UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

REDACTED CIVIL MINUTES - GENERAL

Case No.	SACV 18-01679-JVS(JDEx)	Date	April 5, 2022
Title	PureCircle USA Inc., et al. v. SweeGen, Inc., et al.,		

Present: The Honorable	**James V. Selna, U.S. District Court Judge**

Lisa Bredahl	Not Present
Deputy Clerk	Court Reporter
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
Not Present	Not Present

Proceedings: **[IN CHAMBERS] REDACTED Order Regarding PureCircle's Motion for a Presumption of Infringement and to Shift the Burden to Defendants Under 35 U.S.C. § 295**

See attached redacted order.

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PureCircle USA Inc. et al v. SweeGen, Inc. et al
SACV 18-1679 JVS (JDE)

[redacted] Order Regarding PureCircle's Motion for a Presumption of Infringement and to Shift the Burden to Defendants Under 35 U.S.C. § 295

Plaintiffs PureCircle USA Inc. and PureCircle Sdn Bhd (collectively, "PureCircle") filed a motion for a presumption under 35 U.S.C. § 295 that the accused Bestevia Reb M® ("Bestevia Reb M") products infringe U.S. Patent No. 9,243,273 ("the '273 patent"). Mot., Docket No. 169 (sealed version at Docket No. 173). Defendants SweeGen, Inc. ("SweeGen") and Phyto Tech Corp. d/b/a Blue California ("Blue California") (collectively, "Defendants") opposed and filed evidentiary objections, and PureCircle replied. Opp'n, Docket No. 192 (sealed version at Docket No. 195); Evid. Obj., Docket No. 192-2; Reply, Docket No. 200 (sealed version at Docket No. 203).

For the following reasons, the Court **GRANTS** the motion and **OVERRULES** Defendants' evidentiary objections.

I. BACKGROUND

A. The Asserted Patents

PureCircle accuses Defendants of infringing the '273 Patent and U.S. Patent No. 10,485,257 ("the '257 Patent") (collectively, "the Asserted Patents"). FAC, Docket No. 79. The '273 Patent is titled "Method for Making Rebaudioside X," and "relates to a biocatalytic process for preparing compositions comprising steviol glycosides, including highly purified steviol glycoside compositions. '273 Patent at 1:16-18. The '257 Patent is titled "Method of Making Steviol Glycosides," and has the same specification as the '273 Patent.

The Asserted Patents are generally directed to a method of making specific kinds of artificial sweeteners or sugar substitutes known as "steviol glycosides." Mot. at 1-2 (citing FAC ¶ 29). Steviol glycosides are naturally occurring chemicals derived from the *Stevia rebaudiana* plant. Id. According to PureCircle,

most sweeteners today use a particular kind of steviol glycosiden known as "Rebaudioside A" or "Reb A," "one of the two most prevalent steviol glycosides in the *Stevia rebaudiana* plant." Mot. at 2 (citing Bollinger Rpt., Docket No. 173-1 ¶ 38). The Asserted Patents claim a method for making a different steviol glycoside: "Rebaudioside X," also referred to as "Rebaudioside M" or "Reb M." See Docket No. 143 (granting stipulation that "Rebaudioside X" as used in the Asserted Patents is the same as Reb M).

Reb M is a steviol glycoside with a non-sugar core (steviol) and six "glucose" or sugar units. See Mot. at 2. Annotated Figure 1 of the '273 Patent,

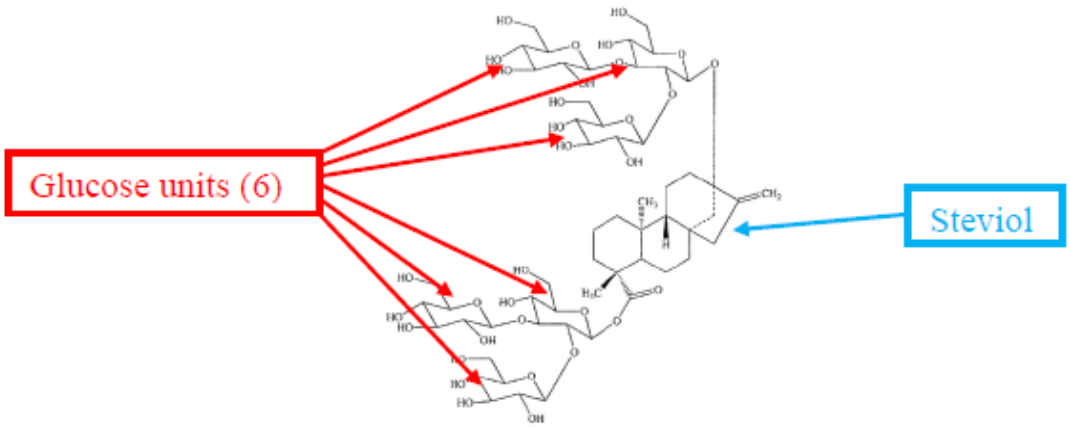

FIG. 1

depicted below, shows a diagram of the structure of Reb M:

See Mot. at 2; '273 Patent, Fig. 1, 3:48. According to Plaintiff, "Reb M is a particularly valuable steviol glycoside because it tastes more like sugar than other steviol glycosides," but "exists only in trace amounts—less than about 0.1% by weight of the total steviol glycoside content—in the natural stevia plant, making it difficult and expensive to obtain in commercial quantities." Mot. at 2-3.

The Asserted Patents claim to solve this problem by "developing new methods for making Reb M using genetic engineering of microorganisms." Id. at 3. The Asserted Patents disclose that Reb M is made by "contacting a starting

composition comprising a steviol glycoside substrate with UDP-glucosyltransferase [i.e., a 'UGT enzyme'], thereby producing a composition comprising a target steviol glycoside comprising one or more additional glucose [or sugar] units than the steviol glycoside substrate." '273 Patent at 1:61-67. In other words, the method of the Asserted Patents makes Reb M by using UGT enzymes to add sugar units to a steviol glycoside with less than six sugar units until it has six, thereby converting it to Reb M. See id. at 2. Microorganisms, such as yeast or bacteria, "are induced to produce" the UGT enzymes, which the microorganisms "would not normally produce." Id. at 3.

Claim 1 of the '253 Patent claims this process. See '253 Patent, Claim 1. Claim 1 of the '273 Patent, however, specifically claims making Reb M from "Rebaudioside D" or "Reb D," a steviol glycoside with five sugar units: two "on the C-19 side"and three "on the C-13 side." Docket No. 143. Claim 1 recites:

> 1. A method for making Rebaudioside X comprising a step of converting Rebaudioside D to Rebaudioside X using a UDP-glucosyltransferase, wherein the conversion of Rebaudioside D to Rebaudioside X is at least about 50% complete.

'273 Patent, Claim 1. PureCircle asserts that Defendants infringe Claims 1-14 of the '273 Patent. See generally Mot. Claim 1 is the only independent claim.

B. Defendants & the Bestevia Reb M Product

Defendants "are related companies and compete with PureCircle in the market for Reb M." Mot. at 4 (citing First Stay Order, Docket No. 63 at 5). Defendants sell Reb M in the United States under the brand name Bestevia Reb M. Id. On February 21, 2017, Defendants announced the commercialization of their Bestevia Reb M products with a global beverage company. FAC ¶ 36.

Defendants are "majority owned and controlled by Steven Chen ('Mr. Chen'), who also serves as Chief Executive Officer and a director" of Defendants. Mot. at 4 (citing Ex. F, Docket No. 173-4 at SGB00012958). "Mr. Chen (either individually or through his family trust) is also the majority-owner of at least two

other companies involved in the development and manufacture of Bestevia Reb M: (1) Conagen, Inc. ('Conagen'), a Massachusetts company that was responsible for developing the manufacturing methods used to make Bestevia Reb M, and that licensed those methods to [Defendants]; and (2) Anhui Longking Biotechnology Co., Ltd. ('Anhui'), a Chinese company that has been primarily responsible for manufacturing Defendants' Bestevia Reb M product." Id. [redacted] Id. "Dr. Oliver Yu ('Dr. Yu')— [redacted] is the Chief Science Officer of SweeGen; the CEO, co-founder, and Chief Science Officer of Conagen; until recently the Chief Science Officer of Blue California; [redacted] Mot. at 5 (citing Ex. H, Docket No. 173-6 ¶¶ 2-6).

On August 9, 2016, Blue California petitioned the FDA for a Generally Regarded as Safe ("GRAS") No Objection Letter for the Bestevia Reb M product, which was assigned GRAS (GRN) Notice No. 667 ("GRN No. 667"). Id. ¶ 41; see GRN No. 667, Docket Nos. 173-8 (part 1), 173-9 (part 2). In the United States, the FDA requires companies to submit GRAS notices to provide "certain safety information before" those companies can sell steviol glycosides to the public. Mot. at 6 (citing Ex. J, Docket No. 173-7 at 69:25-70:13). GRN No. 667 discloses using two UGT enzymes from yeast strains to "carry out multiple steps of glucose addition to naturally occurring steviol glycosides, eventually converting them to Reb M." GRN No. 667 at SGB00000177. Regarding the yeast strains, GRN No. 667 stated, "The detailed transformation protocol and plasmid information has been reported in Blue California's patents, which are listed in Appendix A." Id. Appendix A of GRN No. 667 cited five patent applications, all titled "Non-Caloric Sweeteners and Methods for Synthesizing." GRN No. 667 at SGB00000211. On November 8, 2016, in response to a request for additional information from the FDA, Blue California stated that it produced Reb M from Rebaudioside E ("Reb E"). Ex. II, Docket No. 173-24 at SGB00000358. On March 2, 2017, Defendants announced that the FDA had issued a GRAS No Objection Letter for Bestevia. FAC ¶ 41.

In 2018, Edi Eliezer, Conagen's Senior Vice President of BioProcess Engineering and Manufacturing, gave a presentation at the BIO World Congress

on Industrial Biotechnology ("the BWC Presentation"). Mot. at 7-8 (BWC Presentation, Docket No. 173-12 at PC_00106183). The BWC Presentation disclosed that Conagen produced the Bestevia Reb M product from a combination of Reb D, Reb E, and Reb A. Id.

On November 1, 2019, while this case was stayed pending SweeGen's *inter partes* review ("IPR") petition, Blue California submitted a supplement to the GRN No. 667 ("the GRAS Supplement"), which served to "provide an update on the manufacturing process used to produce yeast-derived Rebaudioside M." FAC ¶ 44; see GRAS Supplement, Docket No. 192-1, Ex. 14 . The GRAS Supplement disclosed that Blue California manufactured Reb M "from [Reb E] via ... [Rebaudiosie D4 ('Reb D4')]," but also stated that the "finished product purity and specifications for" Reb M remained unchanged from GRN 667. GRAS Supplement at SGB00012343, -346. [redacted]

C. Litigation History

PureCircle filed this action on September 17, 2018, initially only asserting that Defendants infringe the '273 Patent. Complaint, Docket No. 1. On November 26, 2018, Defendants moved to dismiss the complaint for failing to state a plausible claim of infringement, arguing that GRN No. 667 only "describes the process of converting Reb E to Reb M, *not* Reb D to Reb M." First MTD, Docket No. 27; First MTD Order, Docket No. 38-1 (emphasis in original). On January 7, 2019, the Court denied Defendants' first motion to dismiss, finding that the evidence could plausibly support a claim for infringement. First MTD Order.

On February 18, 2020, PureCircle filed its FAC, asserting that Defendants also infringe the '257 Patent and adding citations to the GRAS Supplement for PureCircle's claim that Defendants infringe the '273 Patent. FAC ¶¶ 44-47; see redline at Docket No. 69-8. On March 3, 2020, Defendants again moved to dismiss PureCircle's allegations of infringement of the '273 Patent for failing to state a plausible claim of infringement, arguing that the GRAS Supplement shows that they manufactured the Bestevia Reb M product from Reb E via Reb D4

instead of Reb D. Second MTD, Docket No. 80. On April 22, 2020, the Court denied that motion, finding that "there are some concerning discrepancies in the GRAS Supplement," and it remained unclear whether the GRAS Supplement reflected a change in the manufacturing process or clarified the existing process, or sufficiently showed that the process does not infringe the '273 Patent. Second MTD Order, Docket No. 88 at 8.

The Court has stayed this case twice: first, on June 3, 2019, pending resolution on Defendants' IPR Petition, and second, on August 5, 2020, pending resolution on Defendants' post-grant review ("PGR") petition. First Stay Order; Second Stay Order, Docket No. 119. Before both stays, PureCircle moved to compel Defendants to respond to PureCircle's discovery requests regarding Defendants' Bestevia Reb M manufacturing process, including identifying who manufactures the product. First Mot. to Compel, Docket No. 50; Second Mot. to Compel, Docket No. 99. Magistrate Judge Early denied the first as moot on June 4, 2019, and granted-in-part and denied-in-part the second on July 20, 2020, ordering Defendants to produce documents identifying who manufactures the Bestevia Reb M product. First Compel Order, Docket No. 64; Second Compel Order, Docket No. 116 at 5-9. Magistrate Judge Early denied PureCircle's request that Defendants produce records from their manufacturer, however, because Defendants "plausibly asserted that [Conagen] and the manufacturer are separate entities over which Defendants lack 'control' for purposes of Rule 34(a)(1)." Id. at 3-5. On August 3, 2020, Defendants produced documents that disclosed that Anhui manufactured the Bestevia Reb M product. Varughese Decl., Docket No. 192-1 ¶¶ 16, 17.

The Court lifted the second stay on February 1, 2021. Docket No. 122. On April 7, 2021, the parties filed and the Court granted a joint stipulation resolving the parties' claim construction disputes and vacating the claim construction deadlines. Docket Nos. 142, 143; see also Docket Nos. 160, 161. On May 10, 2021, PureCircle filed an unopposed motion for issuance of a letter of request to examine persons and inspect documents pursuant to the Hague Convention, seeking discovery from Anhui. Docket Nos. 144, 147 (sealed version). On June 14, 2021, on its own motion, the Court continued the hearing to June 30, 2021, when it granted PureCircle's motion. Docket Nos. 150, 151. Fact discovery closed on November 5, 2021. Docket No. 155.

II. LEGAL STANDARD

Section 295 provides:

> In actions alleging infringement of a process patent based on the importation, sale, offer for sale, or use of a product which is made from a process patented in the United States, if the court finds--
> (1) that a substantial likelihood exists that the product was made by the patented process, and
> (2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine,
> the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.

35 U.S.C. § 295. This section "applies in cases where a product is manufactured abroad and imported into the United States." Nichia Corp. v. VIZIO, Inc., No. SACV 16-0545 SJO (MRWx), 2019 WL 1966665, at *3 (C.D. Cal. Mar. 25, 2019), vacated, SACV 16-0545 SJO (MRWx), 2019 WL 7281927 (C.D. Cal. Apr. 16, 2019). Congress passed § 295 to solve "'the great difficulties a patentee may have in proving that the patented process was used in the manufacture of the product in question' where the manufacture occurred abroad." Syngenta Crop Prot., LLC v. Willowood, LLC, 944 F.3d 1344, 1363 (Fed. Cir. 2019) (quoting S. Rep. 100-83, at 46 (1987)).

III. DISCUSSION

PureCircle moves for the Court to find that Defendants presumptively infringe the claims of the '273 Patent under § 295. Mot. First, PureCircle argues that there is a substantial likelihood that Anhui manufactures the Bestevia Reb M products using the process claimed in the '273 Patent based on the GRN No. 667, the BCW Presentation, and independent chemical testing. Id. at 13-20. Second, PureCircle asserts that it made reasonable efforts to determine whether Anhui actually used the claimed process and was unable to do so. Id. at 20-25. The Court considers each argument in turn.

A. Substantial Likelihood That Product Was Made by Patented Process

PureCircle asserts that there is a substantial likelihood that Anhui manufactures the Bestevia Reb M product using the process claimed in the Claims 1-14 of the '273 Patent. Mot. at 13-20. According to PureCircle, "Except for the claim limitations related to converting Reb D to Reb M, Defendants do not dispute that all of the other limitations in the asserted claims are present in the accused Bestevia Reb M manufacturing process." Id. at 13. PureCircle argues that "Defendants' own regulatory submissions, their public and customer presentations, and independent chemical testing of the accused products are all evidence that Defendants manufacture Bestevia Reb M by a step of converting Reb D to Reb M." Id. at 14.

Addressing Defendants' regulatory submissions, PureCircle argues that the five patent applications listed in Appendix A of GRN No. 667 "all describe the same process for making Reb M, which includes a step of converting Reb D to Reb M using a UGT enzyme." Id. [redacted] Id. at 14 (quoting Ex. II at SGB0000356-365). According to PureCircle, Defendants asserted that the '070 Publication disclosed UGT enzymes "converting Reb E to Reb M." Id. PureCircle asserts that the '070 Publication "discloses and claims 'a method for synthesizing ***rebaudioside M from rebaudioside D***" using a UGT enzyme. Id. (emphasis in original) (quoting Ex. JJ, Docket No. 173-25 at Claim 19). Additionally, PureCircle asserts that Defendants' regulatory filings submitted in other countries confirm that Anhui's manufacturing process [redacted] Id. at 15 (citing Bollinger Rpt. ¶¶ 112-135, 176-183).

[redacted]

[redacted] which are strong evidence that the Bestevia Reb M manufacturing process involves a step of converting Reb D to Reb M using UGT76G1." Id. at 16-17 (citing Bollinger Rpt. ¶¶ 154-175).

Defendants respond that the record evidence shows that Anhui manufactures Defendants' Bestevia Reb M from Reb D4, not Reb D. Opp. at 16-18. According to Defendants, "PureCircle has not disputed that the Reb D4 pathway is materially distinct from the Reb D pathway and would not infringe the claims of the '273 patent." Id. at 16. Defendants assert that all the evidence cited by PureCircle is outdated because Anhui has since implemented a process that uses Reb D4 instead of Reb D, as evidenced by the GRAS Supplement. Id. at 16-17, 21 (citing GRAS Supplement at SGB00012347). Addressing GRN No. 667, Defendants argue that "[i]t is *silent* on the pathway and precursor to Bestevia Reb M" because only the end-product mattered to the FDA, not the manufacturing process, [redacted] See id. at 20-22 (emphasis in original) (citing Yu Dep. I Tr. at 92:3-8; Emmel Rpt., Docket No. 196-10 ¶ 31; GRN No. 667 at SGB00000177). Defendants also assert that the documents cited by PureCircle disclose that Defendants manufactured the Bestevia Reb M products from Reb D because the Reb D4 process was a trade secret at the time. Id. at 16-17, 22 (citing Varughese Decl. ¶ 4; Yu Dep. I Tr., Docket No. 196-2 at 27:23-28:14, 57:7-13, 98:12-14, 101:20-102:5, 177:21-24; Yu Dep. II Tr. at 78:3-6). Because Defendants provide a plausible non-infringement argument, Defendants argue that PureCircle cannot show a substantial likelihood of infringement. See id. at 19-20.

PureCircle replies that GRN No. 667 is still relevant because "the FDA opted to not even review [the GRAS Supplement], for the simple reason that Defendants told the FDA that nothing in the Bestevia Reb M manufacturing process had changed since their original GRAS submission." Reply at 6-7 (citing Ex. NN at SGB00124503-508). PureCircle argues that the GRAS Supplement was litigation-inspired given that Defendants filed it just after the PTO denied their IPR petition and conceded that it was filed "[b]ecause of this litigation." See id. at 7-8 (quoting Second MTD at 3). PureCircle also argues that the FDA asks parties whether anything in a GRAS notice is a trade secret and specifically asked Blue California about the Bestevia Reb M manufacturing process, yet Blue California never disclosed any trade secrets or that Reb D4 was involved prior to the GRAS Supplement. See id. at 9-10 (citing GRN No. 667 at SGB00000157;

Ex. II at SGB00000358). Further, according to PureCircle, Defendants' arguments regarding the relevance of GRN No. 667 [redacted]. See id. at 10-12. Finally, PureCircle asserts that Defendants' arguments addressing the BCW Presentation and lab testing are without merit. See id. at 12-16.

The evidence shows a substantial likelihood that in actual practice, Anhui manufactures the Bestevia Reb M product using Reb D. GRN No. 667 discloses a process of making Reb M using two microorganisms genetically engineered to produce UGT enzymes, Yeast A and Yeast B. See GRN No. 667 at SGB00000179, 181, Fig. 3. [redacted] See Yu Decl. ¶ 24; Yu Dep. II Tr. at 69:20-70:4. According to Defendants' foreign regulatory filings, [redacted] See Bollinger Rpt. ¶¶ 112-135, 176-183.[1] Similarly, Blue California's response to the FDA's request for additional information states that [redacted]. The five patent applications cited in Appendix A of GRN No. 667 disclose that HV1 UGT enzymes are used to convert steviosides to Reb E and Reb A to Reb D, whereas UGT76G1 UGT enzymes are used to convert steviosides to Reb A, Reb E to Reb D, and Reb D to Reb M. See GRN No. 667 at SGB00000211; U.S. Patent No. 9,783,566 ("the '566 Patent") at 40:3-16, 58:45-52, 59:33-43, 68:4-12, Figs. 21B-21D.[2] Thus, the evidence shows a substantial likelihood that Anhui uses Yeast A to convert steviosides to Reb E and Reb A to Reb D and Yeast B to convert Reb E to Reb D and to convert Reb D to Reb M.

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[1] The Korean filing recites that only [redacted] See Bollinger Rpt. ¶ 114. As seen from the other information submitted to the FDA, this suggests that Anhui only uses or used Reb A to manufacture Reb D, not Reb E, because Reb E requires UGT76G1 enzymes produced by Yeast B to create Reb D.

[2] The patent applications also disclose that steviosides have two sugar units on the C-13 side and one sugar unit on the C-19 side, Reb A has three sugar units on the C-13 side and one sugar unit on the C-19 side, and Reb E has two sugar units on both the C-13 and C-19 sides. See '566 Patent, Figs. 21A, 21B.

Additionally, the GRAS Supplement's disclosure that Anhui manufactured the Bestevia Reb M product from Reb D4 appears to contradict the process disclosed in GRN No. 667 and Blue California's November 8, 2016 response to the FDA's request for additional information. According to the '062 Patent, Reb D4 has two sugar units on the C-13 side and three sugar units on the C-19 side, unlike Reb D, which has the reverse. See '062 Patent, Fig. 1. Citing International Patent Publication No. WO 2018/164747 to Conagen ("the '747 Publication"), the GRAS Supplement discloses that Clm2 or Clm3 enzymes convert Reb E to Reb D4, and UGT76G1, CP1, or CR1 enzymes convert Reb D4 to Reb M. GRAS Supplement at SGB00012347; see also '747 Publication, Docket No. 180-3, Ex. 22 at SGB00010800 (Abstract), 833-834; Opp. at 17 (asserting that the process disclosed in GRAS Supplement shows how SweeGen's product is made). The '747 Publication does not disclose using UGT76G1 to convert Reb E to Reb D4. By contrast, Blue California disclosed to the FDA that only UGT76G1 UGT enzymes are used to convert Reb E to Reb M. See Ex. II at SGB00000358 (disclosing that the UGT76G1 derivative converts Reb E to Reb M); see also '566 Patent at 40:3-16, 58:45-52, 59:33-43, 68:4-12, Figs. 21B-21D (disclosing that UGT76G1 UGT enzymes convert Reb E to Reb D and Reb D to Reb M). The '747 Publication suggests that the process disclosed in GRN No. 667 includes Reb D, not Reb D4.[3]

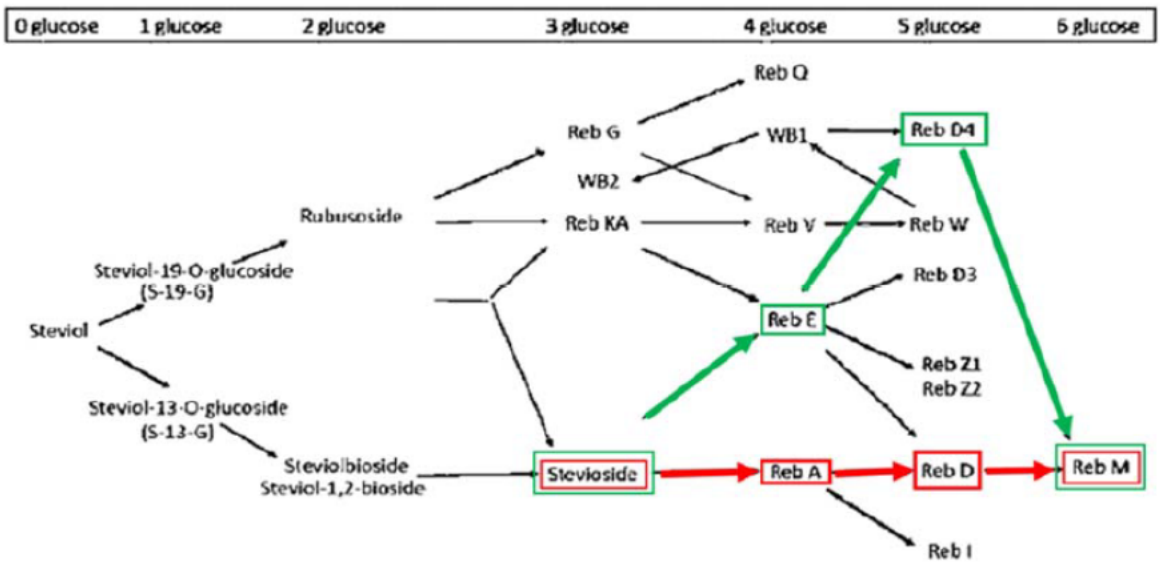
Defendants' arguments that the GRAS Supplement replaces any conflicting disclosure in the GRN No. 667 are unpersuasive. First, the GRAS Supplement was filed during this litigation and Defendants admitted that it was filed "[b]ecause of this litigation." Second MTD at 3. [redacted]

The BCW Presentation also shows a substantial likelihood that Anhui produced Reb M at least partially from Reb D. The BCW Presentation depicts all the pathways from a stevioside to Reb M through Reb E, Reb D, and Reb A, and emphasizes three particular pathways: i) stevioside to Reb E, ii) Reb A to Reb D,

[3] [redacted]

and iii) Reb D to Reb M. See BCW Presentation at PC_00106183; see also Ex. V at CONAGEN-00014075. According to GRN No. 667, Yeast A is used for the first two pathways and Yeast B is used for the third. Defendants only offer attorney argument and Dr. Yu's testimony that the Reb D4 process was a trade secret to rebut this information, which does not explain why Conagen depicted using Reb D instead of just stating that the process was confidential. Absent corroborating evidence from Anhui or Conagen, Defendants' self-serving statements are not persuasive.

Finally, PureCircle produced evidence that the Bestevia Reb M products include larger concentrations of [redacted] than naturally produced, [redacted]. See Bollinger Rpt. ¶¶ 154-175. As the chart below shows (reproduced from Defendants' opposition), only the pathway from Reb A to Reb D produces Reb I, and not the pathway through Reb E and Reb D4:



See Opp. at 7. Although Defendants dispute that the concentration of [redacted] is unnaturally high, Defendants offer no explanation for the high concentration of [redacted][4] The high concentration of [redacted] shows a substantial likelihood that HV1

[4] SweeGen provides a report from a Conagen employee, [redacted] Neither the report nor SweeGen explains the results of the testing, however.

UGT enzymes produced by Yeast A convert both steviosides to Reb E and Reb A to Reb D in Anhui's process.

Defendants assert that Anhui manufactures Reb M only from Reb D4, but provide no evidence other than attorney argument, their own employees' testimony, the contradictory GRAS Supplement, and Conagen's patent applications, which do not show that Anhui actually implemented the patented processes using Reb D4 exclusively. Even assuming Defendants' theory is plausible, the relevant standard for § 295 is whether there is a substantial likelihood that the accused products were made by the patented process, not whether PureCircle satisfied its burden of proving infringement. See Syngenta Crop Prot., LLC v. Willowood, LLC, No. 1:15-CV-274-CCE, 2017 WL 1133378, at *6 (M.D.N.C. Mar. 24, 2017), aff'd in part, vacated in part, rev'd in part on other grounds, 944 F.3d 1344 (Fed. Cir. 2019). Defendants may still rebut the presumption that their Bestevia Reb M products infringe by producing evidence that Anhui manufactures the products using Reb D4, not Reb D. At this stage, however, the Court does not need to decide whether Anhui's manufacturing process actually infringes the '273 Patent; rather, the Court only needs to find that there is a substantial likelihood that it does based on the evidence of record. The Court finds that PureCircle has shown such a likelihood for Claims 1-14 of the '273 Patent.[5]

B. Reasonable Effort to Determine the Process Actually Used in the Production of the Product

[5] [redacted] Given that neither party addresses this document in relation to the "substantial likelihood" element, however, the Court does not consider it.

PureCircle argues that it also made reasonable, albeit unsuccessful, efforts during discovery to determine how the Bestevia Reb M products are made. According to PureCircle, its discovery efforts included: "(1) written discovery of both Defendants under Rules 33 (interrogatories), 34 (requests for production) and 36 (requests for admission); (2) depositions of Defendants' corporate representatives and individual employees under Rule 30(b)(1) and 30(b)(6); (3) third party document and deposition subpoenas under Rule 45; and (4) a request to Defendants' Chinese manufacturer, Anhui, pursuant to the Hague Convention." Mot. at 20. PureCircle argues that it was forced to compel Defendants to identify their manufacturer, Anhui, because Defendants argued that the identity of Anhui was a trade secret. See id. at 20-21 (citing Second Mot. to Compel). PureCircle also asserts that Defendants have maintained throughout this case that they lack control over Anhui, despite Defendants' common ownership with Anhui, and have refused to produce any documents related to Anhui's manufacturing process. See id. at 21 (citing Docket No. 99-1 at 62). According to PureCircle, Defendants have been able to obtain details about Anhui's manufacturing process when it benefitted them, though. See id. at 23 (citing Ex. II at SGB0000356-365).

PureCircle further avers that it sought and received documents from Conagen and third-party Ingredion, "SweeGen's former exclusive distributor for Bestevia Reb M" who has since acquired PureCircle, but neither company had any manufacturing records. Id. at 21-22 (citing Conagen Subpoena, Docket No. 169-12; Ingredion Subpoena, Docket No. 169-13; Yu Dep. I Tr. at 147:9-13). Finally, PureCircle asserts that it sought discovery from Anhui through the Hague Convention despite there being no requirement to do so under § 295. Id. at 22 (citing Dasso Int'l, Inc. v. MOSO N. Am., Inc., No. CV 17-1574-RGA, 2021 WL 4427168, at *6 (D. Del. Sept. 27, 2021)).

Defendants respond that they produced evidence of Anhui's manufacturing process, which shows that Anhui manufactures Bestevia Reb M from Reb D4. See Opp. at 22-23 (citing Ex. CC, Docket No. 168-22 (Defendants' supplemental responses to PureCircle's Interrogatory No. 6); Yu Dep. I Tr. 119:9-11; Yu Dep. II Tr. 52:3-17, 56:4-7; Yu Decl. ¶¶ 19–25; Vecilla Decl. ¶¶ 4, 5, 7, 11-12). Defendants argue that to the extent PureCircle wanted additional information from Anhui, it failed "to take reasonably diligent steps to obtain that discovery." Id. at 23. Defendants assert that PureCircle was not diligent in seeking discovery from Anhui because "PureCircle never used its own relationship through Ingredion to seek information from Anhui." Id. According to Defendants, Ingredion "had

audit authority to Anhui's factory at times during this litigation and documented one of its visits to Anhui in March 2017—including detailed notes on Anhui's manufacturing process." Id. (citing Ex. 17, Docket No. 196-15 at SGB00035166; Ex. 18). Additionally, Defendants argue that PureCircle delayed bringing its request for discovery under the Hague Convention until near the fact discovery deadline. Id. Finally, Defendants argue that this Court already found that Defendants have no control over Anhui, of which PureCircle never sought reconsideration. See id. at 24-25.

PureCircle replies, "[T]he plain language of § 295 indicates that [PureCircle's], and not [Defendants'], actions are determinative to the 'reasonable efforts' question." Reply at 16 (quoting Syngenta, 2017 WL 1133378 at *10). PureCircle reemphasizes that its discovery efforts were more than reasonable. See id. at 16-17. PureCircle also argues that Defendants' conduct prevented PureCircle from requesting discovery from Anhui earlier. See id. at 17-19. PureCircle further asserts that Ingredion did not acquire PureCircle until July 2020, just before the Court stayed this case the second time, and PureCircle sought discovery from Anhui soon after the Court lifted the second stay. See id. at 18-19. Finally, PureCircle argues that it "is not required to accept Defendants' self-serving evidence created for the purpose of papering up its noninfringement positions, particularly where that evidence is internally inconsistent and also contradicts other documents and testimony provided in this case." Id. at 19 (citing Pfizer Inc. v. F & S Alloys & Mins. Corp., 856 F. Supp. 808, 814 (S.D.N.Y. 1994)).

The Court finds that PureCircle made reasonable efforts to determine whether Anhui actually uses PureCircle's patented manufacturing process. As a preliminary matter, Defendants cite no legal authority requiring that PureCircle's discovery efforts to be "diligent" as well as "reasonable," but the Court finds that PureCircle's efforts were both. PureCircle actively sought information during discovery about how Defendants manufactured their Bestevia Reb M products. See Second Compel Order. Defendants refused to disclose the identity of their manufacturer, Anhui, until the Court ordered them to do so. Id. ("the conduct of and positions taken by Defendants' counsel in connection with many of these disputes, as well as positions taken by them in a prior motion..., raise questions about the seriousness with which counsel takes its obligations under the Rules"). Although Magistrate Judge Early found that Defendants plausibly asserted that they had no control over their manufacturer, at the time neither PureCircle nor the

Court knew Anhui was Defendants' manufacturer and that Chen owned Anhui and Defendats. The evidence now shows that Chen controls and owns Defendants, Conagen, and Anhui, yet Defendants continue to assert that they have no access to information on Anhui's manufacturing process. See Ex. F; Ex. G; see also Ex. I, Docket No. 169-4 (decision by California Court of Appeal finding Chen is the "founder and controlling shareholder" of Defendants, Conagen, and Anhui). Thus, PureCircle made reasonable efforts to discover information regarding Anhui's manufacturing process from Defendants.

PureCircle also made reasonable and diligent efforts to obtain information on Anhui's manufacturing process from Anhui, Conagen, and Ingredion. "[C]ourts have recognized the futility of patentees attempting to obtain plant inspections and document production from third parties in China via the Chinese legal system." Dasso Int'l, Inc., 2021 WL 4427168, at *6. Thus, although not required, courts "look favorably on efforts to obtain discovery from a foreign manufacturer" located in China. Id. Defendants produced documents identifying Anhui as their manufacturer two days before the Court stayed this case a second time. Varughese Decl. ¶¶ 16, 17. On May 10, 2021, less than three months after the Court lifted the second stay and issued the third scheduling order in this case, PureCircle filed its request to seek discovery from Anhui through the Hague Convention. See Docket No. 144. Notably, PureCircle's request came approximately one month after the parties filed their joint stipulation resolving the pending clam construction disputes at the time. See Docket Nos. 142, 143. Defendants argue that PureCircle improperly noticed the request, but the Court continued the hearing date for the request on its own motion. See Docket No. 150. PureCircle also served Conagen with a subpoena on May 20, 2021 and served Ingredion with a subpoena on June 30, 2021. See Conagen Subpoena; Ingredion Subpoena.

Defendants argue that PureCircle should have taken advantage of its current relationship with Ingredion to seek discovery about Anhui's manufacturing process, but it is not clear from the evidence provided by SweeGen that Anhui would have produced the necessary information even if Ingredion requested it. See Ex. 18 at 2 ("[Dr. Yu] was unwilling to share any production records or cost information when asked"), 3 ("[redacted], but [redacted] declined to show any production records to validate this point. ... [redacted] declined to share the exact Reb M content [redacted]"). Thus,

PureCircle's efforts to obtain information regarding Anhui's manufacturing process from Anhui was reasonable and diligent as well.

Finally, Defendants assert that § 295 is reserved for cases where an accused infringer asserts a lack of proof and that Defendants' relationship with Anhui is irrelevant. The present circumstances justify shifting the burden to Defendants more than when an accused infringer only asserts a failure of proof, however. Contrary to their arguments, Defendants' relationship with Anhui is highly relevant because Defendants are using their foreign manufacturer's separate entity status as both a sword and a shield. For instance, Defendants rely on Dr. Yu's undocumented communications with Anhui and their own litigation-inspired regulatory filings to describe Anhui's manufacturing process while simultaneously asserting that they lack access to information regarding that process. Both are examples of the "great difficulties a patentee may have in proving" infringement that Congress sought to alleviate by passing § 295. Syngenta, 944 F.3d at 1363; S. Rep. 100-83, at 46. The Court also does not need to decide whether Defendants had any discovery obligations to produce Anhui documents under Ninth Circuit law. Instead, the Court finds that Defendants are "in a far better position than the patentee" to determine whether or not Anhui used the method claimed in the '273 Patent based on Defendants' relationship with Anhui. S. Rep. No. 100-83, at 31; see also H.R. Rep. No. 100-60, at 16 (1987) (Conf. Rep.) ("accused infringer should be in a much better position to establish that the product was made by another method").

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** the motion and **OVERRULES** Defendants' evidentiary objections.

The Court **VACATES** the March 21, 2022 hearing. Any party may file a request for hearing of no more than five pages no later than 5:00 p.m. on Tuesday, March 22 stating why oral argument is necessary. If no request is submitted, the matter will be deemed submitted on the papers and the tentative will become the order of the Court. If the request is granted, the Court will advise the parties when and how the hearing will be conducted.

If no request for hearing is submitted, the Court asks the parties to meet and confer and, within 7 days, notify the Court via email to the Courtroom Deputy Clerk which parts of the order should be redacted from the publicly filed version of the order. If the parties request that any portions of the order remain sealed, when submitting their request, they shall attach a copy thereof with proposed redactions for the Court's review.

IT IS SO ORDERED.