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**

ORDER NO. 38: GRANTING-IN-PART RESPONDENT JENNEWEIN BIOTECHNOLOGIE GmbH'S MOTION TO STRIKE UNTIMELY ARGUMENTS IN GLYCOSYN POST-HEARING BRIEF

(June 14, 2019)

On June 10, 2019, respondent Jennewein Biotechnologie GmbH ("Jennewein") filed a motion (1120-032) to strike untimely arguments in complainant Glycosyn, LLC's ("Glycosyn") initial post-hearing brief under Ground Rule 9.2. The motion represents "[t]he Staff stated that it supports the motion in its entirety." (Mot. at 1.)

Pursuant to Order No. 37, responses to the motion were due June 13, 2019. On June 13, 2019, Glycosyn opposed the motion. No other responses were received.

Jennewein's motion to strike (1120-032) is hereby granted-in-part. Ground Rule 9.2 states, in relevant part:

> The pre-trial brief shall be prefaced with a table of contents and a table of authorities. The pre-trial brief shall set forth a party's contentions on each of the proposed issues, including citations to legal authorities in support thereof, and shall conform to the general outline set forth in Appendix B hereto. . . . Any contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief.

(Order No. 24.) Jennewein identifies four sections of Glycosyn's initial post-hearing brief (EDIS Doc. No. 677661 (hereafter, "CIB")) that allegedly lack prior disclosure in Glycosyn's pre-

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hearing brief (EDIS Doc. No. 672522 (hereafter, "CPB")); specifically: (1) Section IV.D.2 regarding a presumption of infringement under 35 U.S.C. § 295, (2) Section IV.D.1.a regarding a lack of sufficient discovery for Jennewein's TTFL12 process, (3) Section IV.D.1.b regarding the status of the TTFL12 design, and (4) Section IV.D.1.d discussing whether TTFL12 "could" infringe. (*See generally* Mot. Mem. at 1, 3-10.)

Having carefully reviewed the pleadings, I find inadequate support in Glycosyn's pre-hearing brief for Section IV.D.2 of its post-hearing brief. This section is dedicated to an argument that: (1) under the facts of this case, certain statutory factors under 35 U.S.C. § 295 have been met, (2) which satisfaction creates a rebuttal presumption of infringement, and (3) Jennewein has failed to rebut that presumption. (*See* CIB at 84-91.) This is a very particular theory presented in support of Glycosyn's overall claim of "Jennewein has not met its burden to show that TTFL12 does not infringe." (*See* Opp. at 13.)

Glycosyn acknowledges 35 U.S.C. § 295, the very basis for the theory, was not cited in its pre-hearing brief, but seems to argue that that citation to the statute and related cases is all that is missing. (*Id.*) I disagree. Glycosyn's pre-hearing brief is devoid of any comparison between evidence and the statutory factors in substance, if not by name, or even the concept that a "presumption" has been created or that the statute's standard of "substantial likelihood" has been met. The fact that some pre-hearing brief argument given in the context of other issues happens, roughly, to correspond to the factors of 35 U.S.C. § 295 does not allow Glycosyn to introduce a 35 U.S.C. § 295 theory in its post-hearing brief for the first time. (*See* Opp. at 15-16 (citing CPB at 104-105, 145-146); *compare* CPB at 104-105 (discussing invalidity), 145-146 (discussing whether TTFL12 is within the scope of investigation) *with* CIB at 84-91 (discussing presumption

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of infringement).) The same is true for argument presented by Jennewein and the Staff. (*See* Opp. at 16-17 (citing Staff-Pre-HB at 68); EDIS Doc. No. 673388 (Staff Pre-Hearing Brief) at 68 (discussing whether TTFL12 is within the scope of investigation).) Thus, this portion of Jennewein's motion is granted. Section IV.D.2 is hereby struck.

I find inadequate support for Section IV.D.1.a as well. The thrust of this section is that there has been insufficient discovery on the TTFL12 strain so as to meet the "extensive discovery" requirement for adjudication of redesigned products. (*See* CIB at 69-72 (citing *Certain Two-Way Radio Equipment and Systems, Related Software, and Components Thereof*, Inv. No. 337-TA-1053, Comm'n Op. at 27 (Dec. 18, 2018) ("*Two-Way Radios*")).) I find no mention of "discovery" anywhere in Glycosyn's pre-hearing brief, however, and it is difficult to understand how the argument could be made without using that term. Moreover, Glycosyn's pre-hearing arguments, cited in its opposition for alleged support, that: (1) Jennewein "failed to produce sufficient evidence to demonstrate that TTFL12 [] or that 2'-FL produced by TTFL12 has been imported into the United States," and (2) "Jennewein relies upon 'only two documents' to support its position [of non-infringement]" (*see* Opp. at 8 (citing CPB at 145)) are distinct from the argument that an overall insufficient amount of discovery had taken place so as to deny adjudication on a redesigned product. This distinction is further shown by Glycosyn's dedication of discrete sections to each of these three arguments in its post-hearing brief. (*Compare* CIB at 69-72 (alleging insufficient discovery) *with id.* at 75-82 (alleging no showing of importation) *with id.* at 82-84 (alleging the evidence shows possible infringement).) Glycosyn's other arguments—that its earlier filings in the investigation act to preserve the position (Opp. at 8-9) or that Staff's analysis of sufficient discovery in its own pre-hearing brief

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must mean Glycosyn also disclosed it (*id.* at 9-10) are not persuasive. Thus, this portion of Jennewein's motion is granted. Section IV.D.1.a is hereby struck.

I find adequate support for Section IV.D.1.b, however. Here, Jennewein argues "Glycosyn has also abandoned the argument that the TTFL12 strain is not 'sufficiently fixed in design' . . . ." yet acknowledges that "Glycosyn previously argued that 'Jennewein's own evidence suggests that the TTFL12 strain needs significant retooling if it is ever going to be viable.'" (Mot. Mem. at 7 (citing CPB at 147).) I do not agree these are materially different positions—the commercial viability of product is a logical consideration (but by no means a dispositive one) as to whether that product is "fixed in design." I further find that Glycosyn's pre-hearing brief explains this position with sufficient detail. (*See* CPB at 147.) Thus, this portion of Jennewein's motion is denied.

Finally, I find adequate support for Section IV.D.1.d. Glycosyn's pre-hearing brief alleges Jennewein will not be able to sufficiently show the TTFL12 strain does not infringe, based on expert testimony regarding disclosures found in a Jennewein patent application ("host cell . . . comprise[s] a deregulated beta-galactosidase encoding gene"). (CPB at 145 (citation omitted).) This theory is essentially repeated in the first paragraph of Section IV.D.1.d and will not be struck. The remaining paragraphs of Section IV.D.1.d, however, constitute a different theory albeit in support of the same claim. (*See* CIB at 83-84

) It does not appear that Glycosyn's pre-hearing brief contains this theory. Nevertheless, I agree the testimony Glycosyn cites in support arose during the evidentiary hearing in such a way so as to justify the added theory. (*See id.* (citing Hr'g Tr. at 528-529, 305); *see also* Opp. at 12

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and "[t]his testimony came in without objection by Staff or Jennewein").) Thus, this portion of Jennewein's motion is denied.

Regarding Glycosyn's ancillary argument—that the proper course is to address Jennewein's motion in the initial determination (Opp. at 19-20)—I am not persuaded. There is an obvious benefit to addressing Jennewein's motion now. It clarifies the issues Jennewein and the Staff must address in their reply post-hearing briefs due Monday, June 17, 2019. Further, Glycosyn is undercut by its own use of an order from a prior investigation to show what is permitted in post-hearing briefing—an order that issued before that investigation's initial determination. (*See* Opp. at 12 (citing *Certain Automated Media Library Devices*, Inv. No. 337-TA-746, Order No. 33 (Oct. 26, 2011)))

Accordingly, Jennewein's motion (1120-032) is hereby granted-in-part. Glycosyn shall file a corrected version of its initial post-hearing brief with the above-identified redactions no later than Monday, June 17, 2019.

Within seven days of the date of this document, the parties shall submit to the Office of the Administrative Law Judges a joint statement as to whether or not they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit to this office a copy of this document with red brackets indicating the portion or portions asserted to contain confidential

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