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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. 32: GRANTING-IN-PART COMPLAINANT GLYCOSYN LLC'S OMNIBUS MOTION *IN LIMINE*

(May 2, 2019)

On April 15, 2019, complainant Glycosyn LLC ("Glycosyn") filed an omnibus motion *in limine* (1120-026) with four subparts. On April 29, 2019 respondent Jennewein Biotechnologie GmbH ("Jennewein") and the Commission Investigative Staff ("Staff") responded to the motion.

For the reasons detailed below, Glycosyn's motion (1120-026) is granted-in-part.

Glycosyn's Motion *in Limine* No. 1

Glycosyn's Motion *in Limine* No. 1 seeks "to preclude Respondent from providing testimony inconsistent with its representations to the FDA;" in particular, those representations included in Jennewein's "Generally Regarded as Safe ('GRAS')" submission and regarding the processes by which the accused products are manufactured. (*See* Mot. Mem. at 1-2.) Glycosyn argues:

> Where an accused infringer makes representations to the Food and Drug Administration ("FDA") in a manner that directly addresses the issue of patent infringement, the submission to the FDA will control the infringement inquiry. *See Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) ("[A]n [FDA] specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry."); *see also Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249, 2000 U.S. App. LEXIS 9878, *21 (Fed. Cir. 2000) ("[T]he specification in [accused infringer's FDA submission] defines its product in a way that directly addresses the question of infringement . . . . [Accused infringer] is bound by this specification."). While these cases are generally in the context of submissions to the FDA to support Abbreviated New Drug

> Applications ("ANDA"), they are relevant to submissions to the FDA to support Generally Regarded As Safe ("GRAS") status as well. Simply put, there are severe repercussions for submitting false or misleading statements to the FDA, and thus their evidentiary weight and indicia of reliability are deemed high. *See Bayer AG*, 212 F.3d at 1249- 50 (listing various penalties for false or misleading statements to the FDA inside and outside the context of ANDA).

(*Id.*) Glycosyn then identifies four such representations it wishes to hold Jennewein to. (*See id.* at 2-8.) Glycosyn adds that an agreement between third-party Abbott and Jennewein "prohibits Jennewein from making any changes to its manufacturing process without prior written approval from Abbott" and thus, in the absence of any agreements signaling a change, "Jennewein is thus bound to the disclosures in its FDA GRAS submission." (*See id.* at 7-8.)

Jennewein opposes the motion and describes it as "light on legal support but heavy on inflammatory rhetoric." (Opp. at 1.) More specifically, Jennewein contends: the law cited by Glycosyn is specific to ANDA litigation and thus not relevant to a GRAS notice (*id.* at 2-4); GRAS notices "certify the safety of a product and do[] not require any specific process used to make that product" (*id.* at 1, 4-9); and there is no legal basis for the Abbott-Jennewein agreement to exclude argument and evidence in this investigation (*id.* at 1, 9-10).

The Staff also opposes the motion and describes it as "utterly baseless." (Staff Resp. at 2.) According to the Staff, "[t]here is no support in those [cases cited by Glycosyn] for Glycosyn's overbroad statement that in all cases, 'where an accused infringer makes representations to the Food and Drug Administration ('FDA') in a manner that directly addresses the issue of patent infringement, the submission to the FDA will control the infringement inquiry.'" (*Id.*) The Staff adds, "[e]ven if a valid parallel could be drawn between ANDA and GRAS notification procedures, the cases cited do not support Glycosyn's overbroad characterization of ANDA law" because they held that "there will almost never be a genuine dispute of material fact that the claim is infringed with respect to that

limitation" (*id.* at 3 (citing *Abbott Labs.*, 300 F. 3d at 1373)) as opposed to "never a valid dispute concerning infringement" (*id.*).

Upon review, Glycosyn's Motion *in Limine* No. 1 is hereby denied. The central premise of the motion—that any time "an accused infringer makes representations to the Food and Drug Administration ('FDA') in a manner that directly addresses the issue of patent infringement, the submission to the FDA will control the infringement inquiry" (Mot. Mem. at 1)—is not supported by the cited authority. The holdings of both *Abbott Labs.* and *Bayer AG* relied on ANDA submissions to guide the infringement inquiry because of the fact that no accused product actually existed yet—a circumstance specific to ANDA litigation—while also acknowledging that evidence beyond that submission must still be taken into account. As stated in *Abbott Labs.*:

> An infringement inquiry provoked by an ANDA filing under 35 U.S.C. § 271(e)(2)(A) is ***focused on the product that is likely to be sold*** following FDA approval. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568, 42 USPQ2d 1257, 1262 (Fed.Cir.1997). ***This determination is based on consideration of all the relevant evidence, including the ANDA filing, other materials submitted by the accused infringer to the FDA, and other evidence provided by the parties***. *Id.* at 1570, 42 USPQ2d at 1263-64. Because ***drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug***, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry. *Bayer*, 212 F.3d at 1249-50, 54 USPQ2d at 1717. Thus, in *Bayer*, we held that summary judgment of no literal infringement was properly granted where the ANDA specification required the proposed drug to have a specific surface area outside the range claimed by the patent in suit. *Id.* at 1250, 54 USPQ2d at 1717.

300 F. 3d at 1373 (emphasis added). The *Bayer AG* court similarly held:

> The focus, under § 271(e)(2)(A), is on "what the ANDA applicant will likely market if its application is approved, ***an act that has not yet occurred***." *Glaxo*, 110 F.3d at 1569, 42 USPQ2d at 1263. "[T]his ***hypothetical inquiry is properly grounded in the ANDA application and the extensive materials typically submitted in its support.***" *Id.* Therefore, it is proper for the court to consider the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, ***and any other relevant evidence*** submitted by the applicant or

> patent holder. *See id.* at 1570, 110 F.3d 1562, 42 USPQ2d at 1263. However, if the ANDA "is to sell [a] well-defined compound," then the "ultimate question of infringement is usually straightforward." *Id.* at 1569, 110 F.3d 1562, 42 USPQ2d at 1263.

212 F. 3d at 1249 (emphasis added).

In contrast, a GRAS submission is voluntary and Glycosyn cites no authority for the proposition that such a submission binds the manufacturer "to sell only those products that comport with the [GRAS submission's] description" of the product. *Abbott Labs.*, 300 F. 3d at 1373. Thus, Glycosyn's editorial replacements of [ANDA] with [FDA] in its quotation of *Abbot Labs.* and [Elan's ANDA] with [accused infringer's FDA submission] in its quotation of *Bayer AG* (*see* Mot. Mem. at 1) are unpersuasive. Further, as noted by Jennewein (*see* Opp. at 2), Glycosyn cites no legal authority for the proposition that Jennewein's agreement with non-party Abbott also controls the infringement inquiry (*see* Mot. Mem. at 6-7).

Glycosyn's Motion *in Limine* No. 2

Glycosyn's Motion *in Limine* No. 2 seeks "to preclude Respondent from relying on 29 foreign language exhibits, which were served without any translation into English, certified or unofficial, in violation of Ground Rule 9.5.5. (Mot. Mem. at 8.) Glycosyn notes "[o]n April 15, 2019, counsel for Jennewein, in response to our meet and confer, confirmed that it will not be relying upon any of these 29 exhibits" but adds "[i]n the event that Jennewein withdraws all 29 of these exhibits, this motion will become moot." (*Id.*)

In its response, Jennewein states the exhibits "have already been withdrawn" (Opp. at 10), and thus the issues is moot. The Staff took an identical position. (Staff Resp. at 5.)

Based upon Jennewein's representation, Glycosyn's motion is denied as moot.

Glycosyn's Motion *in Limine* No. 3

Glycosyn's Motion *in Limine* No. 3 seeks to preclude "Respondent's expert from offering new enablement, non-infringement, and technical prong of domestic industry opinions advanced for

the first time in his initial and rebuttal witness statements" under Ground Rules 10 and 14.7.6. (Mot. Mem. at 12, 14.)[1] Glycosyn identifies Q179-183, Q192-195, RDX-007, RDX-008, RDX-012 from RX-0384C and Q97-100, Q146-147, Q152, Q197, Q216, Q327-328, Q349-350, RDX-013, and a portion of CX-0038C from RX-409C as the offending content. (*See id.*)

Jennewein opposes the motion, argues "Dr. Stephanopoulos's testimony is supported by his expert reports or deposition testimony" (Opp. at 12), and identifies the alleged support in those reports and deposition transcript for each of the witness statement questions and answers challenged by Glycosyn (*see id.* at 12-20).

The Staff supports Glycosyn's motion in part, finding no adequate support in Dr. Stephanopoulos's reports or deposition for Q179, RDX-007, Q195, and RDX-012 in RX-384C, and Q216 and Q349-350 in RX-409C. (Staff Resp. at 6.) The Staff finds adequate support for the remainder of the testimony and demonstratives challenged by Glycosyn.

Upon review, Glycosyn's Motion *in Limine* No. 3 is hereby granted-in-part. With respect to RX-384C, the Stephanopoulos Direct Witness Statement, Jennewein has not pointed to adequate support for Q179 and RDX-007 in the expert's prior reports or deposition transcript. Moreover, Jennewein tacitly acknowledges the notes presented in RDX-007, and summarized in Q179, were belatedly produced. (Opp. at 13 ("Moreover, his notes were provided at the deposition in response to Glycosyn's request").) With respect to RX-409C, the Stephanopoulos Rebuttal Witness Statement, Q216 and Q349-350 are hereby struck. The paragraphs Jennewein cites as support for Q216 fail to do so. (*See* Opp. at 19 (citing Opp. Ex. 14 at ¶ 91; Opp., Ex. 15 at ¶ [69]).) Further, Q349-350 involve an assertion that Glycosyn does not conduct its Miller unit testing in accordance with the Miller

[1] Here, Glycosyn erroneously refers to Ground Rule 14.7.6 from Order No. 2 (June 21, 2018)—a rule eliminated by Order No. 24 (Feb. 7, 2019). Nonetheless, current Ground Rule 11.5.5, as put into effect with Order No. 24, reflects the same limitation for expert testimony provided at trial.

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