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. 33: GRANTING-IN-PART RESPONDENT JENNEWEIN BIOTECHNOLOGIE GMBH'S MOTIONS *IN LIMINE*

(May 2, 2019)

On April 16, 2019, respondent Jennewein Biotechnologie GmbH ("Jennewein") filed a motion *in limine* (1120-027) with five subparts. On April 29, 2019, complainant Glycosyn LLC ("Glycosyn") and the Commission Investigative Staff ("Staff") responded to the motion. On May 1, 2019, Glycosyn filed a motion for leave (1120-028) to file missing exhibits from its April 29, 2019 opposition. This motion for leave (1120-028) is hereby granted.

For the reasons detailed below, Jennewein's motion (1120-027) is granted-in-part.

Jennewein's Motion *in Limine* No. 1

Jennewein's Motion *in Limine* No. 1 seeks to preclude Glycosyn "from arguing that activity below exactly 0.05 Miller Units would infringe or practice the '018 patent." (Mot. at 1.) Jennewein looks to the *Markman* order in this investigation for support as it construed the claim term "β-galactosidase activity comprises between 0.05 and [200 units / 5 units / 4 units / 3 units / 2 units]" as requiring activity "exactly" within the stated range. (*Id.* at 2-3 (citing Order No. 22 at 22-23).) Jennewein also contends prosecution history estoppel prevents an activity outside of the stated range from infringing under the doctrine of equivalents. (*See id.* at 3-7.) Jennewein identifies pages 72-74 of Glycosyn's prehearing brief and Q542-548 of CX-0004C as material which should be struck. (*Id.* at 7.)

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Glycosyn opposes the motion and disputes that the *Markman* order precludes it from asserting doctrine of equivalents because "[t]he Chief ALJ's construction of this limitation was with regard to *literal* infringement, not the doctrine of equivalents." (Opp. at 2 (emphasis in original).) Glycosyn cites *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1107-1108 (Fed. Cir. 2002) for the proposition "[t]he fact that a claim recites numeric ranges does not, by itself, preclude [Glycosyn] from relying on the doctrine of equivalents." (*Id.* at 2-3.) Glycosyn further disputes that prosecution history estoppel prevents it from asserting doctrine of equivalents; principally because "[its] proposed equivalents, are just hundredths of a Miller unit under the lower limit of claimed range, not the upper limit, which was the focus of the patentee's amendment and the Examiner's repeated rejections." (*Id.* at 8.)

The Staff supports Jennewein's motion and explains:

> All parties agreed that if the term was not indefinite (as Jennewein contended), then claims 1, 18, and 25-28 of the '018 Patent all called for exact numerical ranges. *Id.* In the Staff's view, at that point Glycosyn waived any argument that the disclosed ranges were only approximations, such that β-galactosidase activity slightly below 0.05 Miller units could still infringe.

(Staff Resp. at 2.) Setting aside the *Markman* order, the Staff agrees that Glycosyn's introduction of an exact numerical range to overcome a rejection based on 35 U.S.C. § 112 during the prosecution history triggers an estoppel against any infringement by activity outside the recited numerical range. (*See id.* at 3-4.)

Upon review, Jennewein's Motion *in Limine* No. 1 is hereby denied. With respect to the *Markman* order in this investigation, it did not, as Jennewein argues, define what would or would not be an equivalent amount of enzyme activity as compared to the claimed range. It only adopted the parties' agreement that that claimed ranges were bound "exactly" by the stated numerical values, as opposed to approximations. (Order 22 at 22-23.) With respect to prosecution history estoppel, I find this determination requires further argument from the parties and thus will be made in the final initial determination on violation.

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Jennewein's Motion *in Limine* No. 2

Jennewein's Motion *in Limine* No. 2 seeks to preclude certain testimony from Glycosyn's expert, Dr. Prather, because it "is untimely and extends beyond the scope of her prior disclosures and testimony in this investigation." (Mot. at 7.) Jennewein identifies the offending content as portions of Q124, Q441-442, and Q458 because they "rely[] on documents not cited in her expert reports or discussed at her deposition." (*Id.* at 7-8.)

Glycosyn opposes the motion and argues a first document, discussed in Q124, is not a new document but an updated version of a previously cited document. (Opp. at 11-12.) Glycosyn adds that a second document, discussed in Q441-442, was included in the expert's list of materials considered and is therefore also not new. (*See id.* at 14.) For Q458, Glycosyn contends many of the documents discussed are similarly included in that list of materials considered (*id.* at 15-16), while others are used simply to show "Dr. Prather's understanding of what the files, as represented by Jennewein, contain" resulting in very little prejudice to Jennewein (*id.* at 17).

The Staff supports Jennewein's motion in part. The Staff submits that Q124 should have been limited to the previously cited document, and thus should not discuss the updated version. (Staff Resp. at 5.) The Staff also submits, however, that the effect of striking this testimony is limited given the testimony of Q125 which is not a subject of Jennewein's motion. (*Id.*) For Q441-442, the Staff finds the testimony is appropriate given the listing of the documents in the expert's list of materials considered and otherwise does not exceed the scope of her expert report. (*Id.* at 6.) For Q458, the Staff argues those documents not discussed in either expert report or at deposition should not be discussed in witness statement testimony. (*Id.* at 7.)

Upon review, Jennewein's Motion *in Limine* No. 2 is hereby denied. While it may be true that several of the documents discussed in Q124, 441-442, and 458 were not previously cited in the expert's reports or deposition, I find the testimony itself results in very little prejudice for Jennewein

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as it is limited to an identification of what those documents are without further analysis. (*See* Mot., Ex. 3 at Q124, 441-442, 458). It is also notable that Jennewein does not seek to exclude the documents themselves from the record—only this particular witness's identification of them. The testimony is therefore allowed.

Jennewein's Motion *in Limine* No. 3

Jennewein's Motion *in Limine* No. 3 seeks to preclude additional testimony from Dr. Prather related to the FDA's "Generally Recognized as Safe" or "GRAS" procedures, process, and requirements. (*See* Mot. at 13-15.) Jennewein argues the testimony should be struck either under Fed. R. Evid. 702 as Dr. Prather has no knowledge or expertise in this area (*id.* at 14) or Ground Rule 10 which states, "legal experts or testimony concerning the meaning of laws, treaties, regulations, etc., are typically not permitted" (*id.* at 15 (citing Order No. 2 at 26)). Jennewein identifies the offending content as Q71, Q411, Q413, Q424, Q428, Q433, and Q435 from CX-0004C. (*Id.* at 16.)

Glycosyn opposes the motion and first argues that Jennewein only met and conferred over the exclusion of Q71, warranting the denial of the motion in its entirety. (Opp. at 20.) Further, Glycosyn argues "Dr. Prather's alleged improper testimony are factual assertions not subject to Daubert scrutiny. An examination of the Q/A pairs identified by Jennewein shows that Dr. Prather is examining the factual record and offering opinion testimony by applying those facts using her proven technical expertise." (*Id.* at 21; *see id.* at 21-24 (discussing each question and answer pair).)

The Staff opposes the motion "on the grounds that the contested testimony in fact does not discuss GRAS procedures and requirements." (Staff Resp. at 8.) More specifically, the Staff explains "[a]ll but one of the contested questions and answers discuss the *contents* of Jennewein's GRAS Notice, rather than the procedures and requirements for submitting such a notice to the FDA," which, the Staff's view, does not "require[] expertise in FDA procedures." (*Id.*)

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Upon review, Jennewein's Motion *in Limine* No. 3 is hereby denied. Contrary to Jennewein's assertion, the challenged testimony does not amount to an expert explanation of GRAS procedures, process, and requirements. Rather, it simply: identifies a given exhibit as a GRAS notice (*see* Mot., Ex. 3 at Q411, 413); repeats the contents of the notice (*id.* at Q424, 428, 435); mentions the notice as an item considered in the formation of the expert's opinion (*id.* at Q433); or explains in generalities how GRAS notices are used (*id.* at Q71). Specialized scientific or technical knowledge has not been applied to provide this information.

<u>Jennewein's Motion *in Limine* No. 4</u>

Jennewein's Motion *in Limine* No. 4 seeks to preclude Dr. McCoy, a co-inventor of the asserted patent, "from testifying about the accuracy of , as speculative and lacking foundation pursuant to Federal Rule of Evidence 602, and as improper opinion testimony under Rule 701." (Mot. at 16.) Jennewein notes, "Dr. Merighi himself will be attending the evidentiary hearing and providing live testimony as an adverse witness called by Jennewein." (*Id.*) Jennewein identifies the offending content as portions of Q32, Q36, Q44, Q46, Q49, Q67-69 from CX-0002C and Q12, Q13, Q20, Q21, Q22, Q25, and Q39 from CX-0488C. (*Id.*)

Glycosyn opposes the motion. With respect to foundation, Glycosyn argues the testimony falls within Dr. McCoy's personal knowledge because Dr. McCoy hired Dr. Merighi whereupon Dr. Merighi "started with some of (*Id.* at 26-27 (citations omitted).) Glycosyn adds "Dr. McCoy's direct testimony demonstrates the foundation for his testimony sponsoring the work of all Glycosyn's scientists (including Dr. Merighi)" (*id.* at 28 (citations omitted)) which explains why Jennewein, allegedly, "cites no facts, evidence, or basis, to support its

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