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,

[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.

ability to transport lactose from the culture medium via LacY" but the lacZ (β-galactosidase) gene responsible for lactose catabolism (*i.e.*, breakdown) is deleted. *See id.* at 16:43-47 (Example 1). Therefore, the specification continues, "[a]n intracellular lactose pool is . . . created when the modified strain is cultured in the presence of exogenous lactose." *See id.* at 16:47-49 (Example 1).

The specification also describes "bacterial host cells with the ability to accumulate a[n] intracellular lactose pool while simultaneously possessing low, functional levels of cytoplasmic β-galactosidase activity for example as provided by the introduction of a functional recombinant *E. coli* lacZ gene or by a β-galactosidase gene from any of a number of other organisms." *See id.* at 7:22-28. The specification explains that "low level of cytoplasmic β-galactosidase activity while not high enough to significantly diminish the intracellular lactose pool is nevertheless very useful for tasks such as phenotypic marking of desirable genetic loci during construction of host cell backgrounds, for detection of cell lysis due to undesired bacteriophage contaminations in fermentation processes, or for the facile removal of undesired residual lactose at the end of fermentations." *See id.* at 7:37-45.

With regard to GDP-fucose production, the specification of the '018 patent further states that "[o]ne strategy for GDP-fucose production is to enhance the bacterial cell's natural synthesis capacity," *e.g.*, "by inactivating enzymes involved in GDP-fucose consumption, and/or by overexpressing a positive regulator protein, RcsA, in the colanic acid (a fucose containing exopolysaccharide) synthesis pathway." *See id.* at 17:4-10. The specification explains that "this metabolic engineering strategy redirects the flux of GDP-fucose destined for colanic acid synthesis to oligosaccharide synthesis." *See id.* at 17:10-12.

Still further, the specification of the '018 patent describes a "bacterium [that] possesses fucosyl transferase activity," *e.g.*, "an exogenous fucosyltransferase gene." *See id.* at 5:28-32. The specification explains that "[a]n exemplary . . . fucosyltransferase gene is the wcfW gene" and that "[p]rior to the present invention, this wcfW gene . . . was not suspected to possess the ability to utilize lactose as an acceptor sugar," *i.e.*, as a substrate for HMOS synthesis. *See id.* at 5:28-38; *see also id.* at Figure 3 (involving α(1,2)FT, *i.e.*, fucosyltransferase, in the synthesis of 2'-fucosyllactose).

Claim 1 of the '018, from which the remaining asserted claims depend, patent recites the following invention (with the disputed claim limitations in bold):

> A method for producing a fucosylated oligosaccharide in a bacterium, comprising
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> providing an isolated *E. coli* bacterium comprising,
>
> (i) a deletion or functional inactivation of an endogenous β-galactosidase gene;
>
> (ii) ***an exogenous functional β-galactosidase gene*** comprising a detectable level of β-galactosidase activity that is reduced compared to that of a wild-type *E. coli* bacterium, wherein ***the level of β-galactosidase activity comprises between 0.05 and 200 units***;
>
> (iii) an inactivating mutation in a colanic acid synthesis gene; and
>
> (iv) an exogenous lactose-accepting fucosyltransferase gene;
>
> culturing said bacterium in the presence of lactose; and
>
> retrieving a fucosylated oligosaccharide from said bacterium or from a culture supernatant of said bacterium.

See id. at 111:41-57 (claim 1).

C. Domestic Industry Product

The FID identifies Glycosyn's E997 bacterial strain and its production of 2'-fucosyllactose (2'-FL) as practicing at least one claim of the '018 patent. *See* FID at 7. The FID also determines that Glycosyn satisfies the domestic industry requirement. *See id.* at 61-67,

96-113. No party petitioned for review of these findings, and the Commission determined not to review these findings.

D. Accused and Redesigned or Alternative Products

The accused product in this investigation is Jennewein's 2'-FL product which was produced using *E. coli* bacterial strains #1540 and a derivative thereof, known as "the #1540 derivative" or "the #2410 strain" (collectively, "Accused Strains"). *See* FID at 7. The FID finds that the Accused Strains infringe the Asserted Claims of the '018 patent.

Jennewein also requested adjudication as to its redesigned or alternative TTFL12 bacterial strain in this investigation. Glycosyn did not accuse that strain in this investigation and the FID declined to adjudicate infringement with respect to that strain. *See id.* at 28-35. The Commission determined to review the FID's decision not to adjudicate infringement with respect to the TTFL12 strain. *See* 85 Fed. Reg. at 6574.

II. LEGAL STANDARDS

A. Standard on Review

Commission Rule 210.45(c) provides that "[o]n review, the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge" and that "[t]he Commission also may make any findings or conclusions that in its judgment are proper based on the record in the proceeding." *See* 19 C.F.R. § 210.45(c). In addition, as explained in *Certain Polyethylene Terephthalate Yarn and Products Containing Same*, "[o]nce the Commission determines to review an initial determination, the Commission reviews the determination under a *de novo* standard." Inv. No. 337-TA-457, Comm'n Op., 2002 WL 1349938, *5 (June 18, 2002) (citations omitted). This is "consistent with the Administrative Procedure Act which provides that once an initial agency

decision is taken up for review, 'the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule.'" *Id.* (citing 5 U.S.C. § 557(b)).

B. Infringement

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996) (citations omitted). Infringement must be proven by a preponderance of the evidence. *See SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). The preponderance of the evidence standard "requires proving that infringement was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

Literal infringement requires the patentee to prove that the accused device contains each and every limitation of the asserted claim(s). *See Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004). Where literal infringement is not found, infringement can still be found under the doctrine of equivalents. *See TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1376 (Fed. Cir. 2008) ("Infringement under the doctrine of equivalents may be found when the accused device contains an 'insubstantial' change from the claimed invention.") (citations omitted).

III. DISCUSSION

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 or redesigned bacterial strain, *i.e.*, the TTFL12 strain. *See* 85 *Fed. Reg.* at 6574.

A. Infringement as to the Term Exogenous Functional β-Galactosidase Gene

The previously presiding ALJ[12] construed "functional β-galactosidase gene" to mean "functional sequence of DNA that encodes β-galactosidase." *See* Order No. 22 at 29 (Dec. 18, 2018). No party petitioned for review of that construction. The parties also agreed that "exogenous" is properly construed as "originating outside an organism, tissue, or cell." *See id.* at 12.

The FID finds that the Accused Strains do not literally satisfy the claim term "an exogenous functional β-galactosidase gene," but that the term is satisfied under the doctrine of equivalents. *See* FID at 38-45. The FID reasons that Jennewein's Accused Strains include two distinct DNA sequences, namely, *lacZα* and *lacZ*Ω, which, together, encode for the β-galactosidase enzyme. *See id.* at 38-39. The FID concludes that "Jennewein's Accused Strains do not literally infringe 'an exogenous functional β-galactosidase gene' because they lack a single sequence of DNA which functions to create a β-galactosidase gene." *See id.* at 39. Nevertheless, the FID finds "no difference between the combination of *lacZα* and *lacZ*Ω genes on the one hand, and any particular individual 'functional β-galactosidase gene' on the other." *See id.* at 40.

In addition, the FID recognizes that "*lacZα* in the Accused Strains was not added by Jennewein, but was present in the original BL21 (DE3) strain which Jennewein engineered to achieve the Accused Strains." *See id.* at 44-45. The FID finds, however, that "the exogenous

[12] At the time of Order No. 22, the investigation was assigned to the Chief ALJ. On April 2, 2019, the investigation was transferred to Judge Elliot.

nature of *lacZ*Ω is enough to meet the limitation" at issue. *Id.* The FID explains that "[i]t is the combination of *lacZα* and *lacZ*Ω which is equivalent to the claimed 'β-galactosidase gene,' and this combination does not exist until *lacZ*Ω is inserted into the bacterium's genome from outside the organism." *See id.* at 45. Thus, the FID concludes, "the combination is 'exogenous' and satisfies the claim limitation at least under the doctrine of equivalents." *See id.*

Jennewein petitioned for review of the FID's infringement findings with respect to the claim term "an exogenous functional β-galactosidase gene." Jennewein's Pet. at 30-35. Jennewein did not dispute the FID's findings that the combination of the *lacZα* and *lacZ*Ω genes is equivalent to a functional β-galactosidase gene, but Jennewein argued that the combination is not exogenous because only *lacZ*Ω is exogenous while *lacZα* is endogenous.[13] *See id*. at 31. Jennewein reasoned that the FID "departs from the parties' agreed-upon construction for 'exogenous'" and "incorrectly concludes that '[i]t is the combination of *lacZα* and *lacZ*Ω which is equivalent to the claimed 'β-galactosidase gene,' and this combination *does not exist* until *lacZΩ* is inserted into the bacterium's genome from outside the organism.'" *See id.* (citation omitted) (emphasis in original). Jennewein explained that "[t]he claim language does not encompass a combination of gene fragments that did not 'exist' until one fragment is inserted into the genome" but "[r]ather, it requires that the combination itself originated outside of Jennewein's strain." *See id.* (citation omitted).

The Commission finds that the FID correctly determined that Jennewein's Accused Strains include a combination that is equivalent to the claimed "exogenous functional β-galactosidase gene." *See* FID at 38-45. Jennewein argued that the ID's finding that the

[13] Jennewein explains that "'endogenous' genes are those present in the host strain prior to any genetic engineering." Jennewein's Pet. at 34 (citing Hr'g Tr. (Prather) at 441:25-442:4).

combination "does not exist" in the host strain until *lacZΩ* is inserted into the bacterium's genome, is incorrect because, in Jennewein's view, the construction of "exogenous" (*i.e.*, "originating outside an organism, tissue, or cell") requires that "the combination itself originate[s] outside of Jennewein's strain." *See* Jennewein Pet. at 31. This alleged distinction, however, is unpersuasive. Indeed, as the FID finds, the combination does not exist in the original strain, and therefore the combination itself does not originate from within the organism. *See* FID at 44-45 (citing CX-213 at Figure 2, 5158). Thus, the Commission agrees with the FID that "the exogenous nature of *lacZ*Ω is enough" to make the combination exogenous and any difference between the claim term "an exogenous functional β-galactosidase gene" and the accused products is insubstantial. *See id.* at 45; *accord* Glycosyn's Pet. Resp. at 28; IA's Pet. Resp. at 10.

In addition, the Commission finds that *lacZα*, which is present in the genetically-engineered strain, *i.e.*, BL21[DE3], is also exogenous as compared to the wild-type *E. coli* bacterium. *See* Glycosyn's Pet. Resp. at 30-31. As Glycosyn explains, "[i]t is . . . undisputed that the *lacZα* gene exists in the BL21(DE3) genome only by way of human intervention." *See id.* at 30 (citing CX-213 (Jennewein's GRAS Notice) at CX-213.297 ("Since its isolation in 1818, the *E. coli* B strain has also undergone multiple rounds of genetic manipulation resulting in the strain BL21 (DE3)."); RX-386C (Parschat[14]) at Q/As 68-69). In addition, "it is undisputed that the DE3 is derived from a prophage, or in other words, a virus, that infects *E. coli.* to insert foreign DNA into the *E. coli*." *See id.* at 31 (citing RX-386C (Parschat) at Q/As 133-134 ("We discovered there was actually a lacZ[α] like fragment already present in the DE3 prophage in the

[14] Katja Parschat is Jennewein's Deputy Head of Research and Development.

genome of strain #1540. . . . A prophage is the genome [of] an *E. coli* virus or phage or part of that genome that is integrated into the bacterial chromosome replicate.")).

The language of the Asserted Claims and the specification of the '018 patent make clear that the claimed genetically-engineered bacterium and its "exogenous functional β-galactosidase gene" are to be compared to the native or wild-type *E. coli* bacterium rather than to a genetically-engineered strain, *i.e.*, BL21[DE3]. *See* JX-3, '018 patent at 111:45-49 (claim 1) ("A method for producing a fucosylated oligosaccharide in a bacterium comprising[:] providing an isolated *E. coli* bacterium comprising . . . an exogenous functional β-galactosidase gene comprising a detectable level of β-galactosidase activity that is reduced *compared to that of a wild-type E. coli bacterium*.") (emphasis added); *id.* at 5:1-5 ("The bacteria used herein to produce HMOS are genetically engineered to comprise an increased intracellular guanosine diphosphate (GDP)-fucose pool, an increased intracellular lactose pool (*as compared to wild type*) and to comprise fucosyl transferase activity.") (emphasis added); *id.* at 6:45-53 ("In the case of lactose and GDP-fucose, endogenous *E. coli* metabolic pathways and genes are manipulated in ways that result in the generation of increased cytoplasmic concentrations of lactose and/or GDP-fucose, *as compared to levels found in wild type E. coli*. For example the bacteria contain at least 10%, 20%, 50%, 2x, 5x, 10x or more of the levels in a corresponding wild type bacteria that lacks the genetic modifications described above.") (emphasis added).

There is no dispute that, as compared to the wild-type *E. coli* bacterium, both *lacZα and lacZ*Ω are exogenous, *i.e.*, they "originat[e] outside an organism, tissue, or cell." *See* CX-213 at CX-213.297; RX-386C (Parschat) at Q/As 68-69, 133-34. Thus, the Commission has determined to affirm with modification the FID's finding that the Accused Strains infringe the

Asserted Claims under the doctrine of equivalents, and supplements the FID's analysis as discussed above.

B. Adjudication of Infringement with Respect to the TTFL12 Strain

During the investigation, Jennewein sought adjudication of infringement with respect to its TTFL12 bacterial strain, which Glycosyn did not accuse in its complaint. Jennewein identified the TTFL12 strain on September 14, 2018, in its Ground Rule 7.2 disclosure[15] (CX-226C) and in its interrogatory responses served on November 5, 2018 (CX-237C). Jennewein further provided two documents, RX-320C (a draft article) and RX-382 (European Patent Application No. 14 162 869.3) (both produced on August 21, 2018), to establish the relevant features of the TTFL12 strain.

The FID declines Jennewein's request for adjudication, reasoning that "there can be no dispute that Glycosyn has not accused [the TTFL12 strain] of infringement." *See* FID at 28. The FID states that Commission precedent follows "a four-factor test as to whether a respondent has met its burden to show that infringement of a redesigned product should be adjudicated," namely, whether "[t]he product [is]: (1) within the scope of the investigation, (2) imported, (3) sufficiently fixed in design, and (4) subject to extensive discovery." *See id.* at 29 (citing *Certain Two-Way Radio Equipment and Systems, Related Software, & Components Thereof*, Inv. No. 337-TA-1053, Comm'n Op. at 8, 2018 WL 8648379 (Dec. 18, 2018) ("*Two-Way Radio*")).

"Of these factors, [the FID] finds Respondents have not met their burden as to the fourth factor, subject to extensive discovery." *See id.* Specifically, the FID determines that Jennewein failed to "provide[] 'extensive' or 'sufficient' discovery on the TTFL12 strain." *See*

[15] Ground Rule 7.2 relates to the "Disclosure of Products Within the Scope of the [Notice of Investigation]." *See* Order No. 2 (June 21, 2018).

id. at 32. The FID reasons that "while Jennewein identified TTFL12 as falling under the scope of the investigation in its Ground Rule 7.2 disclosure [(CX-226C)], and identified the 'draft' article, RX-0320C, as evidence of TTFL12's relevant features, it did not identify the patent application [(RX-382)] such that Glycosyn would have been on notice of it," because the patent application "does not refer to TTFL12 by name." *See id.* at 32-33. The FID further finds that "RX-0320C may provide information on the conception of TTFL12, but it does not sufficiently identify and describe a product that could serve as an accused product." *See id.* at 34.

The FID also rejects Jennewein's discovery responses as insufficient because they were served on the last day of discovery, which ended on November 5, 2018. *See id.* The FID determines that Jennewein's failure to identify TTFL12 in response to Glycosyn's request for admission on importation "was more than enough to dissuade Glycosyn from investigating anything other than the #1540 strain during discovery." *See id.* at 34-35. The FID further finds that "Glycosyn [was] on notice of just three things: a strain referred to as TTFL12 exists and was described in an unpublished, undated article as lacking a *lacZ* gene (CX-0226; CX-0320C); at some point the strain was used to create an unspecified amount of 2'-FL (CX-2037C at 1-2); but that 2'-FL had not been imported into the United States (CX-0216C at 5)." *See id.* at 34.

The FID recognizes that "Glycosyn failed to take discovery of its own on [the TTFL12] issue . . . and to respond to Jennewein's own requests for admission on TTFL12," but the FID finds that "it is Jennewein's burden to introduce TTFL12-based 2'-FL into the case." *See id.* at 35 (citing *Two-Way Radio*). Thus, the FID concludes that "adjudication of whether the TTFL12 strain infringes [is not] appropriate at this time because the discovery on TTFL12 was not adequate." *See id.*

Jennewein and the IA petitioned for review of the FID's alleged failure to adjudicate infringement with respect to Jennewein's TTFL12 bacterial strain. Jennewein's Pet. at 35-41; IA's Pet. at 5-22. Jennewein argued that the FID errs in requiring a heightened burden of "extensive discovery" where Commission precedent requires only that the respondent "provid[e] sufficient information to put the complainant on notice that [the TTFL12 strain] may be at issue." *See* Jennewein's Pet. at 37-38 (citing *Certain Television Sets, Television Receivers, Television Tuners, & Components Thereof*, Inv. No. 337-TA-910, Order No. 46 at 23 (Nov. 28, 2014), *unreviewed*, Comm'n Notice (Dec. 3, 2014)); *accord* IA's Pet. at 22 ("[T]he [FID's] conclusion that the disclosure was somehow not 'sufficient' was a clearly erroneous finding of material fact that merits review by the Commission.").

Jennewein also argued that the FID should have adjudicated non-infringement because the "TTFL12 strain lacks a functional β-galactosidase gene, and therefore it is incapable of having any β-galactosidase activity as the claim clearly requires." *See* Jennewein's Pet. at 39. Jennewein asserted that "[its] witnesses explained the structure and capabilities of the TTFL12 strain such that a noninfringement opinion would be straightforward." *See id.* at 39-40 (citing RX-320C (Jennewein draft manuscript produced August 2018) ("[g]enes encoding proteins involved in pathways that compete with 2'-FL biosynthesis were inactivated or deleted"); RX-409C (Stephanopoulos[16] RWS[17]) at Q/A 278 (testifying that the *lacZ* gene has been deleted or inactivated and that TTFL12 was not further engineered to insert a functional exogenous β-galactosidase gene); Hr'g Tr. (Parschat) at 384:10-17 ("The complete *lacZ* gene as occurs in

[16] Gregory Stephanopoulos was Jennewein's technical expert in this investigation.

[17] "RWS" refers to Rebuttal Witness Statement.

the operon is not present in the TTFL-12 strain."); RX-387C (Parkot[18] Witness Statement ("WS")) at Q/A 85 ("The TTFL12 strain is a 2'-FL production strain that has no β-galactosidase (lacZ) gene and does not use lactose to synthesize 2'-FL."); *see also* IA's Pet. at 16-17 ("Unlike in the bacterial strain discussed in the '018 Patent, in the TTFL12 strain the inactivated lacZ gene was not replaced with an exogenous functional β-galactosidase gene.") (citing RX-320C). *Accord* IA's Resp. at 3-7; Jennewein's Resp. at 2-11.

Jennewein further argued that the FID "improperly rewards Glycosyn for its refusal to take discovery on the TTFL12 strain." *See* Jennewein's Pet. at 40. Jennewein reasons that "Glycosyn never tested the TTFL12 strain during its inspection of Jennewein's facilities in Germany, even though it had every chance to do so" and "never asked its expert, Dr. Prather, to opine on TTFL12." *See id.* (citing Hr'g Tr. (Prather[19]) at 558:11-14 ("Q. . . . So you at least never asked, through Dr. Wheeler or otherwise, to test the TTFL-12 strain; correct? A. That's correct. We never asked for it."), 509:17-25); *see also id.* at 530:17-19 ("Q. So you did not analyze the TTFL-12 strain for the purpose of this investigation? A. I did not."); *accord* IA's Pet. at 14-15 ("A complainant cannot willfully ignore evidence of noninfringement presented in discovery and then expect that any remedy imposed will apply to the products that the complainant declined to investigate.") (citing *Certain Electronic Digital Media Devices & Components Thereof*, Inv. No. 337-TA-796, Comm'n Op., 2013 WL 10734395, *71 (Sept. 6, 2013) ("*Electronic Digital Media Devices*") ("When confronted with Samsung's evidence of noninfringement, Apple had an obligation to either present evidence of infringement or withdraw its allegations concerning these products, but it did neither.")).

[18] Julia Parkot is Jennewein's Head of Quality Management.

[19] Kristala L. Jones Prather was Glycosyn's technical expert in this investigation.

Glycosyn argued that Jennewein failed to satisfy its burden under *Two-Way Radio* to establish that the TTFL12 product is fixed in design and that it was imported, and that Jennewein did not provide sufficient discovery on TTFL12. *See* Glycosyn's Pet. Resp. at 33-34. Glycosyn reasoned that "Jennewein failed to produce even the most basic common laboratory documents for any of its strains, including its #1540 production strain." *See id.* at 34. Glycosyn further argued that "Jennewein and Staff are . . . wrong to suggest that Glycosyn should have done more to obtain discovery regarding Jennewein's TTFL12 strain" and that "Glycosyn sought, and Jennewein failed to produce, documents sufficient to describe the nature or use of TTFL12." *See id.* at 41.

The Commission has determined to reverse the FID's decision not to adjudicate the TTFL12 bacterial strain.[20] The Commission previously stated that the test for determining whether a respondent has met its burden for adjudication of a redesigned or alternative product includes four factors: (1) whether the product is within the scope of the investigation; (2) whether it has been imported[21]; (3) whether it is sufficiently fixed in design; and (4) whether it has been sufficiently disclosed by respondent during discovery. *See Two-Way Radio*, 2018 WL 8648379 at *13-14. The Commission also reiterates its policy in favor of adjudicating redesigns to prevent subsequent and potentially burdensome proceedings that could have been resolved in the first instance in the original Commission investigation. *See*, *e.g.*, *Certain*

[20] Commissioner Schmidtlein dissents from Part III(B) of the Commission's decision and has filed a separate opinion concurring in part and dissenting in part.

[21] The Commission notes that while importation may be relevant to the inquiry, actual importation of the redesign is not a mandatory requirement. *See, e.g.*, *Certain Multiple Mode Outdoor Grills and Parts Thereof*, Inv. No. 337-TA-895, Comm'n Op. at 20 (July 23, 2014); *Certain Television Sets, Certain Television Receivers, Television Tuners, and Components Thereof*, Inv. No. 337-TA-910, Order No. 46 (Initial Determination) at 29 (Nov. 28, 2014) (Lord, J.) (not reviewed).

Television Sets, Television Receivers, Television Tuners, & Components Thereof, Inv. No. 337-TA-910, Order No. 46 at 23-24 (Nov. 3, 2014), *unreviewed*, Comm'n Notice (Dec. 3, 2014) ("As a policy matter, 'consideration of design around products during the course of the proceedings before the ALJ provides predictability in enforcement of the order by U.S. Customs and Border Protection.") (quoting *Certain Multiple Mode Outdoor Grills & Parts Thereof*, Inv. No. 337-TA-895, Comm'n Op., 2014 WL 12890485, *10 (July 23, 2014)). However, redesigned products are still within the scope of remedial orders that are issued upon the termination of the investigation even if such products were not adjudicated for infringement in the original investigation. *See Certain Optical Disk Controller Chips & Chipsets & Prods. Containing Same, Including DVD Players & PC Optical Storage Devices*, Inv. No. 337-TA-506, Comm'n Op., 2007 WL 4713920, *64 (Sept. 28, 2005) ("[W]hile individual models may be evaluated to determine importation and infringement, the Commission's jurisdiction extends to all models of infringing products that are imported at the time of the Commission's determination and to all such products that will be imported during the life of the remedial orders.") (internal quotation omitted); *cf.* IA's Pet. at 8 ("[A]lthough it refused to identify TTFL12-based 2'-FL as an accused product, Complainant argued that the product should nevertheless be covered by any exclusion order that issues in this investigation."). To the contrary, once a respondent has been determined to be in violation of the Commission's remedial orders, such orders extend to all infringing products (*e.g.*, respondent's redesigned products), whether or not they were adjudicated in the original investigation.

The Commission agrees with the FID that the record evidence establishes that the first three factors specified above are satisfied. *See* FID at 29. With respect to factor (1) (scope of the investigation), there is no dispute that the 2'-FL produced with the TTFL12 strain is within

the scope of the investigation, which is defined in the notice of investigation as "2'-fucosyllactose oligosaccharides." *See* 83 Fed. Reg. at 28865. As to factor (2) (importation), although Jennewein did not identify TTFL12 in its September 20, 2018 response to Glycosyn's request for admission as to importation (because it had not been imported at the time), *see* CX-216C at 5, there is ample evidence that the 2'-FL product from that strain was subsequently imported on October 11, 2018, prior to the close of fact discovery. *See* IA's Pet. at 10-12 (citing FID at 34; RX-278C (Jennewein shipping invoice); RX-279C (Jennewein 2'-FL material safety data sheet); RX-280C (summary of Jennewein 2'-FL importation); RX-385C (Jennewein WS) at Q/As 135 ("180 g of 2'-FL produced by using the TTFL12 strain were imported into the U.S."), 171-72; RX-387C (Parkot WS) Q/As 101-110); Hr'g Tr. at 347:6-22, 348:7-25 (Parkot); *id.* at 215:24-216:7 (Jennewein)).

The record evidence also demonstrates that the TTFL12 strain satisfies factor (3) (sufficiently fixed in design). As Jennewein's witnesses testified, *see* Hr'g Tr. at 197:12-21 (Jennewein), "[t]he strain has been in development since 2012" and "[a] lot of different fermentation runs have been done since then." *See also id.* at 347:6-22 (Parkot) (discussing certain records showing that Jennewein has actually produced 2'-FL using the TTFL12 strain).

Lastly, as to factor (4) (sufficient disclosure in discovery), the Commission disagrees with the FID's conclusion that Jennewein has not met its burden to establish that this factor is satisfied. *See* FID at 29. Jennewein was required to provide sufficient (not extensive)[22] fact and expert discovery to put Glycosyn on notice of that strain and its relevant features. *Cf. Two-*

[22] The FID recites both "sufficient" and "extensive" evidence (*see*, *e.g.*, FID at 29, 32), but as explained herein, the test for adjudicating redesigns does not require extensive discovery. Rather, the test requires discovery that is sufficient for the complainant to assess the features relevant to the asserted patent claims.

Way Radio, 2018 WL 8648379 at *14 ("[T]he principal issues on review are (1) whether [respondent] produced discovery that is sufficient to inform [complainant] with respect to the redesigned product features relevant to the asserted . . . patents . . . ; and (2) whether [complainant's] decision not to assert infringement by the redesigned products with respect to these [asserted] patents constitutes a failure to satisfy its burden to prove infringement.").

The Commission finds that Jennewein presented sufficient documentary evidence as well as fact and expert testimony to put Glycosyn on notice of the relevant features of the TTFL12 strain.[23] Specifically, Jennewein identified the TTFL12 strain on September 14, 2018, in its Ground Rule 7.2 disclosure (CX-226C) and in its interrogatory responses served on November 5, 2018 (CX-237C). Jennewein also produced two key documents, RX-320C and RX-382 (both produced on August 21, 2018, well before November 5, 2018, the close of fact discovery), supported by expert and witness testimony, showing the relevant features of the TTFL12 strain and establishing that the strain does not infringe the asserted patent because it lacks an exogenous functional β-galactosidase gene (*lacZ*). *See* Jennewein's Resp. (citing RX-382 at 24 (Eur. App. No. 14 162 869.3) (showing that the TTFL12 strain was engineered to make lactose inside the cell and to lack or inactivate the β-galactosidase gene because the gene otherwise destroys the lactose feedstock needed to make 2'-FL)); *see also* RX-409C (Stephanopoulos RWS) at Q/As 279-280 ("[RX-382] describes a preferred bacterial host cell lacking expression of *lacZ* in one embodiment."); RX-386C (Parschat WS) at Q/As 161 ("The *lacZ* gene . . . is

[23] The Dissent dismisses witness testimony provided after the close of discovery and/or at the hearing but such testimony is based on expert reports or deposition testimony which must be produced during discovery (generally, such reports are not included in the record evidence). *See* Order No. 24, Ground Rule 11.5.5 ("An expert's testimony at the trial shall be limited in accordance with the scope of his or her expert report(s), deposition testimony, or within the discretion of the Chief Administrative Law Judge. Direct testimony from an expert that is outside this scope will be excluded.").

actually detrimental since it degrades the lactose substrate needed to make 2'-FL. . . . Since no addition of lactose is needed for 2'-FL production using the TTFL12 strain there is no lactose to remove and the *lacZ* gene is unnecessary."); Hr'g Tr. (Jennewein) at 226:25-227:7 (testifying that TTFL12 strain lacked a *lacZ* gene because there is no surplus of lactose which would have required β-galactosidase to eliminate the surplus); RX-385C (Jennewein[24]) at Q/As 166-174.

The FID finds that exhibits RX-320C and RX-382 have low probative value or provide unreliable evidence of an accused product's features. *See* FID at 33-34. However, the testimonial (fact and expert) evidence establishes the relevance of the documents to Jennewein's non-infringement claims. *See*, *e.g.*, RX-409C (Stephanopoulos RWS) at Q/As 272-86 (discussing RX-320C and Jennewein's non-infringement theory, *i.e.*, that the *lacZ* gene has been deleted or inactivated and that TTFL12 was not further engineered to insert a functional exogenous β-galactosidase gene); Hr'g Tr. (Parschat) at 384:10-17 (testifying that "[t]he complete *lacZ* gene as occurs in the operon is not present in the TTFL-12 strain"); RX-387C (Parkot WS) at Q/A 85 ("The TTFL12 strain is a 2'-FL production strain that has no β-galactosidase (lacZ) gene and does not use lactose to synthesize 2'-FL."); *accord* IA's Pet. at 13-14, 16-17, 19-22, 19-20 ("[T]he ALJ appears to have overlooked the hearing testimony of . . . Ms. Parkot . . . [which] is sufficient to supply the missing link between the 2'-FL that was 'actually produced' and the TTFL12 strain described in the draft Jennewein article, RX-320C."), 20 ("RX-382 demonstrates that Respondent had developed a 'total fermentation' strain by no later than early 2014, when the European patent application was filed.").

With regard to the FID's comment that "[a]n earnest effort to force TTFL12 into the investigation would have seen Jennewein prove to Glycosyn the nature of TTFL12, and how it

[24] Stefan Jennewein is the Managing Director of Jennewein.

had been used to produce imported 2'-FL, before the very last day of fact discovery," FID at 35, the Commission notes that the parties do not dispute that Jennewein produced relevant discovery as to TTFL12 within the fact discovery period established by the procedural schedule. If Glycosyn and its expert deemed such evidence to be insufficient, Glycosyn could and should have taken available procedural steps, such as a motion to reopen discovery or to compel further discovery, because the burden of establishing infringement remains with Glycosyn.[25]

The Commission also finds that Glycosyn failed to satisfy its burden of establishing infringement with respect to Jennewein's TTFL12 strain. *See Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191, 194 (2014) (holding that the burden of proving infringement remains with the patentee even in a declaratory judgment action to establish non-infringement); *Electronic Digital Media Devices*, 2013 WL 10734395, *71 ("When confronted with Samsung's evidence of noninfringement, Apple had an obligation to either present evidence of infringement or withdraw its allegations concerning these products, but it did neither.").

Unlike the accused #1540 strain and its derivative, there is no evidence that a *lacZΩ* fragment was inserted into the TTFL12 strain or any of its precursors. *See* RX-320C at 17-18

[25] In Glycosyn's submissions to the Commission in response to the notice of review, Glycosyn does not contend that the testimony of fact witnesses or the opinions of Jennewein's expert witness provided in discovery were insufficient to apprise it of information relating to the TTFL12 strain or Jennewein's non-infringement theory. Glycosyn's Resp. at 35-39, Glycosyn's Reply at 13-16. Indeed, the IA points out that "Glycosyn failed to question any witnesses about the product during fact discovery, or to test a sample of the TTFL12 strain or 2'-FL made using the TTFL12 strain during its onsite testing at Jennewein's facility." IA's Resp. at 34; *see also* Jennewein Resp. at 32-33 ("Glycosyn never questioned any of Jennewein's fact witnesses at their depositions about the properties of the TTFL12 strain. SIB at 71. And when it traveled to Jennewein's German facility to conduct testing of Jennewein's other production strains – six weeks after Jennewein had disclosed TTFL12 and its genetic composition – Glycosyn never asked to test it."). Glycosyn does not deny the IA and Jennewein's assertions that it chose not to question witnesses or to test the TTFL12 strain or 2'-FL made using the TTFL12 strain during its on-site testing in Germany. Glycosyn's Reply at 15.

(Table 1); RX-409C (Stephanopoulos RWS) at Q/As 277-278 (testifying that "the *lacZ* gene has been deleted or inactivated" and that "TTFL12 was not further engineered to insert a functional exogenous β-galactosidase gene"); *see also* Hr'g Tr. (Parschat) at 384:10-17 ("The complete *lacZ* gene as occurs in the operon is not present in the TTFL-12 strain."); RX-386C (Parschat WS) at Q/As 159-160 ("[T]here is no β-galactosidase gene so the strain cannot produce β-galactosidase."); RX-387C (Parkot WS) at Q/A 85 ("The TTFL12 strain is a 2'-FL production strain that has no β-galactosidase (lacZ) gene and does not use lactose to synthesize 2'-FL."); RX-385C (Jennewein) at Q/As 160-62, 176-177 (testifying that "[Jennewein] deleted the *lacZ* gene and also did not insert any β-galactosidase gene or complementary β-galactosidase gene fragments so there can be no β-galactosidase activity"); Hr'g Tr. (Jennewein) at 227:8-13 (testifying that he wrote the RX-320 article). Thus, based on the record evidence, the Commission finds that the TTFL12 strain does not contain an "exogenous functional β-galactosidase gene comprising a detectable level of β-galactosidase activity" as required by the Asserted Claims. *Accord* IA's Resp. at 3-7; Jennewein's Resp. at 2-11.

Unlike Jennewein, Glycosyn presented no expert evidence to establish the presence of a *lacZ* gene or *lacZΩ* fragment in the TTFL12 strain, and thereby infringement by that strain, arguing instead that Jennewein presented insufficient discovery. *See* Glycosyn's Resp. at 11; *see also Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1370 (Fed. Cir. 2004) (finding no infringement where "a patent law plaintiff who presents complex subject matter without inputs from experts qualified on the relevant points in issue when the accused infringer has negated

infringement with its own expert.").[26] Glycosyn asserts that "TTFL12[] contain[s] a functional *lacZα* β-galactosidase gene," but Glycosyn says nothing about *lacZ*Ω. *See* Glycosyn's Resp. at 11-14. As the FID finds, "[i]t is the combination of *lacZα* and *lacZ*Ω which is equivalent to the claimed 'β-galactosidase gene,' and this combination does not exist until *lacZ*Ω is inserted into the bacterium's genome from outside the organism." *See* FID at 45; *see also* Hr'g Tr. (Prather) at 436:1-6 (agreeing that "the alpha fragment[] . . . cannot make beta-galactosidase on its own"). Nor is there any evidence that the *lacZ*Ω was inserted in the TTFL12 strain. Thus, the Commission finds that Glycosyn failed to establish that the TTFL12 strain contains an "exogenous functional β-galactosidase gene comprising a detectable level of β-galactosidase activity" as required by the Asserted Claims. Accordingly, Glycosyn failed to satisfy its burden to establish infringement by the TTFL12 strain.[27]

Thus, the Commission has determined to reverse the FID's decision not to adjudicate infringement with respect to the TTFL12 strain and provides its reasoning above as to why such adjudication is warranted. The Commission further finds that the TTFL12 strain does not infringe the Asserted Claims as discussed above.

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[26] The ALJ determined that "one of ordinary skill in the art would have (1) a Ph.D in molecular biology, biochemistry, or chemical engineering, or an equivalent field, and 1-2 years of experience working with *E. coli* bacteria or related systems, or (2) a lower level degree (*e.g.*, a M.A.) in a similar field to those listed above, but a greater amount of relevant working experience (*e.g.*, 5-6 years of experience working with *E. coli* bacteria or related systems)." *See* Order No. 22 at 7.

[27] Glycosyn also argues that 35 U.S.C. § 295 creates a presumption that Jennewein's product was made by the patented process, and that Jennewein has the burden to establish that the product was not made by the patented process. *See* Glycosyn's Resp. at 14-18. Glycosyn waived this argument both before the ALJ and the Commission. *See* Order No. 38 at 2-3 (June 14, 2019); 19 C.F.R. § 210.43(b)-(c); *see Finnigan Corp. v. ITC*, 180 F.3d 1354, 1362-63 (Fed. Cir. 1999) ("A party seeking review . . . of a determination by the Commission must specifically assert the error made by the ALJ in its petition for review to the Commission."). In any event, the record in this investigation shows that any presumption under 35 U.S.C. § 295 is overcome by Jennewein as to the TTFL12 strain.

IV. REMEDY, PUBLIC INTEREST, AND BONDING

The RD recommends that the Commission issue an LEO barring entry of Jennewein's articles that infringe the asserted patent claims. *See* RD at 116-18. The RD does not recommend that the Commission issue a CDO against Jennewein.[28] The RD further recommends that the Commission impose a five (5) percent bond during the period of Presidential review. *See id.* at 118-19. Still further, as directed by the Commission, 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. *See id.* at 119-20.

A. Limited Exclusion Order

The Commission has "broad discretion in selecting the form, scope, and extent of the remedy." *Viscofan, S.A. v. US. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986).

Section 337(d)(1) provides that "[i]f the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the [public interest], it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d)(1). *See also Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1358 (Fed. Cir. 2010) ("[T]he Commission is required to issue an exclusion order upon the finding of a Section 337 violation absent a finding that the effects of one of the statutorily-enumerated public interest factors counsel otherwise.").

The RD recommends that the Commission issue an LEO excluding Jennewein's infringing 2'-FL product. *See* RD at 117. Consistent with its decision not to adjudicate the

[28] Glycosyn does not request a CDO against Jennewein.

TTFL12 strain, the RD recommends against a carve-out for 2'-FL product made with the TTFL12 strains. *See id.* The RD, however, recommends "a certification provision, wherein said certification is required to state with particularity the grounds of non-infringement of the imported oligosaccharide and be accompanied by sufficient corroborating evidence of the type provided in discovery in this investigation." *See id.* at 118.

The Commission has determined to issue an LEO barring importation of 2'-fucosyllactose oligosaccharides that infringe the Asserted Claims. Consistent with its finding that the TTFL12 strain does not infringe the Asserted Claims, the Commission has determined to include an explicit carve-out for 2'-FL product made with the TTFL12 strain. In addition, the Commission has determined that the LEO should include the standard certification provision. The Commission finds that the certification provision is justified because it may not be readily apparent by inspection whether the imported article is covered or exempted by the LEO, *i.e.*, whether the imported 2'-FL product is made by an infringing strain (*e.g.*, bacterial strains #1540 and its derivative) or by a non-infringing strain (*i.e.*, the TTFL12 strain). *See Certain Graphics Sys., Components Thereof, & Consumer Prods. Containing the Same*, Inv. No. 337-TA-1044, Comm'n Op. at 65-66 (Sept. 18, 2018). To be clear, as the Commission has previously held, "[t]he standard certification 'does not apply to redesigns that have not been adjudicated as non-infringing.'" *See Automated Teller Machines, ATM Modules, Components Thereof, & Prods. Containing the Same*, Inv. No. 337-TA-972, Comm'n Op., 2017 WL 11198798, *16-17 (June 12, 2017) (quoting *Certain Marine Sonar Imaging Devices, Including Downscan & Sidescan Devices, Prods. Containing the Same, & Components Thereof*, Inv. No. 337-TA-921, Commn Op., 2016 WL 10987364, *53 (Jan. 6, 2016)).

Thus, the Commission has determined to issue an LEO: (1) covering "2'-fucosyllactose oligosaccharides that infringe the Asserted Claims"; (2) including the standard certification provision in the LEO; and (3) including an explicit carve-out for 2'-FL product made with the TTFL12 strain.

B. The Public Interest

Section 337 requires the Commission, upon finding a violation of section 337, to issue an LEO "unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d)(l).

The RD "do[es] not find the requested [LEO] would meaningfully impact public health and welfare, competitive conditions, domestic production of articles, or U.S. consumers." *See* RD at 120. The RD finds that "the purpose of providing 2'-FL in infant formula is to improve public health, [but] the evidence shows that the otherwise well-established market has only recently begun including 2'-FL into its products, and with amounts that have unclear efficacy levels." *See id.* The RD concludes that "[t]he U.S. public is therefore not dependent on such products, as of yet." *See id.*

1. Public Health and Welfare

Jennewein argues that "2'-FL has important health benefits, including its use in infant formula," and "at this time, Jennewein is the only company that can supply 2'-FL to the U.S. market in commercial quantities." *See* Jennewein's PI Br. at 1. Jennewein further argues that its product is incorporated as an ingredient in Abbott's Similac® product which is "the number one selling infant formula" in the U.S. *See id.* (citing RX-385C (Jennewein WS) at Q/A 187).

Jennewein faults the RD for stating that the "market has only recently begun including" its 2'-FL product. *See id.* at 2. To the contrary, Jennewein continues, "Abbott has been adding 2'-FL in its infant formula since 2016" and "there is no reason to doubt that Abbott chooses to include 2'-FL in its Similac® because of the health benefits of 2'-FL." *See id.* (citing CX-205); *accord* Abbott's PI Br. at 1-3.

Glycosyn does not dispute that "HMOs provide health benefits." *See* Glycosyn's Remedy Br. at 2. Glycosyn, however, argues that the proposed LEO will not adversely impact the public health or welfare. *See id.* at 2-4. Glycosyn reasons that "only a subsection of infant formulas in the United States contain 2'-FL, and that even in those that do, the amounts 'have unclear efficacy levels.'" *See id.* at 3 (citing RD at 120); *accord* IA's Resp. at 39-40. Glycosyn also explains that there are "many entities that can meet the demand for 2'-FL in the United States." *See* Glycosyn's Remedy Br. at 4; IA's Resp. at 40-42; DuPont PI Br. at 1-2.

The Commission finds no evidence that the LEO would adversely affect the public health and welfare, particularly in view of the Commission's determination that using the TTFL12 strain does not infringe the Asserted Claims. For example, Jennewein can import its 2'-FL product if it certifies that such product was produced using the TFL12 strain.

Thus, the Commission finds that the LEO discussed *supra* section IV(A) would not have an adverse effect on the public health and welfare.

2. Competitive Conditions in the United States Economy

Jennewein argues that "[it] is the only company currently producing 2'-FL for infants in the U.S. market on a commercial scale." *See* Jennewein's PI Br. at 4 (citing Hr'g Tr. (Newburg[29]) at 57:3-4; RX-385C (Jennewein WS) at Q/A 188). According to Jennewein, "there

[29] Howard Newburg is Co-Chief Executive Officer and Chief Financial Officer of Glycosyn.

is no showing that Glycosyn can offer any product at this time or in the near future, let alone produce quantities sufficient to replace Jennewein's production." *See id.* at 4.

Glycosyn disagrees and argues that "[its] licensee, Friesland, and other third-party industry leaders can replace the subject articles in the U.S. in a commercially reasonable time." *See* Glycosyn's Remedy Br. at 4-5; *accord* IA's Resp. at 44; DuPont PI Br. at 1-2.

The Commission finds no evidence that the LEO would adversely affect the competitive conditions in the United States economy, particularly in view of the Commission's determination that using the TTFL12 strain does not infringe the Asserted Claims. For example, Jennewein can import its 2'-FL product if it certifies that such product was produced using the TTFL12 strain. Moreover, the evidence indicates alternative suppliers (including Glycosyn, FrieslandCampina, Glycom, and DuPont) can also replace the excluded products within a commercially reasonable time. *See* IA's Resp. at 41-42 (citing, *inter alia*, RX-385C (Jennewein WS) at Q/A 135; CX-3C (Newburg WS) Q/As 76, 79-80).

Thus, the Commission finds that the LEO discussed *supra* section IV(A) would not have an adverse effect on the competitive conditions in the United States economy.

3. The Production of Like or Directly Competitive Articles

Jennewein does not address this factor specifically, but its arguments as to this factor appear to be the same as discussed above in connection with competitive conditions in the United States economy. *See* Jennewein's PI Br. at 3-4. Both Glycosyn and the IA argue that the proposed LEO will have no effect on this factor because there is no evidence that the 2'-FL product is produced domestically in the United States. *See* Glycosyn's Remedy Br. at 7; *accord* IA's Resp. at 45.

The Commission finds that the presence of alternative suppliers capable of providing alternative non-infringing 2'-FL product (including Glycosyn, DuPont, and Jennewein itself)

negates any evidence that the LEO would adversely affect the production of like or directly competitive articles, particularly in view of the Commission's determination that using the TTFL12 strain does not infringe the Asserted Claims. For example, Jennewein can import its 2'-FL product if it certifies that such product was produced using the TTFL12 strain.

Thus, the Commission finds that the LEO discussed *supra* section IV(A) would not have an adverse effect on the production of like or directly competitive articles.

4. United States Consumers

Jennewein argues that the requested LEO would have a severely negative impact on U.S. consumers. *See* Jennewein's PI Br. at 4-5. Jennewein explains that it is "the only company making GRAS-approved 2'-FL on a commercial scale for the U.S. market." *See id.* Glycosyn asserts that "alternative suppliers of biosynthesized 2'-FL by Glycosyn's licensee Friesland, Glycom, and DuPont can provide ample replacement articles of like or directly competitive products." *See* Glycosyn's Remedy Br. at 8; *accord* IA's Resp. at 46. Glycosyn also notes that "Friesland received GRAS approval from the FDA on April 6, 2018, to manufacture 2'-FL." *See* Glycosyn's Remedy Br. at 4.

The Commission finds that the presence of alternative suppliers capable of providing non-infringing 2'-FL product (including DuPont and Jennewein itself) negates any evidence that the LEO would adversely affect U.S. consumers, particularly in view of the Commission's determination that using the TTFL12 strain does not infringe the Asserted Claims. For example, Jennewein can import its 2'-FL product if it certifies that such product was produced using the TTFL12 strain.

Thus, the Commission finds that the LEO discussed *supra* section IV(A) would not have an adverse effect on U.S. consumers.

5. Conclusion

Based on the record evidence, the Commission finds that an LEO directed against Jennewein's infringing articles, and including a standard certification provision and an explicit carve-out for articles produced using Jennewein's non-infringing TTFL12 strain, would cause little to no harm to the public health and welfare, the competitive conditions in the United States economy, the production of like or directly competitive products in the United States, and United States consumers. Thus, after considering the parties' submissions and the effect that remedial orders would have on the public interest, the Commission has determined to issue a limited exclusion order.

C. Bonding

If the Commission enters an exclusion order or a cease and desist order, a respondent may continue to import and sell its products during the 60-day period of Presidential review under a bond in an amount determined by the Commission to be "sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3); *see also* 19 C.F.R. § 210.50(a)(3).

When reliable price information is available in the record, the Commission has often set the bond in an amount that would eliminate the price differential between the domestic product and the imported, infringing product. *See Certain Microsphere Adhesives, Processes for Making Same, & Prods. Containing Same, Including Self-stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. No. 2949, Comm'n Op. at 24 (Jan. 16, 1996). The Commission also has used a reasonable royalty rate to set the bond amount where a reasonable royalty rate could be ascertained from the evidence in the record. *See, e.g., Certain Audio Digital-to-Analog Converters & Prods. Containing Same*, Inv. No. 337-TA-499, Comm'n Op. at 25 (Mar. 3, 2005). Where the record establishes that the calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has

imposed a 100 percent bond. *See, e.g., Certain Liquid Crystal Display Modules, Prods. Containing Same, & Methods Using the Same*, Inv. No. 337-TA-634, Comm'n Op. at 6-7 (Nov. 24, 2009). The complainant, however, bears the burden of establishing the need for a bond. *Certain Rubber Antidegradants, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-533, USITC Pub. No. 3975, Comm'n Op. at 40 (July 21, 2006).

As stipulated by the parties, the RD recommends a bond of five (5) percent of the entered value of Jennewein's 2'-FL product during the period of Presidential review. *See* RD at 114-115 (citing JX-7 (stipulation regarding bond)). Consistent with the parties' agreement and the RD's recommendation, the Commission has determined that a bond in the amount of five (5) percent of the entered value of the imported products is appropriate for subject imports entered during the period of Presidential review.

V. CONCLUSION

For the reasons set forth herein, the Commission determines that complainant Glycosyn has established a violation of section 337 by respondent Jennewein based on the infringement of the Asserted Claims of the '018 patent. Accordingly, the investigation is terminated with a finding of a violation of section 337. The Commission determines that the appropriate remedy is an LEO directed against Jennewein's infringing human milk oligosaccharides, that the public interest factors do not weigh against issuing that remedy, and that the bond during the Presidential review period is set in the amount of five (5) percent of the entered value of the infringing articles.

By order of the Commission.

Lisa R. Barton

Secretary to the Commission

Issued: June 8, 2020

CERTAIN HUMAN MILK OLIGOSACCHARIDES AND METHODS OF PRODUCING THE SAME **Inv. No. 337-TA-1120**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served via EDIS upon the Commission Investigative Attorney, **Lisa Murray, Esq.**, and the following parties as indicated, on **June 8, 2020**.

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