PUBLIC VERSION

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 OPINION

The Commission has determined that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("section 337"), on review of the final initial determination ("FID") of the presiding administrative law judge ("ALJ"), based on the infringement of U.S. Patent No. 9,970,018 by respondent's accused bacterial strains. The Commission has also determined to reverse the FID's decision declining to adjudicate respondent's alternative TTFL12 strain and finds no infringement as to that strain. This opinion sets forth the Commission's reasoning in support of that determination. In addition, the Commission adopts the findings in the FID that are not inconsistent with this opinion.

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 LLC ("Glycosyn") of Waltham, Massachusetts. *See* 83 Fed. Reg. 28865-66 (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 Nos. 9,453,230 ("the '230 patent") and 9,970,018 ("the '018 patent"). *See id.* The complaint also alleges the existence of a domestic industry.

The notice of investigation named Jennewein Biotechnologie GmbH of Rheinbreitbach, Germany ("Jennewein") as respondent in this investigation. *See id.* The Office of Unfair Import Investigations ("OUII") is also a party to this investigation. *See id.*

The Commission later terminated the investigation as to all asserted claims of the '230 patent and certain asserted claims 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); 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 remain pending in this investigation.

The ALJ conducted an evidentiary hearing on May 14-17, 2019. On September 9, 2019, the ALJ 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 (hereinafter, "the Asserted Claims") but not claim 23 of the '018 patent, based on non-infringement of that claim.[1] *See* FID at 35. Furthermore, the FID finds that the domestic industry requirement is satisfied.

The FID also contains a Recommended Determination ("RD") recommending, should a violation of section 337 be found, that the Commission issue a limited exclusion order ("LEO") barring entry of articles that infringe the Asserted Claims.[2] The RD also recommends that the Commission impose a bond in the amount of five (5) percent of the entered value of the infringing articles during the period of Presidential review. Furthermore, as directed by the

[1] Glycosyn did not petition for review of the FID's finding that Jennewein does not infringe claim 23.

[2] Glycosyn did not request, and the RD does not recommend, a cease and desist order against Jennewein.

Commission (*see* 83 Fed. Reg. at 28865), 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.

On September 23, 2019, Jennewein and the Commission's Investigative Attorney ("IA") filed petitions for review of the FID.[3] Jennewein petitioned for review of the FID's findings with respect to claim construction and infringement, and both Jennewein and the IA petitioned for review of the FID's decision not to adjudicate infringement with respect to Jennewein's TTFL12 bacterial strain, which Glycosyn did not accuse in its complaint. On October 1, 2019, Glycosyn and the IA filed responses to the various petitions.[4]

On October 9 and 10, 2019, respectively, Glycosyn and Jennewein filed statements on the public interest pursuant to Commission Rule 210.50(a)(4), 19 C.F.R. 210.50(a)(4).[5] On October 23, 2019, non-party DuPont Nutrition & Health ("DuPont") filed a public interest submission pursuant to the Commission's notice requesting public interest comments, *see* 84 Fed. Reg. 49335 (Sept. 19, 2019), supporting the ALJ's recommended LEO and asserting that it has the capacity to replace the excluded products in a commercially reasonable time.[6]

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[3] *See* Respondent Jennewein Biotechnologie GmbH's Petition for Commission Review (Sep. 23, 2019) (hereinafter, "Jennewein's Pet."); OUII Petition for Review (Sep. 23, 2019) (hereinafter, "IA's Pet.").

[4] *See* Complainant Glycosyn LLC's Consolidated Response to Respondent Jennewein Biotechnologie GmbH's and Office of Unfair Import Investigations' Petitions for Commission Review (Oct. 1, 2019) (hereinafter, "Glycosyn's Pet. Resp."); Office of Unfair Import Investigations' Response to Respondent's Petition for Review (Oct. 1, 2019) (hereinafter, "IA's Pet. Resp.").

[5] *See* Complainant Glycosyn LLC's Statement of Information Relating to the Public Interest (Oct. 9, 2019) (hereinafter, "Glycosyn's PI Br."); Public Interest Statement of Respondent Jennewein Biotechnologie GmbH (Oct. 10, 2019) (hereinafter, "Jennewein's PI Br.").

[6] *See* Public Interest Submission of DuPont Nutrition & Health (hereinafter, "DuPont PI Br.").

On January 30, 2020, the Commission issued a notice determining to review the FID in part. *See* 85 Fed. Reg. 6573-75 (Feb. 5, 2020) ("the WTR/Remedy Notice"). Specifically, the Commission determined to review: (1) the FID's infringement findings with respect to Jennewein's bacterial strains adjudicated in this investigation; and (2) the FID's decision not to adjudicate infringement as to Jennewein's alternative bacterial strain, *i.e.*, the TTFL12 strain. *See id.* The Commission determined not to review the remainder of the FID. *See id.* The notice invited written submissions from the parties on issues under review, and from the parties, interested government agencies, and any other interested parties on issues of remedy, the public interest, and bonding. *See id.*

On February 18, 2020, the parties, including OUII, filed written submissions in response to the WTR/Remedy Notice,[7] and on February 25, 2020, the parties filed responses to each other's submissions.[8] Also on February 18, 2020, non-party Abbott Laboratories ("Abbott") filed a written submission concerning the public interest in response to the WTR/Remedy Notice,

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[7] *See* Complainant Glycosyn LLC's Response to Questions in the Commission's Notice of Commission Decision to Review in Part a Final Initial Determination Finding a Violation of Section 337 (Feb. 18, 2020) (hereinafter, "Glycosyn's Resp."); Complainant Glycosyn LLC's Initial Submission on the Form of Remedy, the Public Interest, and Bonding Pursuant to the Commission's Notice of Commission Decision to Review in Part a Final Initial Determination Finding a Violation of Section 337 (Feb. 18, 2020) (hereinafter, "Glycosyn's Remedy Br."); Respondent Jennewein Biotechnologie GmbH's Responses to Questions Raised by the Commission (Feb. 18, 2020) (hereinafter, "Jennewein's Resp."); Brief of the Office of Unfair Import Investigations on Issues under Review and on Remedy, the Public Interest, and Bonding (Feb. 18, 2020) (hereinafter, "IA's Resp.").

[8] *See* Complainant Glycosyn LLC's Reply to Respondent's and OUII's Responses to the Commission's Questions regarding Final Initial Determination Finding a Violation of Section 337 (Feb. 25, 2020) (hereinafter, "Glycosyn's Reply"); Respondent Jennewein Biotechnologie GmbH's Reply to Responses by Glycosyn LLC and the Office of Unfair Import Investigations to Questions Raised by the Commission and Responses to Glycosyn's and OUII's Submissions on Remedy, the Public Interest, and Bonding (Feb. 25, 2020) (hereinafter, "Respondents' Reply"); Reply Brief of the Office of Unfair Import Investigations on Issues under Review and on Remedy, the Public Interest, and Bonding (Feb. 25, 2020) (hereinafter, "IA's Reply").

and alleged that "Jennewein is the only supplier whose product has been fully qualified through Abbott's quality and regulatory processes, raising public interest concerns from remedial relief."[9]

B. The Asserted Patent

The '018 patent issued on May 15, 2018. *See* JX-3, '018 Patent. The '018 patent, titled "Biosynthesis of Human Milk Oligosaccharides in Engineered Bacteria," relates to "compositions and methods for producing fucosylated oligosaccharides" which are "typically found in human milk" and which "serve critical roles in the establishment of a healthy gut microbiome, in the prevention of disease and in immune function." *See id.* at 1:27-39. The specification of the '018 patent states that "the invention . . . makes use of an engineered bacterium *E. coli* or other bacteria engineered to produce" fucosylated oligosaccharides. *See id.* at 15:66-16:4.

The '018 patent specification explains that "[b]iosynthesis of fucosylated HMOS[10] requires the generation of an enhanced cellular pool of both lactose and GDP[11]-fucose." *See id.* at 16:27-29; *see also id.* at Figure 3 (requiring both lactose and GDP-fucose for the synthesis of 2'-fucosyllactose). For example, the specification discloses that "[t]he ability of the *E. coli* host strain to accumulate lactose was . . . engineered by simultaneous deletion of the endogenous β-galactosidase gene (lacZ) and the lactose operon repressor gene (lacI)" while "the lacIq promoter was placed immediately upstream of the lactose permease gene, lacY." *See id.* at 16:37-43 (Example 1). The specification states that "[t]he modified strain thus maintains its

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[9] *See* Public Interest Submission of Abbott Laboratories (Feb. 18, 2020) (hereinafter "Abbott's PI Br.").

[10] "HMOS" refers to Human Milk Oligosaccharides.

[11] "GDP" refers to guanosine diphosphate. *See* JX-3, '018 Patent at 1:61-63.

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