NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

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**PURECIRCLE USA INC., PURECIRCLE SDN BHD,**
*Plaintiffs-Appellants*

**v.**

**SWEEGEN, INC., PHYTO TECH CORP., DBA BLUE CALIFORNIA,**
*Defendants-Appellees*

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2022-1946

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Appeal from the United States District Court for the Central District of California in No. 8:18-cv-01679-JVS-JDE, Judge James V. Selna.

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Decided: January 2, 2024

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STANLEY JOSEPH PANIKOWSKI, III, DLA Piper US LLP, San Diego, CA, argued for plaintiffs-appellants. Also represented by RICHARD T. MULLOY; STUART ERIC POLLACK, Kilpatrick Townsend & Stockton LLP, New York, NY.

JOHN CHRISTOPHER ROZENDAAL, Sterne Kessler Goldstein & Fox PLLC, Washington, DC, argued for defendants-appellees. Also represented by MICHAEL E. JOFFRE,

ANNA G. PHILLIPS, SASHA RAO, DENNIES VARUGHESE, DEIRDRE M. WELLS.

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Before DYK, SCHALL, and STARK, *Circuit Judges*.

DYK, *Circuit Judge*.

PureCircle USA Inc. and PureCircle Sdn Bhd (collectively, "PureCircle"), the owners of U.S. Patent Nos. 9,243,273 ("'273 patent") and 10,485,257 ("'257 patent"), brought suit for infringement against defendants SweeGen, Inc. and Phyto Tech Corp. d/b/a Blue California (collectively, "SweeGen"). The District Court for the Central District of California granted summary judgment to defendants, concluding that all claims of the asserted patents were invalid due to a lack of written description, and that claims 1–11 and 14 of the '273 patent and claims 1–5 of the '257 patent were unpatentable under 35 U.S.C. § 101. We conclude that claims 1–13 of the '273 patent and all claims of the '257 patent are invalid for lack of written description, and we also conclude that claim 14 of the '273 patent is unpatentable under § 101. We *affirm*.

## BACKGROUND

Steviol glycosides are naturally occurring compounds found in stevia plants that can be used as non-caloric sweeteners. One particular steviol glycoside, known as Rebaudioside X ("Reb X") or Rebaudioside M ("Reb M"), was identified in trace amounts in stevia plants. Because only small amounts of Reb X naturally occur in stevia plants, it would be expensive and inefficient to extract Reb X from the plants. PureCircle's two patents at issue in this case, U.S. Patent Nos. 9,243,273 and 10,485,257, claim a method of producing Reb X using enzymes called UDP-glucosyltransferases ("UGTs"), the same enzymes used in plants to synthesize the compound. Claims 1 and 14 of the '273 patent are representative, and provide:

> 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.
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> 14. The method of claim 1, wherein the UDP-glucosyltransferase comprises UGT76G1.

PureCircle filed suit in district court against defendants alleging infringement of the '273 and '257 patents. The parties stipulated to the claim construction of UGTs as "[a] type of enzyme that is capable of transferring a glucose unit from a uridine diphosphate glucose molecule to a steviol glycoside molecule." J.A. 5159–60. The district court held that based on the parties' stipulation, the term was functionally defined. SweeGen moved for summary judgment of invalidity for lack of written description under 35 U.S.C. § 112 and subject matter ineligibility under 35 U.S.C. § 101. The district court partially granted SweeGen's motion, finding all claims of the '273 and '257 patents invalid due to a lack of written description and claims 1–11 and 14 of the '273 patent and claims 1–5 of the '257 patent unpatentable under § 101. PureCircle appeals.

We have jurisdiction under 28 U.S.C. § 1295(a)(1).

## DISCUSSION

We review the grant of summary judgment de novo. *E.g., Monzon v. City of Murrieta*, 978 F.3d 1150, 1155 (9th Cir. 2020). "A grant of summary judgment is 'proper only where there is no genuine issue of any material fact or where viewing the evidence and the inferences which may be drawn therefrom in the light most favorable to the adverse party, the movant is clearly entitled to prevail as a matter of law.'" *Clarkson v. Alaska Airlines, Inc.*, 59 F.4th 424, 432 (9th Cir. 2023) (quoting *Sandvik v. Alaska Packers Ass'n*, 609 F.2d 969, 974 (9th Cir. 1979)).

## I

Section 112 requires that a patent's "specification shall contain a written description of the invention." 35 U.S.C. § 112(a). To satisfy the written description requirement, the specification must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (alteration in original) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)). That is it must "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* "What is required to meet the written description requirement 'varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.'" *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1335 (Fed. Cir. 2021) (quoting *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005)). For genus claims the specification must "provide sufficient 'blaze marks' to guide a reader through the forest of disclosed possibilities toward the claimed compound." *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1346 (Fed. Cir. 2013) (quoting *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967)).

In the context of a genus claim, written description "requires the disclosure of 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." *Ariad*, 598 F.3d at 1350 (quoting *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568–69 (Fed. Cir. 1997)). The claims of the '273 and '257 patents are properly construed as genus claims using functional language, as the district court concluded. The patents claim a genus of UGT enzymes, and PureCircle and SweeGen stipulated to a construction of UGTs that defines the enzyme by what it does, i.e., its function – transferring

a glucose unit from a uridine diphosphate glucose molecule to a steviol glycoside molecule.

SweeGen argues that the '273 and '257 patents are invalid because they do not disclose a representative number of species nor common structural features of the claimed UGT genus to identify which enzymes would function to convert Reb D to Reb X at a 50% completion level or higher.[1] SweeGen contends that the claim language covers at least one trillion enzymes that could potentially perform that function.[2] SweeGen's expert reached this number by assuming UGT enzymes consisted of 100 amino acids, there were 733 known UGT sequences as of 2012, five amino acids could be substituted to make mutations, and each substitution could consist of 19 different amino acids. SweeGen further argues that while the genus claimed is enormous, only one enzyme (UGT76G1) was given as a representative species. There is no dispute that the common specification of the '273 and '257 patents identifies only one UGT that it says can make Reb X. Because only one enzyme of the potentially vast class of UGTs is disclosed, SweeGen argues, the patent does not disclose a representative number of species. SweeGen also argues that there was no known common structure of UGTs as of the patent's priority date.

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[1] Claim 11 recites "[t]he method of claim 1, wherein the conversion is at least about 95% complete." '273 patent, col. 36, ll. 9–10.

[2] SweeGen contends this is an underestimate because the claims also cover fusion enzymes. Fusion enzymes are two or more individual enzyme segments linked together to form a single enzyme. In this case, the parties dispute whether any enzyme fused with UGT76G1 would count as separate enzymes for purposes of written description. For the purposes of this opinion, we assume they are not.

PureCircle contends that the potential trillions of enzymes claimed by SweeGen can drastically be reduced. There were only five known enzymes that had been shown to be capable of steviol glycoside synthesis, i.e., enzymes that come within the scope of the claims.[3] While each of these enzymes would have a large number of mutations, PureCircle argues that the mutations capable of the required synthesis can be determined with reasonable certainty through homology modeling. Homology modeling consists of entering the amino acid sequence of an enzyme into the modeling program, then (based on the amino acid sequence) the computer predicts how the enzyme will fold, ultimately producing a 3-D model of the enzyme. Looking at the model of a working enzyme, PureCircle argues, a person of ordinary skill in the art (POSA) could find the active site where that enzyme converts Reb D to Reb X, and then compare the structure of that active site to the structure of mutant enzymes. If the structure of the active sites is the same, then the mutant enzyme is likely capable of the conversion of Reb D into Reb X.

Using such modeling, PureCircle provided evidence that there were only 1,800 possible mutations for each of the five known enzymes, or a total of 9,000 possible UGTs. While these mutants would have to be tested to ascertain

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[3] A total of twelve enzymes were known to belong to the family named UGTs. Only one of the five enzymes, UGT76G1, was known to produce Reb X. While the patent cites one other UGT enzyme, UGT91D2, and contains a nucleic acid sequence of that enzyme, the patents do not indicate that UGT91D2 can convert Reb D to Reb X. *See* J.A. 92-93 at col. 2, l. 66–col. 3, l. 3. By contrast, the patents explicitly state that UGT76G1 is a UGT "capable of adding at least one glucose unit to rebaudioside D to form rebaudioside X." *See* J.A. 93 at col. 3, ll.4–6.

if they could actually convert Reb D to Reb X, PureCircle argues that such testing was routine.

II

PureCircle argues that disclosure of a single enzyme can satisfy the written description requirement, and that under our cases, disclosure of a single compound (here, a single enzyme) may be representative of the genus. *See, e.g.*, *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1073 (Fed. Cir. 2005); *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1124 (Fed. Cir. 2004) ("[T]his court has continued to apply the rule that disclosure of a species may be sufficient written description support for a later claimed genus including that species."). While a single example can provide written description support for a genus, that is not the case unless the specification provides the required "blaze marks."[4]

PureCircle contends that the single disclosed enzyme here is representative of the genus because the structure of its active site was common to all claimed UGTs. In other words, PureCircle contends that the compound here (the UGT76G1 enzyme) discloses common structural features sufficient to define the genus.

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[4] *See, e.g.*, *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1346 ("Thus, a patentee cannot always satisfy the requirements of section 112, in supporting expansive claim language, merely by clearly describing one embodiment of the thing claimed."); *Juno*, 10 F.4th at 1337 ("The disclosure of one scFv that binds to CD19 and one scFv that binds to a PSMA antigen on prostate cancer cells in the manner provided in this patent does not provide information sufficient to establish that a skilled artisan would understand how to identify the species of scFvs capable of binding to the limitless number of targets as the claims require.").

Construing the evidence in the light most favorable to PureCircle, it is clear that any structural features common to the members of the genus were not sufficiently disclosed so as to allow one of skill in the art to visualize or recognize the members of the genus. First, there is no mention in the claims or specification of homology modeling for determining common structure. PureCircle argues that homology modeling does not need to be disclosed because it was already a known technique to a POSA.[5] Even if homology modeling did not need to be disclosed in the specification, even for the five known enzymes, extensive trial and error testing *after* homology modeling (which by PureCircle's admission would result in 9,000 compounds) would be required to identify potential active candidates. In general the need for extensive trial and error testing argues against a finding of adequate written description. Our decision in *Novozymes* is instructive. There, the patentee argued that "one of ordinary skill in the art . . . would have known how to test every possible variant at that position and thus would have found the claimed variants as a matter of course." 723 F.3d at 1350. We explained that "[t]he question before us is not whether one of ordinary skill in the art presented with the [relevant] application would have been enabled to take those final steps, but whether the [relevant] application 'discloses the [variants] to him, specifically, as something appellants actually invented.'" *Id.* (second alteration in original) (quoting *Ruschig*, 379 F.2d at 995).[6]

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[5] *Compare Capon*, 418 F.3d at 1358 ("When the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh.") (emphasis in original).

[6] S*ee also In re Alonso*, 545 F.3d 1015, 1020 (Fed. Cir. 2008) ("[I]t is not enough to describe[] the procedure for

Second, there are potentially additional unknown enzymes that could achieve the conversion to produce Reb X, as PureCircle admits.[7] These additional enzymes would not necessarily share common structure with UGT76G1. The specification contains the amino acid sequence of UGT76G1, but it does not identify which part of the amino acid sequence is necessary for the conversion function of the enzyme. PureCircle repeatedly points to testimony by its expert, Dr. Bollinger, that UGTs "all had common structural features," J.A. 5570 ¶ 286, though inconsistently stating that "no experimentally determined structure of a UDP-glucosyltransferase was known in 2012." J.A. 5571 ¶ 290. However, Dr. Bollinger did not relate any common structure to the function of the enzyme, other than to mention homology modeling. If other enzymes do exist, PureCircle admits that homology modeling cannot be used to

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making a human-human hybridoma from neurofibrosarcoma, and teach how to determine whether a given antibody, specific to a patient's neurofibrosarcoma, will function in the claimed method."); *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 925 (Fed. Cir. 2004) ("[O]ne of skill in the art would [not], from reading the patent, understand what compound or compounds—which, as the patent makes clear, are necessary to practice the claimed method—would be suitable, nor would one know how to find such a compound except through trial and error." (citation omitted)).

[7] THE COURT: "And then, there is the possibility that in the future that additional enzymes would be identified which achieve the conversion and the claims would cover those new enzymes as well, right?"

COUNSEL FOR PURECIRCLE: "Correct your Honor."

Oral Argument at 1:17–1:31.

identify those unknown enzymes.[8] Homology modeling alone cannot determine what structural features are common to enzymes capable of producing Reb X. It can only create 3-D structures of enzymes with known amino acid sequences which can be used by a POSA to determine common structures of mutants of a known enzyme, not the structures of other enzymes.

As to other enzymes that could perform the function, PureCircle offered no evidence as to whether it was likely or unlikely that those additional enzymes exist or what their structure might be. In our prior cases where there has been a large genus, encompassing both known and unknown compounds, we have held that in order for the disclosed species to be representative of the genus, it has to provide blaze marks that would allow a POSA to identify other members of the genus. No such blaze marks are present here.

In *Juno*, the patent claimed a large genus of "*any* scFv for binding *any* target." *Juno*, 10 F.4th at 1336. We explained that "[t]o satisfy written description, however, the inventors needed to convey that they possessed the claimed invention, which encompasses all scFvs, known and unknown, as part of the claimed [chimeric antigen receptor] CAR that bind to a selected target." *Id.* at 1338. We held written description was not satisfied because "the specification provides no means of distinguishing which scFvs will bind to which targets," *id.*, and the patent "contains no details about these scFv species beyond the alphanumeric

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[8] THE COURT: "But as I understand it, homology modeling would not help you identify other enzymes, not mutations, but other enzymes besides the four or five that perform the conversion, correct?"

COUNSEL FOR PURECIRCLE: "Correct your Honor."

Oral Argument at 15:26–15:41.

designations J591 and SJ25C1 for a skilled artisan to determine how or whether they are representative of the entire claimed genus," *id.* at 1336. Apart from the one specific example, here, as in *Ariad*, 598 F.3d at 1353, "[s]uch claims merely recite a description of the problem to be solved while claiming all solutions to it and . . . cover any compound later actually invented and determined to fall within the claim's functional boundaries—leaving it to the pharmaceutical industry to complete an unfinished invention."

In short, the one enzyme disclosed in the patents here has not been shown to be typical of the entire genus of UGTs claimed.[9] Under such circumstances, there is no adequate written description. In *AbbVie*, we found a lack of written description because "AbbVie's patents only describe one type of structurally similar antibodies and [] those antibodies are not representative of the full variety or scope of the genus." *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014). Likewise, in *Idenix*, we held that because the patents provided "lists or examples of supposedly effective nucleosides, but d[id] not explain what makes them effective, or why . . . a POSA is deprived of any meaningful guidance into what compounds beyond the examples and formulas, if any, would provide the same result." *Idenix Pharms.*

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[9] PureCircle points to a decision by the United States Patent and Trademark Office ("PTO") denying post-grant review because it found that it was more likely than not that written description was satisfied. A decision from the PTO "may be persuasive but it is not binding precedent on this court." *Noelle v. Lederman*, 355 F.3d 1343, 1350 (Fed. Cir. 2004). Here, the PTO misunderstood the limits of homology modeling and did not take into account that unknown enzymes could convert Reb D to Reb X.

*LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1164 (Fed. Cir. 2019).[10]

PureCircle finally contends that the original claims doctrine provides sufficient written description support. However, the claims of the original application—Application No. PCT/US2013/030439—do not help PureCircle because they do not provide any additional information about common structural features or representative species of the genus. "If a purported description of an invention does

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[10] PureCircle relies on *Ajinomoto Co. v. Int'l Trade Comm'n*, 932 F.3d 1342, 1360 (Fed. Cir. 2019) for the proposition that the knowledge of a POSA should be taken into account. *Ajinomoto* is inapposite. In *Ajinomoto*, the patent claimed a "more potent promoter" but disclosed four examples of promoters and cited an article that "provide[d] data about the relative strength of fourteen promoters and describe[d] a general methodology for determining promoter strength." 932 F.3d at 1347, 1359. Further, there was a "well-known link between consensus sequence and promoter strength" as "promoters having fewer departures from a 'consensus sequence' in a promoter are generally stronger" and "the genus of more potent promoters was already well explored in the relevant art." *Id.* at 1359–60. Even though there was some evidence that "deviations from [the consensus] sequence d[id] not *always* decrease promoter strength," this Court held that "[a]dequate written description does not require a perfect correspondence between the members of the genus and the asserted common structural feature." *Id.* at 1360. Thus, *Ajinomoto* stands for the idea that where there are structural features common to a genus, the structure-function correlation does not need to be perfect and some testing—appropriate to the knowledge of a POSA—is allowed, not that an unknown structure-function correlation along with extensive testing can satisfy written description.

not meet the requirements of the statute, the fact that it appears as an original claim or in the specification does not save it. A claim does not become more descriptive by its repetition, or its longevity." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968–69 (Fed. Cir. 2002). Thus, the original claims doctrine does not provide adequate written description support.

Under these circumstances, we hold that claims 1-13 of the '273 patent and claims 1-7 of the '257 patent are invalid for lack of written description.

III

PureCircle contends that even if the other claims lack written description support, claim 14 of the '273 patent satisfies the written description requirement because, unlike the other claims, it names a specific enzyme, UGT76G1. Thus, PureCircle argues, through homology modeling only 1,800 possible mutations would be covered and testing that small group of enzymes for functionality does not run afoul of the written description requirement. We need not decide that issue, because we conclude that, as the district court held, claim 14 is unpatentable under § 101.

Section 101 of Title 35 provides that "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" is patent-eligible subject matter. 35 U.S.C. § 101. However, the Supreme Court has recognized an important exception, and "[l]aws of nature, natural phenomena, and abstract ideas are not patentable." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013) (quoting *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 70 (2012)).

The proper § 101 analysis was described by the Supreme Court in *Alice* and *Mayo*. At step one of the *Alice*/*Mayo* test, we determine whether the claims are directed to a law of nature, natural phenomenon, or an

abstract idea. *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014) (citing *Mayo*, 566 U.S. at 77). If the claims are so directed, we then at step two determine if the claims embody an "inventive concept," meaning "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.'" *Id.* at 217–18 (alteration in original) (quoting *Mayo*, 566 U.S. at 72–73).

To the extent that claim 14 claims a "method for making Rebaudioside X comprising a step of converting Rebaudioside D to Rebaudioside X using a UDP-glucosyltransferase," it claims a natural phenomenon. The enzyme in claim 14, UGT76G1, is naturally found in stevia plants and naturally converts Reb D to Reb X. If that were the extent of claim 14, it would clearly claim an unpatentable natural phenomenon. As the district court noted "there is no dispute that the conversion of steviol glycosides and Reb D to Reb [X] using UGT enzymes is a natural process." J.A. 10.

PureCircle argues that the outcome should be different because in nature only small amounts of Reb X are produced, whereas claim 1 (from which claim 14 depends) provides "conversion of Rebaudioside D to Rebaudioside X is at least about 50% complete." '273 patent, col. 35, ll. 4–5. PureCircle contends that because the conversion of Reb D to Reb X would never reach 50% completion in nature, claim 14 is not directed to a natural phenomenon. The problem with PureCircle's argument is that the 50% completion is itself an abstract idea.

To be eligible under § 101, an invention must have the "specificity required to transform a claim from one claiming only a result to one claiming a way of achieving it." *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1167 (Fed Cir. 2018). "[I]n the context of claims to results, we have explained that claims that 'simply demand[] the production of a desired result . . . without any limitation on how to

produce that result' are directed to an abstract idea." *In re Killian*, 45 F.4th 1373, 1382 (Fed. Cir. 2022) (quoting *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1345 (Fed. Cir. 2018)); *see also Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1292 (Fed. Cir. 2020) ("[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.'"). As the district court explained, claim 14 of the '273 patent "d[id] not specify how to achieve a particular purity or conversion percentage; rather, [it] only recite[s] the resulting percentages." J.A. 12. Claim 14 simply states a result, conversion of Reb D to Reb X wherein the conversion is at least about 50% complete. The claim does not provide any steps or give guidance as to how to achieve a 50% conversion other than the direction to use a natural enzyme. Claim 14 is directed to subject matter that is a natural phenomenon or abstract idea at step 1 of *Alice*/*Mayo*. [11]

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[11] PureCircle points to *Natural Alternatives*, where the patent claimed a "method of increasing anaerobic working capacity in a human subject" through "elevat[ing] beta-alanine above natural levels to cause an increase in the synthesis of beta-alanylhistidine dipeptide in the tissue." 918 F.3d 1338, 1343–44 (Fed. Cir. 2019) (citation omitted). While the claims in *Natural Alternatives* similarly claimed a compound which existed in nature in quantities higher than natural levels, we explained that the method of application involved the method of affirmatively treating patients with quantities that did not exist in nature, thereby altering an individual's natural state. *Id.* at 1344; *see also id.* at 1346 (holding that the "treatment claims . . . cover using a natural product in unnatural quantities to alter a patient's natural state, to treat a patient with specific dosages outlined in the patents"). Claim 14, by contrast, is not

PureCircle made no step two *Alice*/*Mayo* arguments before us or the district court. Claim 14 is therefore invalid as directed to unpatentable subject matter.

## CONCLUSION

We affirm the district court's grant of summary judgment that claims 1–13 of the '273 patent and claims 1–7 of the '257 patent are invalid for lack of written description, and that claim 14 of the '273 patent is unpatentable under 35 U.S.C. § 101.

**AFFIRMED**

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a treatment claim. Thus, reliance on *Natural Alternatives* is misplaced.