIMITED EXCLUSION
ORDER; TERMINATION OF THE INVESTIGATION**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 of the Tariff Act of 1930 (“section 337”), as amended, in this investigation. The Commission has issued a limited exclusion order (“LEO”) prohibiting the importation by respondent Jennewein Biotechnologie GmbH (“Jennewein”) of Rheinbreitbach, Germany of certain human milk oligosaccharides that infringe complainant’s asserted claims. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 21, 2018, based on a complaint, as amended and supplemented, filed on behalf of Glycosyn LLC of Waltham, Massachusetts (“Glycosyn”). *See* 83 Fed. Reg. 28865 (June 21, 2018). The complaint, as amended and supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (“section 337”), based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain human milk oligosaccharides by reason of infringement of claims 1-40 of U.S. Patent No. 9,453,230 (“the ’230 patent”) and claims 1-28 of U.S. Patent No. 9,970,018 (“the ’018 patent”).

See id. The notice of investigation named Jennewein as a respondent in this investigation. *See id.* The Office of Unfair Import Investigations (“OUII”) is also named as a party to the investigation. *See id.*

The ALJ conducted an evidentiary hearing on May 14-17, 2019, and on September 9, 2019, issued the FID finding a violation of section 337 based on the infringement of claims 1-3, 5, 8, 10, 12, 18, and 24-28 of the '018 patent (hereinafter, the “Asserted Claims”). In addition, the FID finds that the Asserted Claims are neither invalid under 35 U.S.C. §§ 103 and 112, nor unenforceable for inequitable conduct. Furthermore, the FID finds that the domestic industry requirement is satisfied. All asserted claims in the '230 patent were withdrawn during the investigation. The FID also contains a recommended determination (“RD”) recommending that the Commission issue an LEO barring entry of articles that infringe the '018 patent. The RD also recommends that the Commission impose a 5 percent bond during the period of Presidential review. Furthermore, as directed by the Commission, the RD provides findings with respect to the public interest and recommends that the Commission determine that the public interest factors do not preclude entry of the proposed LEO. Glycosyn does not seek and the RD does not recommend issuance of a cease and desist order.

On October 9 and 10, 2019, respectively, Glycosyn and Jennewein filed statements on the public interest pursuant to Commission Rule 210.50. On October 23, 2019, non-party DuPont Nutrition & Health filed a public interest submission pursuant to the Commission’s notice requesting public interest comments. *See* 84 Fed. Reg. 49335 (Sept. 19, 2019).

On January 30, 2020, the Commission issued a notice determining to review the FID in part. *See* 85 Fed. Reg. 6573 (Feb. 5, 2020). The Commission’s notice requested written submissions in response to certain questions relating to issues under review and on issues of remedy, the public interest, and bonding. On February 18, 2020, the parties, including OUII, filed written submissions in response to the notice, and on February 25, 2020, the parties filed responses to each other’s submissions. On February 18, 2020, non-party Abbott Laboratories filed a written submission concerning the public interest.

Having examined the record of this investigation, including the FID, the RD, and the parties’ and non-parties’ submissions, the Commission has determined to affirm with modification the FID’s determination of a violation of section 337 with respect to claims 1-3, 5, 8, 10, 12, 18, and 24-28 of the '018 patent. Specifically, as explained in the Commission Opinion filed concurrently herewith, the Commission has determined to affirm with modification the FID’s findings with respect to infringement by the accused Jennewein bacterial strains and to reverse the FID’s decision not to adjudicate infringement with respect to Jennewein’s TTFL12 bacterial strain. As to the TTFL12 strain, the Commission has determined that it does not infringe the Asserted Claims. All findings in the FID that are not inconsistent with the Commission’s determination are affirmed.

The Commission has determined that the appropriate remedy is an LEO against Jennewein’s infringing products. The Commission has also determined that the public interest factors enumerated in subsection 337(d)(1) (19 U.S.C. 1337(d)(1)) do not preclude the issuance of the LEO. The Commission has further determined to set a bond during the period of

Presidential review at five (5) percent of the entered value of Jennewein's infringing products (19 U.S.C. 1337(j)).

The Commission's order and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance.

The Commission's vote for these determinations took place on May 19, 2020.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

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