

UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, D.C.

**In the Matter of**

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

**Inv. No. 337-TA-1120**

**COMMISSION ORDER**

On May 19, 2020, the Commission issued a final determination finding a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337) (“section 337”), based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain bacterial strains and 2’-fucosyllactose oligosaccharides produced therefrom that infringe certain claims of U.S. Patent No. 9,970,018 (“the ’018 patent”). *See* 85 Fed. Reg. 31549 (May 26, 2020); *see also* 83 Fed. Reg. 28865 (June 21, 2018) (defining the scope of the investigation as “2’-fucosyllactose oligosaccharides”). The Commission also adjudicated infringement with respect to a TTFL12 bacterial strain imported by the named respondent and determined that it does not infringe the ’018 patent. *See id.* The Commission issued a limited exclusion order (“LEO”) barring entry of 2’-fucosyllactose (“2’-FL”) oligosaccharides that infringe the asserted patent claims but also including an explicit carve-out for 2’-fucosyllactose oligosaccharides made with the non-infringing TTFL12 bacterial strain.

On June 2, 2020, complainant Glycosyn LLC (“Glycosyn”) filed a petition for Commission reconsideration of part III(B) of the Commission Opinion (*i.e.*, “Adjudication of Infringement with Respect to the TTFL12 Strain”). Having considered Glycosyn’s petition, the responses thereto, and the record in this investigation, the Commission has determined to deny Glycosyn’s petition for reconsideration.

## I. BACKGROUND

### A. Procedural Background

The Commission instituted this investigation on June 21, 2018, based on a complaint, as amended and supplemented, filed by Glycosyn of Waltham, Massachusetts. *See* 83 Fed. Reg. 28865 (June 21, 2018). The complaint alleged violations of 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 certain claims of U.S. Patent No. 9,453,230 (“the ’230 patent”) and the ’018 patent. *See id.* The notice of investigation named Jennewein of Rheinbreitbach, Germany as respondent in this investigation. *See id.* The Office of Unfair Import Investigations was also a party to this investigation. *See id.*

The Commission partially terminated the investigation as to certain claims of the ’018 patent and all asserted claims of the ’230 patent based on the withdrawal of the allegations pertaining to those patent claims. *See* Order No. 5 (Aug. 9, 2018), *unreviewed*, Comm’n Notice (Aug. 29, 2018); Order No. 15 (Oct. 30, 2018), *unreviewed*, Comm’n Notice (Nov. 29, 2018); Order No. 17 (Nov. 19, 2018), *unreviewed*, Comm’n Notice (Dec. 12, 2018); 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 remained pending in this investigation.

On September 9, 2019, the administrative law judge (“ALJ”) issued a final initial determination (“FID”) finding a violation of section 337 based on the infringement of claims 1-3, 5, 8, 10, 12, 18, and 24-28, but not claim 23 of the ’018 patent based on non-infringement of that claim. *See* FID at 35. On May 19, 2020, the Commission affirmed the FID’s finding of infringement and issued a final determination finding a violation by certain bacterial strains.

*See* 85 Fed. Reg. 31549 (May 26, 2020). In particular, the Commission reversed the FID’s decision not to adjudicate the TTFL12 bacterial strain and determined that it does not infringe any of the asserted claims. *See id.* The Commission issued an LEO barring entry of 2’-FL oligosaccharides that infringe the Asserted Claims but also including an explicit carve-out for 2’-FL oligosaccharides made with the non-infringing TTFL12 bacterial strain.<sup>1</sup> The Commission also set a bond in the amount of five (5) percent of the entered value of Jennewein’s 2’-FL product during the period of Presidential review.

On June 2, 2020, pursuant to Commission Rule 210.47 (19 C.F.R. § 210.47), Glycosyn petitioned for reconsideration of part III(B) of the Commission Opinion (*i.e.*, “Adjudication of Infringement with Respect to the TTFL12 Strain”).<sup>2</sup> On June 8 and 9, 2020, respectively, Jennewein and the Commission’s Investigative Attorney opposed Glycosyn’s petition.<sup>3</sup>

## II. STANDARD FOR RECONSIDERATION

Commission Rule 210.47 governs petitions for reconsideration and provides that:

Within 14 days after service of a Commission determination, any party may file with the Commission a petition for reconsideration of such determination or any action ordered to be taken thereunder, setting forth the relief desired and the grounds in support thereof. Any petition filed under this section must be confined to new questions raised by the determination or action ordered to be taken thereunder and upon which the petitioner had no opportunity to submit arguments. . . .

*See* 19 C.F.R. § 210.47.

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<sup>1</sup> Complainant did not request, and the Commission did not issue, a cease and desist order.

<sup>2</sup> *See* Complainant Glycosyn LLC’s Petition for Reconsideration of Part III(B) of the Commission Opinion (June 2, 2020).

<sup>3</sup> *See* Respondent Jennewein Biotechnologie GmbH’s Opposition to Complainant Glycosyn LLC’s Petition for Reconsideration of Part III(B) of the Commission Opinion (June 8, 2020); Response of the Office of Unfair Import Investigations to Complainant’s Petition for Reconsideration of Part III(B) of the Commission Opinion (June 9, 2020).

### III. DISCUSSION

Glycosyn's petition for reconsideration does not identify new questions raised by the ALJ's FID or the Commission's final determination or present arguments that Glycosyn did not have the opportunity to address in previous filings before either the ALJ or the Commission. As such, the Commission has determined that Glycosyn's petition for reconsideration does not satisfy the requirements of Commission Rule 210.47.<sup>4</sup>

### IV. CONCLUSION

Accordingly, upon consideration of the record and the submissions in this matter, the Commission hereby ORDERS that:

1. Glycosyn's petition for reconsideration is DENIED.
2. The Secretary will serve this Order on all parties to the investigation.

By order of the Commission.



Lisa R. Barton  
Secretary to the Commission

Issued: October 1, 2020

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<sup>4</sup> Commissioner Schmidlein respectfully dissents. In light of the particular facts (including the new evidence cited by Glycosyn in its petition for reconsideration) and the procedural history of this investigation, and given the rationale provided in her dissent, in her view, Glycosyn's petition should be granted and Part III(B) of the majority's opinion should be reconsidered.

**PUBLIC CERTIFICATE OF SERVICE**

I, Lisa R. Barton, hereby certify that the attached **COMMISSION ORDER** has been served via EDIS upon the Commission Investigative Attorney, **Lisa Murray, Esq.**, and the following parties as indicated, on **October 1, 2020**



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U.S. International Trade Commission  
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