7020-02

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1120]

Certain Human Milk Oligosaccharides and Methods of Producing the Same

Commission Decision to Review in Part a Final Initial Determination Finding a Violation of Section 337; Schedule for Filing Written Submissions on the Issues under Review and on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part a final initial determination ("FID") of the presiding administrative law judge ("ALJ") finding a violation of section 337 of the Tariff Act of 1930, as amended. The Commission requests briefing from the parties on certain issues under review, as set forth in this notice. The Commission also requests briefing from the parties, interested persons, and government agencies on the issues of remedy, the public interest, and bonding.

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 Biotechnologie GmbH ("Jennewein") of Rheinbreitbach, Germany 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.*

On August 9, 2018, the ALJ partially terminated the investigation as to claims 4-7, 9-12, 14, 23-26, 28-31, 33, and 39-40 of the '230 patent and claims 6, 7, 9, 11, 13-17, 19, and 22 of the '018 patent based on the withdrawal of the allegations pertaining to those claims. *See* Order No. 5 (Aug. 9, 2018), *unreviewed*, Comm'n Notice (Aug. 29, 2018). On October 30, 2018, the ALJ partially terminated the investigation as to claims 1-3, 8, 13, and 15-20 of the '230 patent based on the withdrawal of the allegations pertaining to those claims. *See* Order No. 15 (Oct. 30, 2018), *unreviewed*, Comm'n Notice (Nov. 29, 2018). On November 19, 2018, the ALJ partially terminated the investigation as to claim 27 of the '230 patent and claims 4, 20, and 21 of the '018 patent based on the withdrawal of the allegations pertaining to those claims. *See* Order No. 17 (Nov. 19, 2018), *unreviewed*, Comm'n Notice (Dec. 12, 2018). On February 8, 2018, the ALJ

partially terminated the investigation as to claims 21, 22, 32, and 34-38 of the '230 patent based on the withdrawal of the allegations pertaining to those claims. *See* Order No. 25 (Feb. 8, 2019), *unreviewed*, Comm'n Notice (Feb. 28, 2019). Claims 1-3, 5, 8, 10, 12, 18, and 23-28 of the '018 patent remain pending in this investigation.

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. 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. The FID also contains a recommended determination ("RD") recommending that the Commission issue a limited exclusion order ("LEO") barring entry of articles that infringe the '018 patent. The RD also recommends that the Commission impose a 5% 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 LEO.

On September 23, 2019, Jennewein and OUII filed petitions for review of the FID. On October 1, 2019, Glycosyn and OUII filed responses to Jennewein's and the IA's petitions.

Having examined the record of this investigation, including the FID, the RD, and the parties' submissions, the Commission has determined to review the FID in part. Specifically, the Commission has determined to review the FID's infringement findings with respect to Jennewein's bacterial strains adjudicated in this investigation. In addition, the Commission has determined to review the FID's decision not to adjudicate infringement as to Jennewein's

alternative bacterial strain, the TTFL12 strain. The Commission has determined not to review the remainder of the FID.

In connection with its review, the Commission requests written responses regarding the following inquiries:

1. Assuming that the Commission determines to adjudicate infringement with respect to Jennewein's TTFL12 bacterial strain, please provide your position, with support from the evidentiary record, as to whether the TTFL12 strain infringes or does not infringe the asserted patent claims.
2. Should the Commission adjudicate infringement with respect to Jennwein's alternative strain? Is the Commission's determination of whether to adjudicate an alternative or redesigned product a legal question, a factual question, a mixed question of law or fact, an exercise of discretion, or something else?
3. Is the TTFL12 strain within the scope of the investigation? What criteria and evidence normally informs this analysis?
4. Does a respondent need to import an alternative or redesigned product for the product to be adjudicated?
5. What evidence corroborates Jennewein's assertion that the products listed in the shipping documents (RX-278C and RX-280C) were produced with the TTFL12 strain? Please

provide your answers in a table with citations in one column and a brief explanation in a second column.

6. What is the effect of Jennewein's responses to Glycosyn's request for admission? Why has Jennewein failed to amend its responses if they are incorrect or misleading?
7. Is the TTFL12 strain sufficiently fixed in design? What criteria and evidence normally informs this analysis? Is there any declaratory judgment precedent that is relevant? Which party bears the burden of showing that an alternative or redesigned product is fixed in design?
8. Has the TTFL12 strain been subject to sufficient discovery? What criteria and evidence normally informs the "sufficient discovery" analysis?
9. Should the Commission issue remedial orders that are directed to the adjudicated strains (the #1540 and #1540 derivative) at this juncture?

Responses to the above questions should not exceed 40 pages, and replies should not exceed 20 pages.

In addition, in connection with the final disposition of this investigation, the statute authorizes issuance of (1) an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) a cease and desist order that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that

address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of any remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions limited to the briefing questions above. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions

on the issues of remedy, the public interest, and bonding. Such initial written submissions should include views on the recommended determination by the ALJ on remedy, the public interest, and bonding. Complainant and the Commission Investigative Attorney are also requested to identify the form of remedy sought and to submit proposed remedial orders for the Commission's consideration in their initial written submissions. Complainant is further requested to state the date that the asserted patent expires and the HTSUS numbers under which the accused products are imported, and to supply the names of known importers of the products at issue in this investigation.

Initial written submissions and proposed remedial orders must be filed no later than close of business on **February 18, 2020**. Reply submissions must be filed no later than the close of business on **February 25, 2020** and must be limited to issues raised in the initial written submissions. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1120") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission

and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel[1], solely for cybersecurity purposes. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

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.

Issued: January 30, 2020.

Lisa Barton,
Secretary to the Commission.

[1] All contract personnel will sign appropriate nondisclosure agreements.

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