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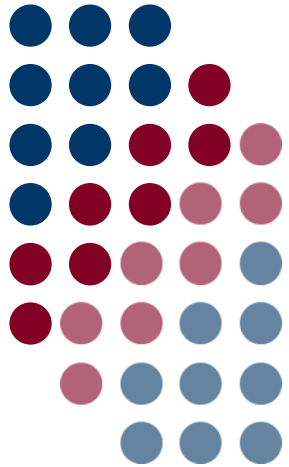
PureCircle USA Inc. v. SweeGen, Inc. (Fed. Cir. 2024)

Whitney Remily



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Overview

- In *PureCircle USA Inc. v. SweeGen, Inc.* (Fed. Cir. 2024), the Fed. Cir. affirmed the District Court's invalidation of the claims asserted against Defendant SweeGen
  - The District Court granted summary judgment against PureCircle, finding that asserted claims were invalid for reciting **patent-ineligible subject matter under 35 U.S.C. § 101.**
  - The District Court also found that asserted claims were invalid for failure to satisfy the **written description requirement of 35 U.S.C. § 112(a)**

35 U.S.C. § 101

- 35 U.S.C. § 101 states:

  Whoever invents or discovers any **new and useful process, machine, manufacture, or composition of matter**, or any **new and useful improvement** thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101

- Judicial Exceptions:
  - Abstract ideas
  - Laws of nature
  - Natural phenomena

35 U.S.C. § 101

- **Two-Step Analysis**
  - **Step 1 –** Is the claim directed to a process, machine, manufacture, or composition of matter?
  - **Step 2A –**

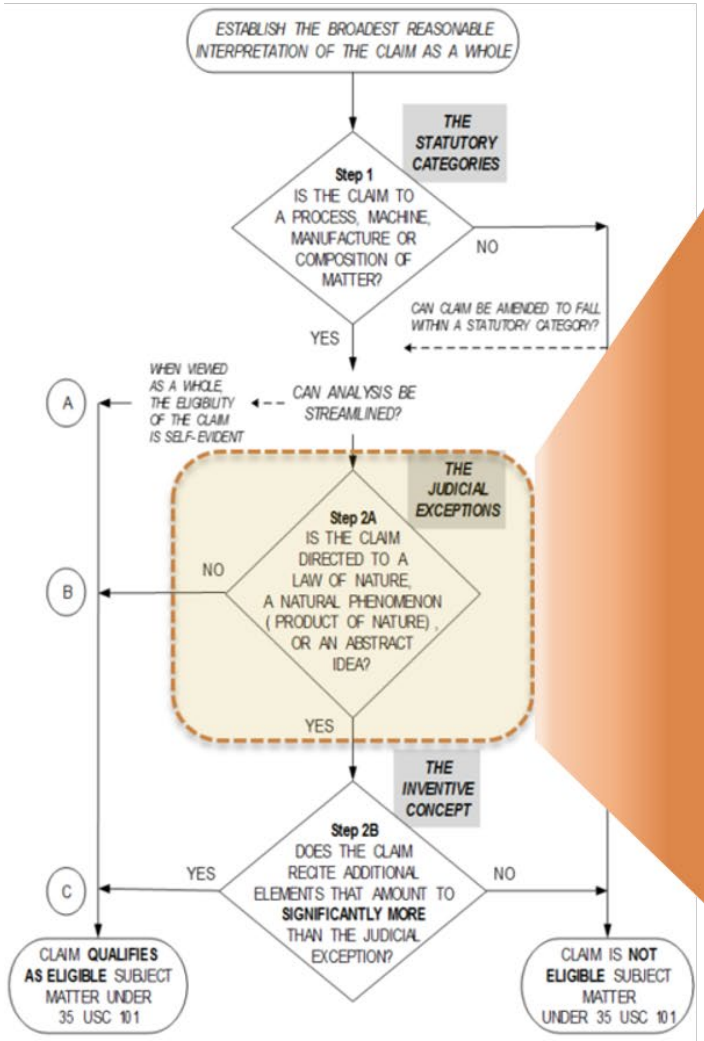
    Prong 1—Is the claim **directed to** a law of nature, a natural phenomenon, or an abstract idea (judicial exceptions)?

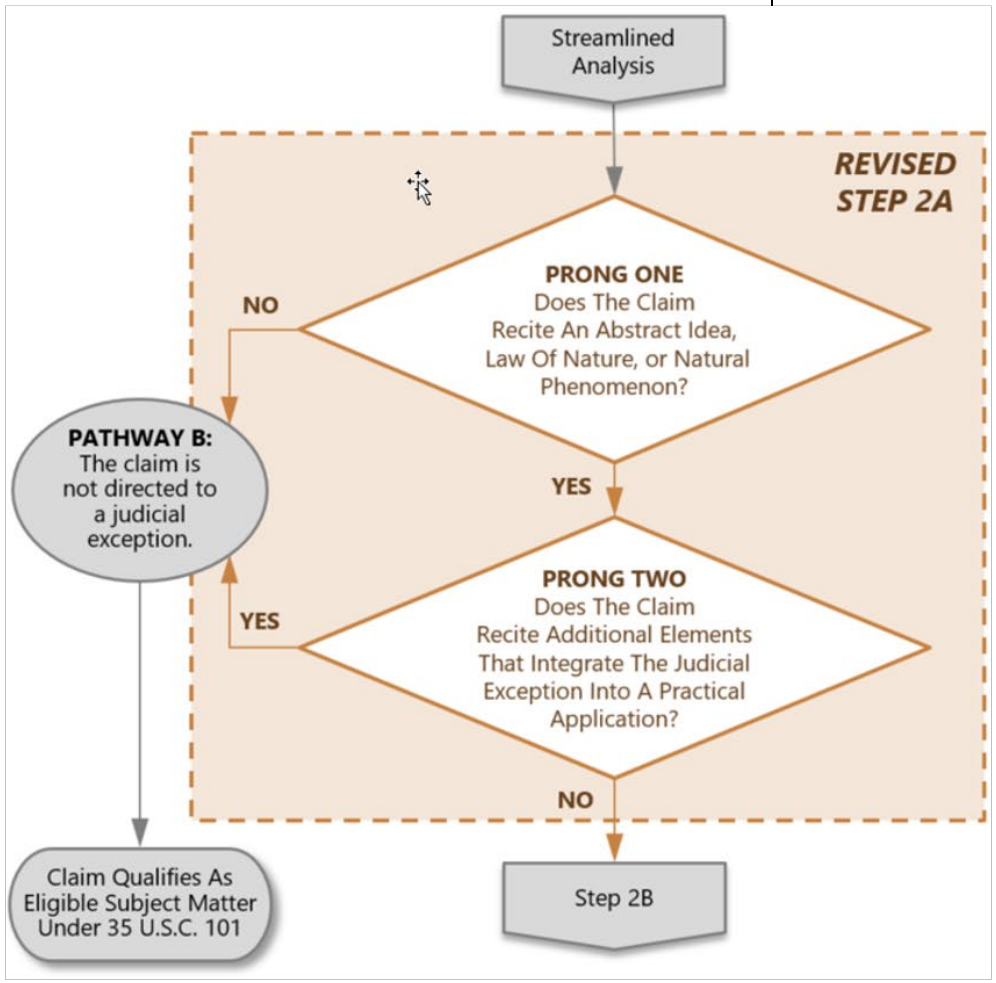
    - "directed to" means the exception is **recited** in the claim, i.e., the claim sets forth or describes the exception

    Prong 2— "evaluate whether the claim integrates the law of nature or natural phenomenon into practical application".

35 U.S.C. § 101

- **Two-Step Analysis**
  - **Step 2B –** Is any element, or combination of elements, in the claim sufficient to ensure that the claim as a whole amounts to **significantly more** than the judicial exception?


ESTABLISH THE BROADEST REASONABLE INTERPRETATION OF THE CLAIM AS A WHOLE
THE STATUTORY CATEGORIES
Step 1
IS THE CLAIM TO A PROCESS, MACHINE, MANUFACTURE OR COMPOSITION OF MATTER?
NO
YES
CAN CLAIM BE AMENDED TO FALL WITHIN A STATUTORY CATEGORY?
A
WHEN VIEWED AS A WHOLE, THE ELIGIBILITY OF THE CLAIM IS SELF-EVIDENT
CAN ANALYSIS BE STREAMLINED?
THE JUDICIAL EXCEPTIONS
Step 2A
IS THE CLAIM DIRECTED TO A LAW OF NATURE, A NATURAL PHENOMENON (PRODUCT OF NATURE), OR AN ABSTRACT IDEA?
NO
B
YES
THE INVENTIVE CONCEPT
Step 2B
DOES THE CLAIM RECITE ADDITIONAL ELEMENTS THAT AMOUNT TO SIGNIFICANTLY MORE THAN THE JUDICIAL EXCEPTION?
YES
NO
C
CLAIM QUALIFIES AS ELIGIBLE SUBJECT MATTER UNDER 35 USC 101
CLAIM IS NOT ELIGIBLE SUBJECT MATTER UNDER 35 USC 101

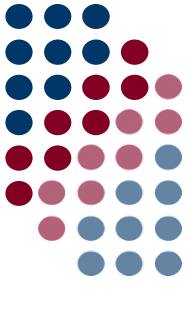

Streamlined Analysis
REVISED STEP 2A
PRONG ONE
Does The Claim Recite An Abstract Idea, Law Of Nature, or Natural Phenomenon?
NO
YES
PATHWAY B:
The claim is not directed to a judicial exception.
PRONG TWO
Does The Claim Recite Additional Elements That Integrate The Judicial Exception Into A Practical Application?
YES
NO
Claim Qualifies As Eligible Subject Matter Under 35 U.S.C. 101
Step 2B

Written Description

- 35 U.S.C. §112(a):

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.

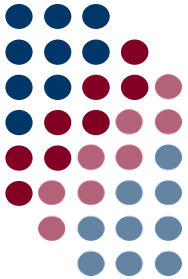
Current Written Description Test (*Ariad*)



- Under ***Ariad***, **"possession as shown in the disclosure"** is now the test.
- The test requires an objective inquiry into the 'four corners' of the specification from the perspective of a person of ordinary skill in the art.
- Based on that inquiry, the specification must describe an invention understandable to a skilled artisan and show that the inventor actually invented the invention claimed.

Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1341 (Fed. Cir. 2010)

Current Written Description Test (*Ariad*)



- The test for adequate written description "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**." *Ariad Pharms*., 598 F.3d at 1351.

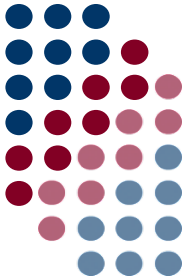
- "A 'mere wish or plan' for obtaining the claimed invention is not adequate written description." *Centocor Ortho Biotech, Inc. v. Abbott Labs*., 636 F.3d 1341, 1348 (Fed. Cir. 2011).

Current Written Description Test

- 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." *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005); *see also Ariad*, 598 F.3d at 1351.

- Whether a claim satisfies the written description requirement is a question of fact :
  - Existing knowledge in the field
  - Extent/content of the prior art
  - Maturity of the science or technology
  - Predictability of the aspect at issue

Written Description--Broad Genus Disclosed But Narrow Species Or Subgenus Claimed



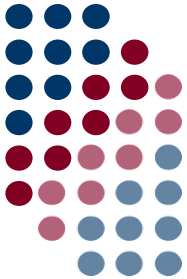
- “In cases where the specification describes a broad genus and the claims are directed to a single species or a narrow subgenus, we have held that the specification must contain ‘"blaze marks" that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities.’ " *Novartis Pharms. Corp. v. Accord Healthcare, Inc.* , 21 F.4th 1362, 1370 (Fed. Cir. 2022) (quoting *Novozymes A/S v. DuPont Nutrition Biosciences APS* , 723 F.3d 1336, 1349 (Fed. Cir. 2013)).

Written Description--Broad Genus Disclosed

- For genus claim: "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."

See 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)).

Written Description--Broad Genus Disclosed



- "One cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000).

Written Description--Broad Genus Disclosed

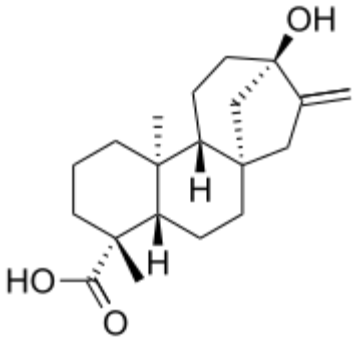
- "It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared — or have not yet been made, which is more like the case here — to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none." *In re Ruschig*, 379 F.2d 990, 995 (CCPA 1967) (aff'g written description rejection of application claims)

PureCircle Technology

- Stevia is a sugar substitute, about 50-300x sweeter than sugar, extracted from the leaves of a plant native to the Amazon rainforest
- The active compounds in are steviol glycosides (mainly stevioside and rebaudioside)

PureCircle Technology

Steviol backbone:



Steviol glycoside, “Reb X”:

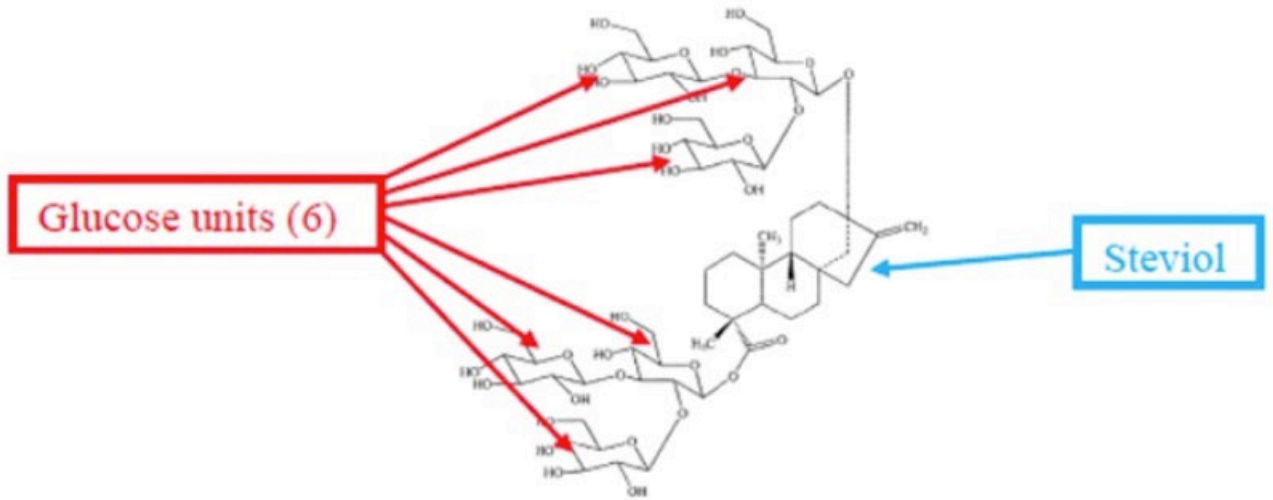
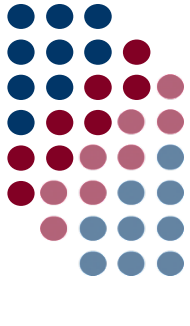


FIG. 1

PureCircle Technology



- PureCircle owns U.S. Patent Nos. 9,243,273 (“’273 patent”) and 10,485,257 (“’257 patent”)
- Because plants have only trace amounts of Reb X, it is not commercially viable to extract from the plants.
- PureCircle patented a method for producing Reb X using UDP-glucosyltransferases (“UGTs”), the same enzymes used in plants to synthesize the compound

PureCircle Technology

- Claims 1 and 14 of the ’273 patent:

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

14. The method of claim 1, wherein the UDPglucosyltransferase comprises UGT76G1.

PureCircle Technology

- Claim 1 and 14 of the ’257 patent:

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.*

District Court

- PureCircle asserted their patents against SweeGen

- District Court granted summary judgment against PureCircle, finding that:
  - claims 1-5 of the '257 patent and claims 1-11 and 14 of the '273 patent were invalid for reciting patent-ineligible subject matter under 35 U.S.C. § 101.
  - all claims of the ’273 and ’257 patents invalid due to a lack of written description

District Court

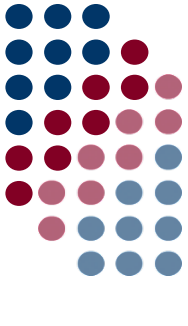
- The patents claim the use of a genus of UGT enzymes

- 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."

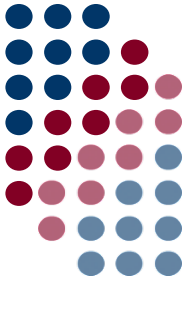
- The district court held that based on the parties' stipulation, the term was functionally defined, *e.g.,* the enzyme is defined by what it does—its function—**transferring** a glucose unit **from** a uridine diphosphate glucose molecule **to** a steviol glycoside molecule

SweeGen's Arguments



- SweeGen argues that the UGT genus covers at least one trillion enzymes that could potentially perform that function
- The patents only identify one species of UGT enzyme
- The claims are invalid because they don't disclose a representative number of species
- There is no 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

PureCircle's arguments



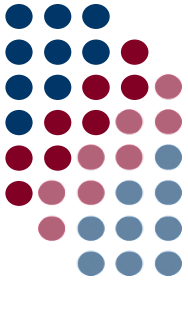
- The potential trillions of enzymes claimed can be reduced because there were only five known enzymes shown to be capable of steviol glycoside synthesis
- While each of these enzymes could have a large number of mutations, the mutations capable of the required synthesis can be determined through homology modeling
- testing of the possible mutants was routine
- PureCircle argues that disclosure of a single enzyme can satisfy the written description requirement; disclosure of a single species may be representative of the genus.

PureCircle's arguments

- Issue: 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."

- PureCircle argued: the single disclosed enzyme is representative of the genus because the structure of its active site was common to all claimed UGTs. The UGT76G1 enzyme discloses common structural features sufficient to define the genus.

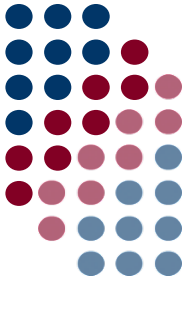
Fed. Cir.—No Written Description



- Held 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: no mention of homology modeling for determining common structure; PureCircle argued that it did not need to be disclosed because it was already a well-known technique
  - Even so, the Fed. Cir. Noted that extensive trial and error testing after homology modeling would be required

Fed. Cir.—No Written Description



- SECOND, there are potentially additional unknown enzymes that could achieve the conversion to produce Reb X, which do not necessarily share common structure with UGT76G1
- The specification does not identify which part of the amino acid sequence is necessary for the conversion function of the enzyme.
- The one enzyme disclosed has not been shown to be typical of the entire genus of UGTs claimed

Juno Therapeutics, Inc. v. Kite Pharma, Inc.

- In *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, the Fed. Cir. addressed written description in context of a patent for antigen receptors used in T cell therapy.

- Kite, the alleged infringer, argued that Juno's patent failed § 112(a) because it only identified two species of the "millions of billions" of the claimed genus of antigen receptors. Kite argued that it also failed to disclose the shared structural features that would bind to specific targets, or allow recognition of genus members capable of binding to those targets from those that were not capable.

Juno Therapeutics, Inc. v. Kite Pharma, Inc.

- The Federal Circuit found that because the patent claimed such a large genus, the disclosure of two species was insufficient.

- A POSA would be unable to distinguish between members of the genus that achieve the claimed function and those that do not.

- The patent did not sufficiently indicate that the inventors possessed the full scope of the genus claimed.

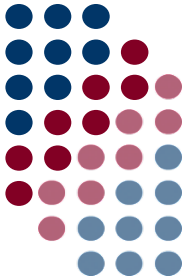
Fed. Cir.—patent-ineligible subject matter

- Claims 1 and 14 of the ’273 patent:

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

14. The method of claim 1, wherein the UDPglucosyltransferase comprises UGT76G1.

Fed. Cir.—patent-ineligible subject matter



- Step 1: Claim 14 claims a natural phenomenon because the enzyme UGT76G1 is naturally found in stevia plants, and naturally converts Reb D to Reb X

- PureCircle argues that in nature only small amounts of Reb X are produced, while the claims require "the conversion of Rebaudioside D to Rebaudioside X is at least about 50% complete," which does not occur in nature.

- Fed. Cir.: "the 50% completion is itself an abstract idea"

Fed. Cir.—patent-ineligible subject matter

- 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).

Fed. Cir.—patent-ineligible subject matter

- "[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)

Fed. Cir.—patent-ineligible subject matter

- 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.”

- 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.

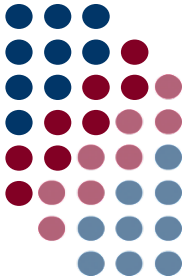
- Natural phenomenon or abstract idea at Step 1 of *Alice/Mayo*

Fed. Cir.—patent-ineligible subject matter

- PureCircle made no Step 2 *Alice/Mayo* arguments

- Claim 14 is therefore invalid as directed to unpatentable subject matter.

- Q & A



Thank you!!

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