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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	SA CV 18-01679 JVS (JDEx)	Date	May 23, 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] Order Regarding PureCircle's Motion for Summary Judgment of Infringement of U.S. Patent No. 10,485,257 and Defendants' Motion for Summary Judgment of Invalidity of US. Patent Nos. 9,243,273 and 10,485,257**

Plaintiffs PureCircle USA Inc. and PureCircle Sdn Bhd (collectively, "PureCircle") filed a motion for summary judgment that the accused Bestevia Reb M® ("Bestevia Reb M") products infringe U.S. Patent No. 10,485,257 ("the '257 patent"). PureCircle Mot., Docket No. 176 (sealed version at Docket No. 188). Defendants SweeGen, Inc. ("SweeGen") and Phyto Tech Corp. d/b/a Blue California ("Blue California") (collectively, "Defendants") opposed, and PureCircle replied. Defs. Opp'n, Docket No. 207 (sealed version at Docket No. 215); PureCircle Reply, Docket No. 234 (sealed).

Defendants also moved for summary judgment that the '257 Patent and U.S. Patent No. 9,243,273 (collectively, "the Asserted Patents") are invalid. Defs. Mot., Docket No. 180 (sealed version at Docket No. 184). PureCircle opposed, and Defendants replied. PureCircle Opp'n, Docket No. 211 (sealed version at Docket No. 219); Defs. Reply, Docket No. 225.

On May 6, 2022, the Court held a hearing on Defendants' summary judgment motion. See Docket No. 308. For the following reasons, the Court **GRANTS** PureCircle's motion and **GRANTS-IN-PART** and **DENIES-IN-PART** Defendants' motion.

I. BACKGROUND

PureCircle accuses Defendants of infringing 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." Docket No. 169 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 glycoside known as "Rebaudioside A" or "Reb A," "one of the two most prevalent steviol glycosides in the *Stevia rebaudiana* plant." Id. at 2 (citing Bollinger Opening 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 Docket No. 169 at 2. Annotated Figure 1 of the '273 Patent, depicted below, shows a diagram of the structure of Reb M:

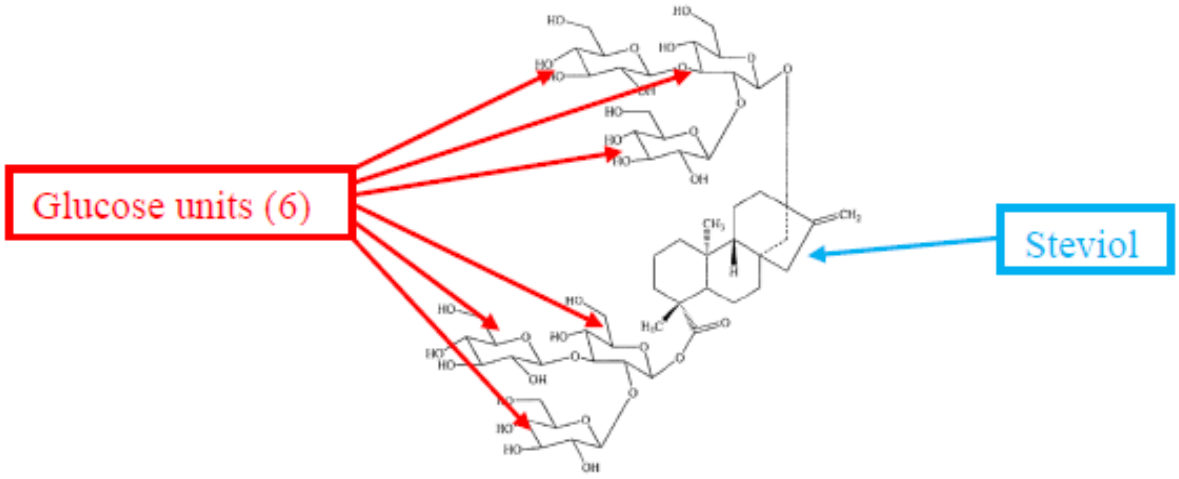

FIG. 1

See id. 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." Id. 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'][1], 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 '257 Patent claims this process. See '257 Patent, Claim 1. Specifically, Claim 1 of the '257 Patent recites:

> 1. A method for adding at least one glucose unit to a steviol glycoside substrate to provide a target steviol glycoside, comprising contacting the steviol glycoside substrate with a recombinant biocatalyst protein enzyme comprising UDP-glucosyltransferase, wherein the target steviol glycoside is Rebaudioside X.

'257 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 and Claims 1-7 of the '253 Patent (collectively, "the Asserted Claims"). See generally Docket No. 169; PureCircle Mot. Claim 1 of both patents are the only independent claims.

[1] For the purposes of this order, the Court uses the phrase "UGT enzymes" to refer to UDP-glucosyltransferase, not UDP-glycosyltransferase.

II. LEGAL STANDARD

A. Summary Judgment

Summary judgment is appropriate where the record, read in the light most favorable to the nonmovant, indicates "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a)[2]; see also MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp., 420 F.3d 1369, 1373 (Fed. Cir. 2005). The burden initially is on the moving party to demonstrate an absence of a genuine issue of material fact. Id.; see also Celotex Corp. v. Catrett, 477 U.S. 317, 322–24 (1986). If, and only if, the moving party meets its burden, then the non-moving party must produce specific evidence to rebut the moving party's claim and create a genuine dispute of material fact. MEMC, 420 F.3d at 1373; see also Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986). If the non-moving party meets this burden, then the motion will be denied. See generally Bose Corp. v. JBL, Inc., 274 F.3d 1354, 1360 (Fed. Cir. 2001).

B. Patent Invalidity

To obtain summary judgment of invalidity, a moving party must overcome the statutory presumption of 35 U.S.C. § 282 that issued patent claims are valid. Section 282 mandates that "[a] patent shall be presumed valid" and that "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282. A party seeking to overcome the statutory presumption and establish the invalidity of an issued patent claim must prove the invalidity by clear and convincing evidence. Microsoft Corp. v. I4I Ltd. P'ship, 564 U.S. 91, 112 (2011).

Every patent must contain a written description and be enabled:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

35 U.S.C. § 112(a). The written description is distinct from the enablement requirement, although the two "often rise and fall together." Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1352 (Fed. Cir. 2010).

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[2] Rule 56 was amended in 2010. Subdivision (a), as amended, "carries forward the summary judgment standard expressed in former subdivision (c), changing only one word — genuine 'issue' becomes genuine 'dispute.'" Fed. R. Civ. P. 56, Notes of Advisory Committee on 2010 amendments.

III. DISCUSSION

A. PureCircle's Motion

PureCircle argues that there is no dispute that the accused Bestevia Reb M products infringe Claims 1-7 of the '257 Patent. PureCircle Mot. Defendants do not dispute that the accused products infringe Claims 1-7 of the '257 Patent to the extent that the claims are valid. See Defs. Opp'n at 3-4. Accordingly, the Court **GRANTS** PureCircle's motion.

B. Defendants' Motion

Defendants argue that the Asserted Claims are invalid for three reasons: 1) they are patent ineligible under § 101, 2) they lack written description support under § 112, and 3) they lack an enabling disclosure under § 112. Defs. Mot. The Court considers each argument.

1. Patent Ineligibility Under 35 U.S.C. § 101

An invention or a discovery is patentable if it is a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. "In choosing such expansive terms . . . Congress plainly contemplated that the patent laws would be given wide scope." Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980). Still, the Supreme Court has identified exceptions to this wide scope to "distinguish patents that claim the building blocks of human ingenuity, which are ineligible for patent protection, from those that integrate the building blocks into something more." Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2350 (2014) (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 89 (2012)) (internal quotations omitted). These exceptions to patent protection are "laws of nature, natural phenomena, and abstract ideas." Diamond v. Diehr, 450 U.S. 175, 185 (1981).

In Mayo and Alice, the Supreme Court set forth a two-step framework for determining patent eligibility under § 101. A claim is ineligible under section 101 if "(1) it is 'directed to' a patent-ineligible concept, i.e., a law of nature, natural phenomenon, or abstract idea, and (2), if so, the particular elements of the claim, considered 'both individually and as an ordered combination,' do not add enough to 'transform the nature of the claim' into a patent-eligible application.'" Elec. Power Grp., LLC v. Alstom S.A., 830 F.3d 1350, 1353 (Fed. Cir. 2016) (quoting Alice, 573 U.S. at 217 (internal quotations omitted)).

If the claims are not directed to a patent-ineligible concept, the claims fall within the scope of § 101 and are patent-eligible. If the claims fail step one, however, under step two, "the court must search for an inventive concept—i.e., an element or

combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." Alice, 134 S. Ct. at 2355 (citing Mayo, 566 U.S. at 72-73). The question in the law of nature context is whether the claims at issue add more than "well-understood, routine, conventional activity already engaged in by the scientific community" to the law of nature. Rapid Litig. Mgmt Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (quoting Mayo, 566 U.S. at 79-80). "[G]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 577 (2013). "Whether the claim elements or the claimed combination are well-understood, routine, conventional is a question of fact." Aatrix Software, Inc. v. Green Shades Software, Inc., 882 F.3d 1121, 1128 (Fed. Cir. 2018).

Defendants argue that the Asserted Claims are patent ineligible under § 101 because they are directed to a law of nature. Defs. Mot. at 6-18. Specifically, Defendants assert that the claims of the '257 Patent are directed to the natural law of converting steviol glycosides to Reb M using UGT enzymes, and the claims of the '273 Patent are directed to the natural law of converting a particular steviol glycoside, Reb D, to Reb M using UGT enzymes. See id. at 7, 13. According to Defendants, "The patent recognizes that all the components of the claimed biocatalytic process, (*e.g.*, steviol substrates, target Reb M, and UDP-glucosyltransferase) are also found in nature." Id. at 7 (citing Defs. SUF, Docket No. 185 (sealed) ¶¶ 33-35). Defendants also argue that none of the additional limitations found in the dependent claims "alters the fact that these claims are directed to naturally occurring processes." Id. at 8.

Defendants argue that the Asserted Claims do not recite an inventive concept either. Defendants address five groups of limitations that they anticipate Plaintiff will argue provide an inventive concept: 1) the use of "recombinant" UGT enzymes in Claims 1-7 of the '257 Patent; 2) the use of "host microorganisms" to "express" the UGT enzymes in Claims 6-7 of the '257 Patent and Claims 12-13 of the '273 Patent; 3) the purity percentages for Reb M in Claims 3-5 of the '257 Patent and Claims 4-6 of the '273 Patent; 4) the conversion percentages of Reb D to Reb M in Claims 1 and 7-11 of the '273 Patent; and 5) the use of the UGT76G1 UGT enzyme in Claim 14 of the '273 Patent. See id. at 9-13, 15-18. For Groups 1 and 2, Defendants assert those "limitations merely limit the source of the UDP-glucosyltransferase enzyme but specify nothing regarding the *structure* or *function* of the enzyme produced, which can be identical to the wild type (as embodied in the only example provided in the specification) nor any non-natural role the enzyme plays in the claimed process." Id. at 10 (emphasis in original) (citing Defs. SUF ¶¶ 55-56). For Groups 3 and 4, Defendants aver that the Asserted Claims do not specify any steps or methods for achieving the claimed purity or completion percentages. See id. at 12-13 (citing Defs. SUF ¶¶ 60-62, 64), 15-17 (citing Defs. SUF ¶¶ 38-40, 43-46, 48-49, 60, 62). Finally, for Group 5, Defendants argue that

UGT76G1 is also naturally occurring and cannot supply the inventive concept. See id. at 18.

PureCircle responds that the Asserted Claims are patent eligible under step one of the Mayo/Alice test because they are directed to methods of preparation not found in nature. According to PureCircle, "in contrast to claims directed to diagnostics, method-of-preparation claims like the '273 and '257 Patents' claims are usually found to be patent-eligible." PureCircle Opp'n at 11 (citing Illumina, Inc. v. Ariosa Diagnostics, 967 F.3d 1319, 1325-29 (Fed. Cir. 2020); CellzDirect, 827 F.3d at 1048-50). PureCircle argues that the Asserted Claims go beyond the natural law of converting steviol glycosides to Reb M because "it is impossible to make significant amounts of" Reb M in nature due to the combination of enzymes that add and remove glucose to rebaudiosides in the *Stevia rebaudiana* plant. Id. at 5-6 (citing PureCircle AMF, Docket No. 218-1 at 44-67 (sealed version at Docket No. 219) ¶¶ 59, 60).

PureCircle also argues that the claims of the '257 Patent are eligible because they recite "recombinant" UGT enzymes, which are not found in nature. See id. at 5. PureCircle further avers for the purity percentage claims that "a process of preparing purified Rebaudioside M does not occur in nature." Id. at 7 (citing PureCircle AMF ¶¶ 22, 23). Similarly, PureCircle asserts for the conversion percentage claims that "[t]here is no evidence indicating that conversion levels required by the claims of the '273 Patent occur in nature." Id. at 8-9. Finally, PureCircle argues the "microorganisms identified in the claims do not produce the claimed enzymes in nature, but only when they are bioengineered by humans to do so." Id. at 7-8 (citing PureCircle AMF ¶¶ 25, 27).

Defendants reply that PureCircle commits two legal errors in its patent eligibility analysis. First, according to Defendants, claims that recite man-made elements may still be directed to natural laws under step one of the Mayo/Alice test. See Defs. Reply at 2-4 (citing Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743, 750, 753-54 (Fed. Cir. 2019); Roche Molecular Systems, Inc. v. CEPHEID, 905 F.3d 1363, 1371-73 (Fed. Cir. 2018); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1373-74, 1376-77 (Fed. Cir. 2015)). Defendants assert that the "recombinant" UGT enzymes are structurally and functionally identical to the naturally occurring UGT enzymes and do "not overcome ineligibility under § 101." Id. at 5-6 (citing Biogen MA Inc. v. EMD Serono, Inc., 976 F.3d 1326, 1332 (Fed. Cir. 2020); In re Roslin Institute (Edinburgh), 750 F.3d 1333 (Fed. Cir. 2014)). Defendants also argue, "Although the 'recombinant biocatalyst protein enzyme' is produced in an expression system (*e.g.*, a host microorganism), the claims allow that enzyme to be *used* in *any* environment to make Reb M." Id. at 6 (emphasis in original). Defendants further argue that the purity and conversion percentage limitations do not change the underlying natural process, making them irrelevant under the step one inquiry. See id. at 7-9. Second, Defendants argue that methods-of-preparation are not per se eligible and PureCircle's cited cases are inapposite. See

id. at 9-10.

The Court finds that Claims 1-5 of the '257 Patent and Claims 1-11 and 14 of the '273 Patent are patent ineligible. As shown by the intrinsic evidence, each of those claims is directed to the natural law of converting steviol glycosides, and specifically Reb D in the case of the claims of the '273 Patent, to Reb M using UGT enzymes. The Asserted Patents disclose that Reb M occurs naturally in the *Stevia rebaudiana* plant. See '257 Patent at 1:28-40. PureCircle does not dispute that "[t]he conversion of certain steviol glycosides, such as Reb D, to Reb M by a [UGT enzyme] occurs naturally in [the *Stevia rebaudiana* plant]." See Defs. SUF ¶ 34; PureCircle SGD, Docket No. 218-1 at 1-44 (sealed version at Docket No. 219) ¶ 34. Thus, there is no dispute that the conversion of steviol glycosides and Reb D to Reb M using UGT enzymes is a natural process.

The specification also indicates that the claimed invention is directed to that process. As the Asserted Patents disclose, "The present invention provides a biocatalytic process for preparing a composition comprising a target steviol glycoside by contacting a starting composition comprising a steviol glycoside substrate with UDP-glucosyltransferase, thereby producing a composition comprising a target steviol glycoside comprising one or more additional glucose units than the steviol glycoside substrate." '257 Patent at 1:51-57; see also id. at Abstract, 1:6-8, 4:9-14. The Asserted Patents define "biocatalytic" to mean "the use of natural catalysts, such as protein enzymes, to perform chemical transformations on organic compounds," and disclose that "[b]iocatalyst protein enzymes can be naturally occurring or recombinant proteins." Id. at 4:20-26. The Asserted Patents also disclose that the invention provides "simple, efficient, and economic methods for preparing compositions comprising steviol glycosides, including highly purified steviol glycoside compositions." Id. at 1:44-47. Thus, the specification demonstrates that the invention disclosed in the Asserted Patents is directed to the natural law of converting steviol glycosides to Reb M using UGT enzymes.

When viewed as a whole, Claims 1-5 of the '257 Patent and Claims 1-11 and 14 of the '273 Patent do not recite any additional limitations that would indicate that the claims are directed to more than just the natural law described in the specification either. First, for the claims of the '257 Patent, the "recombinant" UGT enzyme limitations do not make the claims directed to something more than the natural law. Synthetically-created chemical compositions that are structurally and functionally identical to their naturally-occurring counterparts, e.g., genetic clones, are not patent eligible. *See* Athena, 915 F.3d at 752 ("use of a man-made molecule in a method claim employing standard techniques to detect or observe a natural law may still leave the claim directed to a natural law"); Roche, 905 F.3d at 1371-73 (citing In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755, 760-61 (Fed. Cir. 2014)); Roslin, 750 F.3d at 1337. The Asserted Patents disclose that the "recombinant" UGT enzymes may be both structurally and functionally identical to

the naturally occurring UGT enzymes." See id. at 4:20-26. Further, the Court construed the term "recombinant biocatalyst protein enzyme" to mean "[a] protein enzyme made from a gene that has been cloned and introduced into an expression system." Claim Construction Order, Docket No. 143 at 3. Thus, the recited "recombinant" enzymes are no different than the naturally occurring UGT enzymes.

Citing the Federal Circuit's decisions in Illumina and CellzDirect, PureCircle argues that the claims are still eligible because they are methods-of-preparation claims using genetic copies rather than diagnostic method claims using genetic copies or claims to a genetic copy itself. In CellzDirect, the Federal Circuit found that patent eligible claims directed to an "improved process of preserving hepatocytes," that comprised freezing hepatocytes, thawing the hepatocytes, removing the non-viable hepatocytes, and refreezing the viable hepatocytes. 827 F.3d at 1045. In Illumina, the Federal Circuit found that patent eligible claims reciting "a method of preparing a fraction of DNA that includes physical process steps with human-engineered size parameters to selectively remove some maternal DNA in blood to produce a mixture enriched in fetal DNA." 967 F.3d at 1328. In both cases, the claimed method involved at least one step performed by a human that went beyond the natural law itself. By contrast, Claims 1-5 of the '257 Patent recite only a naturally occurring process, the "recombinant" UGT enzymes are necessary for that process, and that the process is the same for both "recombinant" and naturally-occurring UGT enzymes.

To the extent PureCircle argues that method-of-preparation claims are per se eligible, the Court disagrees. The Court does not read the Federal Circuit's decisions to hold that methods-of-preparation are per se eligible. In Alice, the Supreme Court found method claims that recited "an abstract idea while adding the words 'apply it with a computer'" were ineligible. 134 S. Ct. at 2350–51. The court stated that "wholly generic computer implementation is not generally the sort of additional feature that provides any practical assurance that the process is more than a drafting effort designed to monopolize the abstract idea itself." Id. at 2358 (internal quotation marks omitted). Similarly, a method of preparation that recites a natural law and steps to apply it without more would be ineligible, too. Otherwise, any diagnostic claim could be drafted as a method of preparation claim by rephrasing the claim as a method of preparing a sample and then analyzing the sample with a diagnostic test. In each case, the Court must look to the claim as a whole to determine whether the claim is directed to a natural law or something else. Here, despite being method-of-preparation claims, Claims 1-5 of the '257 Patent as a whole are directed to a natural law.

Second, the purity and conversion percentage limitations also do not change that the claims are directed to a natural law. "[T]o avoid ineligibility, a claim must 'ha[ve] the specificity required to transform [the] claim from one claiming only a result to one claiming a way of achieving it.'" Am. Axle & Mfg., Inc. v. Neapco

Holdings LLC, 967 F.3d 1285, 1296 (Fed. Cir. 2020). PureCircle argues that significant amounts of Reb M, the claimed purity percentages of Reb M, and the claimed conversion percentages do not occur in nature. As Defendants argue, however, the claims are broad enough to encompass the conversion of one Reb D compound to one Reb M compound, which would be a 100% conversion rate. Thus, the conversion percentage limitations are also naturally occurring, contrary to Plaintiff's assertion. Further, Claims 3-5 of the '257 Patent and Claims 1-11 and 14 of the '273 Patent do not specify how to achieve a particular purity or conversion percentage; rather, they only recite the resulting percentages. Accordingly, those limitations also do not make the claims directed to more than just the natural law.

PureCircle does not argue that the Asserted Claims recite an inventive concept under step 2 of the Mayo/Alice test. Accordingly, the Court holds that Claims 1-5 of the '257 Patent and Claims 1-11 and 14 of the '273 Patent are patent ineligible as a matter of law.

The Court also finds that Claims 6 and 7 of the '257 Patent and Claims 12 and 13 of the '273 Patent, i.e., the "host microorganism" claims, are directed to patent-eligible methods of preparation. Unlike Claims 1-5 of the '257 Patent and Claims 1-11 and 14 of the '273 Patent, the "host microorganism" claims recite a particular step performed by a human for achieving a particular result, i.e., creating UGT enzymes to convert steviol glycosides to Reb M. Like the steps in the claims in Illumina and CellzDirect, that step takes those claims beyond the natural law itself. Defendants do not dispute that the claimed microorganisms do not naturally produce UGT enzymes. Further, Defendants' argument that the enzymes can be used in any environment to make Reb M does not support ignoring the "host microorganism" limitations in the eligibility analysis.

For the above stated reasons, the Court **GRANTS** Defendants' motion as to Claims 1-5 of the '257 Patent and Claims 1-11 and 14 of the '273 Patent and **DENIES** Defendants' motion as to Claims 6 and 7 of the '257 Patent and Claims 12 and 13 of the '273 Patent.

2. The Written Description Requirement Under 35 U.S.C. § 112

To satisfy the written description requirement, "the description 'must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" Ariad, 598 F.3d at 1351 (quoting In re Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). "In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." Id. (quoting Ralston Purina Co. v. Far–Mar–Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985)). This "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." Id. To meet this requirement, "[a]n applicant is not required to describe in the specification every

conceivable and possible future embodiment of his invention." Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1365 (Fed. Cir. 2003) (quoting Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed. Cir. 2001)). Thus, "[a] specification may, within the meaning of 35 U.S.C. § [112(a)], contain a written description of a broadly claimed invention without describing all species that [the] claim encompasses." Id. (quoting Utter v. Hiraga, 845 F.2d 993, 998 (Fed. Cir. 1988)). Further, "[a] patent need not teach, and preferably omits, what is well known in the art." Epistar Corp. v. Int'l Trade Comm'n, 566 F.3d 1321, 1336 (Fed. Cir. 2009) (quoting Spectra–Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534 (Fed. Cir. 1987)).

Compliance with the written description requirement of 35 U.S.C. § 112 is a question of fact. Ariad, 598 F.3d at 1355. A patent also can be held invalid for failure to meet the written description requirement based solely on the face of the patent specification. Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927 (Fed. Cir. 2004).

Defendants assert that the term "UDP-glucosyltransferase" as used in the Asserted Claims lacks written description support because it is a broad, functionally-defined genus limitation. Defs. Mot. at 18-26. According to Defendants, the term "UDP-glucosyltransferase" is defined by its function: "the ability to transfer a glucose unit." Id. at 19. Defendants argue that under that definition, the term "covers not just naturally occurring UDP-glucosyltransferases, but 'any' UDP-glucosyltransferase mutant, fusion, and UDP-glucosyltransferase known or discovered *after* the patents' May 22, 2012 filing date." Id. (emphasis in original) (citing Defs. SUF ¶¶ 94-102). Defendants estimate that may include "1.1×10^{12} candidates (one thousand billion)," which is effectively "a 'limitless number' of compounds." Id. at 20 (quoting Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1337 (Fed. Cir. 2021)). Defendants assert that although Claims 2, 3, and 14 of the '273 Patent limit the term "UDP-glucosyltransferase," Claims 2 and 3 only limit the term functionally and Claim 14 uses the phrase "comprises," meaning the term still encompasses an unreasonable number of enzymes. See id.

Defendants also argue that the specification does not describe a representative number of species or identify any common structural features for UGT enzymes. Id. at 21. Instead, as Defendants argue, the specification only discloses one example: "the conversion of Reb D to Reb M using *in-vitro*-produced wild type UGT76G1." Id. at 21-22 (citing Defs. SUF ¶¶ 48, 49, 83). Further, according to Defendants, the other examples of UGT enzymes in the specification show that "sequence similarity" and "enzymatic activity" are not correlated. Id. at 22 (citing Defs. SUF ¶¶ 110, 111). Moreover, Defendants aver that PureCircle's expert, Dr. Martin Bollinger, concedes that "no experimentally determined structure of a [UGT enzyme] was known in 2012," and further research would have been necessary to discover additional candidates. See id. at 23-25 (citing Defs. SUF ¶¶ 66-70, 74, 75, 80, 82, 112-115).

Finally, Defendants argue, "As of the May 22, 2012 filing date, only 12 [UGT enzymes] had been identified and only four had been proven capable of adding glucose to steviol glycosides." Id. at 25 (citing Defs. SUF ¶¶ 71, 81). Thus, Defendants argue that the Asserted Patents provide no written description support for other UGT enzymes, such as those used to convert Rebaudioside D4 ("Reb D4") to Reb M in Defendants' manufacturing process. See id. at 23 (citing Defs. SUF ¶¶ 91-93).

PureCircle responds that the Asserted Claims have adequate written description support under the Original Claims doctrine. See PureCircle Opp'n at 14-20. According to PureCircle, the Original Claims doctrine states that claims filed in an original patent application can serve as written description support for the limitations found in those claims, with the exception of "claims to a functionally defined genus." See id. at 13-14 (citing Crown Packaging Tech. v. Ball Metal Beverage, 635 F.3d 1373, 1380 (Fed. Cir. 2011); Mentor Graphics Corp. v. EVE-USA, Inc., 851 F.3d 1275, 1297 (Fed. Cir. 2017); In re Koller, 613 F.2d 819, 823 (CCPA 1980)). As PureCircle emphasizes, Defendants does not dispute that the limitations in the Asserted Claims are found in the original claims. See id. at 15 (citing PureCircle SUF, Docket No. 219-1 (sealed) ¶¶ 3, 4).

PureCircle also argues that the term "UDP-glucosyltransferase" is structurally, not functionally, defined, as there are other enzymes that perform the same function as UGT enzymes, i.e., add glucose units to steviol glycosides, but are not UGT enzymes. See id. at 15-16 (citing PureCircle SUF ¶ 5-9)). PureCircle asserts that Dr. Gervay-Hague, Defendants' expert, testified that the term is structural. Id. at 16 (citing PureCircle SUF ¶¶ 11, 12). PureCircle further avers the Court's construction of the term "UDP-glucosyltransferase" limits the term to particular kinds of UGT enzymes, not that all UGT enzymes perform the same function. See id. at 17-18. Thus, Plaintiff argues that the Court should deny Defendants' motion as to their written description defense and grant summary judgment in its favor. See id. at 13, 16.

Further, PureCircle argues that there are material disputes of fact with regard to many of Defendants' assertions. First, PureCircle asserts, "mutants are not an unlimited structural class: after all, the reason they are called 'mutants' is that they are minor adjustments based on the original on the original wild-type enzymes, homology modelling can show which mutants will be most active, and the vast majority of mutants were shown to be active." Id. at 18-19 (internal citations omitted) (citing PureCircle SUF ¶¶ 15-17; Defs. SUF ¶ 73). Second, PureCircle argues, "the structure of [UGT enzymes] capable of adding glucose units had been determined by modelling based upon the known crystal structures of several [UGT enzymes]." Id. at 20 (citing PureCircle SUF ¶¶ 18-20). Third, PureCircle argues that the Asserted Patents did not need to specifically describe the enzymes used to convert Reb D4 to Reb M because the term "UDP-glucosyltransferase" is structural, and, at a

minimum, there are factual disputes whether the Asserted Patents provided written description support for that enzyme. See id. at 21-23.

Defendants reply that there is no dispute that the Asserted Patents do not provide written description support for "every 'enzyme that is capable of transferring a glucose unit from a [UDP] molecule to a steviol glycoside molecule' as required by the Court's construction of 'UDP-glucosyltransferase[.]'" Defs. Reply at 11. Thus, Defendants assert that the Asserted Claims are invalid because they satisfy the "functionally defined genus" exception to the Original Claims doctrine. See id. at 11-15. Specifically, Defendants assert that the Court's construction of the term "UDP-glucosyltransferase" still limits the scope of the term based on the function of certain UGT enzymes. See id. at 13. Defendants also argue that whether a term is structurally or functionally defined does not turn on whether the term has some structural elements, as even functionally-defined terms may find written description support if the specification discloses "structural features common to the members of the genus." See id. 13-14 (quoting AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1299, 1301 (Fed. Cir. 2014)). Defendants assert that the specification fails to disclose those common structural features or sufficient representative examples, and thus the Court must find the Asserted Claims invalid. See id. at 15-16.

Defendants also ague that PureCircle presents several mischaracterizations of the facts in its opposition brief. Specifically, Defendants argue that its expert never testified that the term "UDP-glucosyltransferase" was structural, and that the structure of "UDP-glycosyltransferase" enzymes, not UGT enzymes, was known in 2012. See id. at 17. Additionally, Defendants argue that determining what mutant UGT enzymes would satisfy the claims still requires extensive experimentation, and thus the scope of the term "UDP-glucosyltransferase" still encompasses a nearly limitless amount of UGT enzymes. See id. at 19-20.

The parties' dispute largely turns on whether the term "UDP-glucosyltransferase" is a structurally or functionally defined genus. Based on the parties' stipulation, the Court construed the term "UDP-glucosyltransferase" to mean "[a] type of enzyme that is capable of transferring a glucose unit from a uridine diphosphate glucose molecule to a steviol glycoside molecule." Claim Construction Order at 2-3. That is a functional definition. Even accepting PureCircle's argument that there are UGT enzymes that do not perform this function, those UGT enzymes are not at issue given the parties' construction. Thus, the Court is only concerned with enzymes that "transfer[] a glucose unit from a uridine diphosphate glucose molecule to a steviol glycoside molecule." Further, even functionally defined terms may have common structural features, as that is one of the ways of showing the functionally defined term has written description support. Because the term is functionally defined, the exception to the Original Claim doctrine applies, and the Court must determine whether the term has adequate written description support in

the specification.

For functionally defined genus limitations, "the written description 'must demonstrate that the applicant has made a generic invention that achieves the claimed result and do[es] so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.'" Juno, 10 F.4th at 1335 (quoting Ariad, 598 F.3d at 1349). "Generally, a genus can be sufficiently disclosed by 'either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus.'" Id. (quoting Ariad, 598 F.3d at 1350). Factors used to evaluate the adequacy of the disclosure include "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." Id. (quoting Ariad, 598 F.3d at 1351). "One factor in considering [whether the specification sufficiently describes a representative number of species] is how large a genus is involved and what species of the genus are described in the patent." AbbVie, 759 F.3d at 1299.

There is no genuine dispute that the specification does not disclose structural features common to all UGT enzymes that "transfer[] a glucose unit from a uridine diphosphate glucose molecule to a steviol glycoside molecule." The Asserted Patents disclose, "On [sic] of skill in the art will recognize that the particular UDP-glucosyltransferase used in each reaction can either be the same or different, depending on the particular site on the steviol glycoside substrate where glucose is to be added." '257 Patent at 14:52-57. The Asserted Patents also disclose at most four examples of a UGT enzyme: UGT76G1, UGT91D2, UGT91D2e, and UGT91D11. See, e.g., id. at 10:1-8, 11:11-26, 12:18-31, 13:13-26. The specification discloses using UGT76G1 and UGT91D2 enzymes to convert steviol glycosides. See, e.g., id. Additionally, the specification provides a "nucleic sequence" for both the UGT76G1 and UGT91D2 enzyme examples, as well as methods for producing each. See id. at 20:51-23:33. The specification otherwise fails to provide structural features related to the claimed UGT enzymes.

As PureCircle emphasizes, the patent office previously rejected Defendants written description argument, finding that "a person of ordinary skill in the art could envision the ... UDP-glycosyltransferases encompassed by the claims because they have common structural feature." Docket No. 211-3 at 32. Specifically, the patent office found that the Asserted Patents "provide the DNA sequences for the UGT76G1 and UGT91D2 UDP-glycosyltransferase enzymes which could be used in the process of creating Reb X from a steviol glycoside substrate," and "working examples that show how to make the UDP-glucosyltransferase enzymes UGT761 and UGT91D2." Id.

PureCircle does not dispute that the patent office's findings are not binding on

this Court, however. See Noelle v. Lederman, 355 F.3d 1343, 1350 (Fed. Cir. 2004) ("[A] decision from the [patent office]… may be persuasive but it is not binding precedent on this court."). As the parties agree, "[a]n enzyme's amino acid sequence does not necessarily predict the enzyme's activity (or functionality) and, therefore, testing is always required to determine the enzyme's activity (or functionality)." Defs. SUF ¶ 68; PureCircle SGD ¶ 68. Following, two enzymes with the similar sequences can have different functions and two enzymes with very different sequences can have the same function. See Defs. SUF ¶¶ 69, 70, 110, 111; PureCircle SGD ¶¶ 69, 70, 110, 111. Thus, there is no genuine dispute that the DNA sequences of UGT76G1 and UGT91D2 are not common structural features of the entire class of UDP-glucosyltransferases. Further, the examples of how to produce the UGT76G1 and UGT91D2 enzymes do not show structural features common to all UGT enzymes either.

PureCircle cites to several examples of structural characteristics that are allegedly common to the claimed "UDP-glucosyltransferase" genus. See PureCircle Opp'n at 20. For example, PureCircle contends, "crystal structures of many UDP-glucosyltransferases had been determined in the prior art," and well-known homology modelling could be used to identify additional, functional UGT enzymes based on that crystal structure. Id. (citing PureCircle SUF ¶¶ 18-20). None of those structural characteristics are described in the specification, however.

Further, PureCircle's evidence shows that as of 2012, there were no known structural features common to the claimed UGT enzymes. Dr. Bollinger concedes that "no experimentally determined structure of UDP-glucosyltransferase was known in 2012[.]" Bollinger Rebuttal Rpt., Docket No. 179-10 ¶ 290. Dr. Bollinger opines that UGT enzymes "have an identifying signature amino-acid sequence," but also opines that sequence "is not precisely identical in all UDP-glucosyltransferases, including in UGT76G1[.]" Id. ¶¶ 283, 284. Additionally, although Dr. Bollinger opines that the "signature" sequence was used to identify 12 UGT enzymes as of 2012 and those UGT enzymes have common structural features, he also opines that only five of those UGT enzymes "have been shown to be functional." Id. ¶¶ 285, 286. Thus, a person of ordinary skill in the art could not use the sequence or the structural features to identify the claimed, functionally-defined genus of UGT enzymes.[3] Finally, contrary to PureCircle's assertion that the structure of UGT enzymes had been modeled using "homology modelling" in 2009, the evidence shows that "homology modelling" was only used to model the genus "UDP-glycosyltransferases," not the subgenus "UDP-glucosyltransferases." See id. ¶¶ 42-

[3] Generally, an inventor cannot show possession of a subgenus by way of disclosing structural characteristics common to the broader genus alone. For instance, although all enzymes generally have common structural features, those features would not show that the inventor had possession of all UGT enzymes. Rather, the structural features have to be characteristic of the subgenus.

46.[4]

For the first time at the hearing on Defendants' motion, PureCircle asserted that this case in analogous to *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629 (E.D. Tex. 2017), *aff'd*, 739 F. App'x 643 (Fed. Cir. 2018).[5] There, the district court held that the patentee presented sufficient evidence to support a jury's verdict that a functional genus term, "PDE5 inhibitors," was not invalid for lack of written description support. See id. at 643-659. The court found that the patentee provided evidence that the patent-in-suit described both a sufficient number of representative species within the scope of that genus and structural features common to the members of the genus. See id. Regarding the common structural features, the court pointed to unrebutted evidence produced by the patentee that "all PDE5 inhibitors share a common 'physical' structure." Id. at 653. By contrast, PureCircle has not produced any evidence that shows that there was a physical structure common to all UGT enzymes that was known in 2012.

There is also no genuine dispute that the examples of UGT enzymes disclosed in the Asserted Patents are not representative of the entire genus. The Federal Circuit's decision in Juno is instructive. There, the Federal Circuit found that the specification's disclosure of "two example scFvs for binding two different targets" were not representative of the entire genus of scFvs that could bind to any target, where the only detail about each scFv species disclosed was their "alphanumeric designations." 10 F.4th at 1336-37. The court found, "To satisfy the written description requirement, the patent needed to demonstrate to a skilled artisan that the inventors possessed and disclosed in their filing the particular species of scFvs that would bind to a representative number of targets." Id. In rejecting expert testimony that the examples were representative because all scFvs bind to antigens, the court stated, "Nothing about that testimony explains which scFvs will bind to which target or cures the [patent's] deficient disclosure on this score." Id. at 1337.

Similarly, the Asserted Patents only disclose two working examples of UGT enzymes. PureCircle does not argue that those examples are representative of all the

[4] Dr. Bollinger references an international patent application in his report that discloses a potential "conserved pattern of secondary structure" in UGT enzymes. See Bollinger Rebuttal Rpt. ¶ 304. PureCircle does not provide the underlying reference or full application number for the Court to review the date of the application or the context of the disclosure in the application. It is not clear whether that disclosure relates to "UDP-glycosyltransferases" or "UDP-glucosyltransferases." Further, the application discloses that "the secondary structure appears to be conserved," suggesting that it was not proven at the time of the application whether the secondary structure was actually conserved. Without more, Dr. Bollinger's discussion of that application is insufficient to create a triable issue of fact.

[5] PureCircle only raised this case in its opposition brief in response to Defendants' enablement arguments, not their written description arguments.

possible UGT enzymes that "transfer[] a glucose unit from a uridine diphosphate glucose molecule to a steviol glycoside molecule." Dr. Bollinger effectively admits that the working example for UGT76G1 may not be representative of the UGT76G1 subclass. See Defs. SUF ¶ 88; PureCircle SGD ¶ 88. The parties agree that "there were only 5 UDP-glucosyltransferases at the time of filing that were known to be capable of transferring a glucose unit." PureCircle Opp'n at 18; see Defs. SUF ¶ 71; PureCircle SUF ¶ 14. PureCircle also does not dispute that there were an almost limitless number of mutations even for the five known UGT enzymes, but argues that there were known ways to discover which mutations are "active," such as through homology modelling. PureCircle Opp'n at 18-19. As Defendants argue, however, "A specification that necessitates such 'further research' is insufficient because it evinces a lack of possession." Defs. Reply at 19 (citing Ariad, 598 F.3d at 1353, 1356).

Finally, the court in Juno suggested that disclosing nucleotide or amino acid sequences for a claimed genus could satisfy the written description requirement if the nucleotide sequence was representative of the genus. 10 F.4th at 1337. As stated above, however, there is no genuine dispute that the nucleotide sequences of the UGT76G1 and UGT91D2 enzymes are not representative of the entire UGT enzyme genus.

Accordingly, the Court **GRANTS** Defendants' motion as to their written description defense and **DENIES** PureCircle's request for summary judgment in its favor on Defendants' written description defense.

3. The Enablement Requirement Under 35 U.S.C. § 112

Because the Court grants Defendants' motion as to their written description defense, the Court **DENIES-AS-MOOT** Defendants' motion as to their enablement defense.

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** PureCircle's motion and **GRANTS-IN-PART** and **DENIES-IN-PART** Defendants' motion.

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. Defendants shall file a proposed judgment for this case within 14 days of the issuance of the final order.

IT IS SO ORDERED.

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