

# 3 PTAB Cases Offer Guidance For Drafting Method Claims

By **Aaron Morrow and Abe Weill** (December 15, 2022, 5:44 PM EST)

The Patent Trial and Appeal Board has issued three recent decisions for three different appeals from the U.S. Patent and Trademark Office relating to subject matter eligibility under Title 35 of the U.S. Code, Section 101.

The PTAB evaluated each appeal under the 2019 revised USPTO guidance for Section 101.[1] Each of these decisions hinged on whether the claims under appeal added a practical application to a judicial exception of the revised Step 2A analysis or if the claims met the significantly more aspect of Step 2B.

The decisions provide guidance for claims that arguably include an abstract idea and suggest that practitioners may be able to establish patent eligibility by integrating potentially abstract subject matter to transform them into practical applications.

## Background

For evaluating claims that initially appear to be directed to a patent-ineligible concept, the 2019 revised USPTO guidance and Manual of Patent Examining Procedures Section 2106 break down patent subject matter eligibility into the following steps:

- Step 1: Statutory Category — Whether the claim is directed to a process, machine, manufacture, or composition of matter; and if so
- Step 2A: Judicial Exceptions — Prong 1: Whether the claim is directed to a law of nature, a natural phenomenon — product of nature — or an abstract idea:
  - If "No" — patent eligible; and
  - If "Yes" — patent ineligible.
- Step 2A: Judicial Exceptions — Prong 2: Whether the recited judicial exception is integrated into a practical application of that judicial exception:
  - If "Yes" — patent eligible; and
  - If "No" — Step 2B.
- Step 2B: Inventive Concept: Whether the claim recites additional elements that amount to significantly more than the judicial exception:
  - If "Yes" — patent eligible; and
  - If "No" — patent ineligible.

These are shown in the USPTO's flow chart:

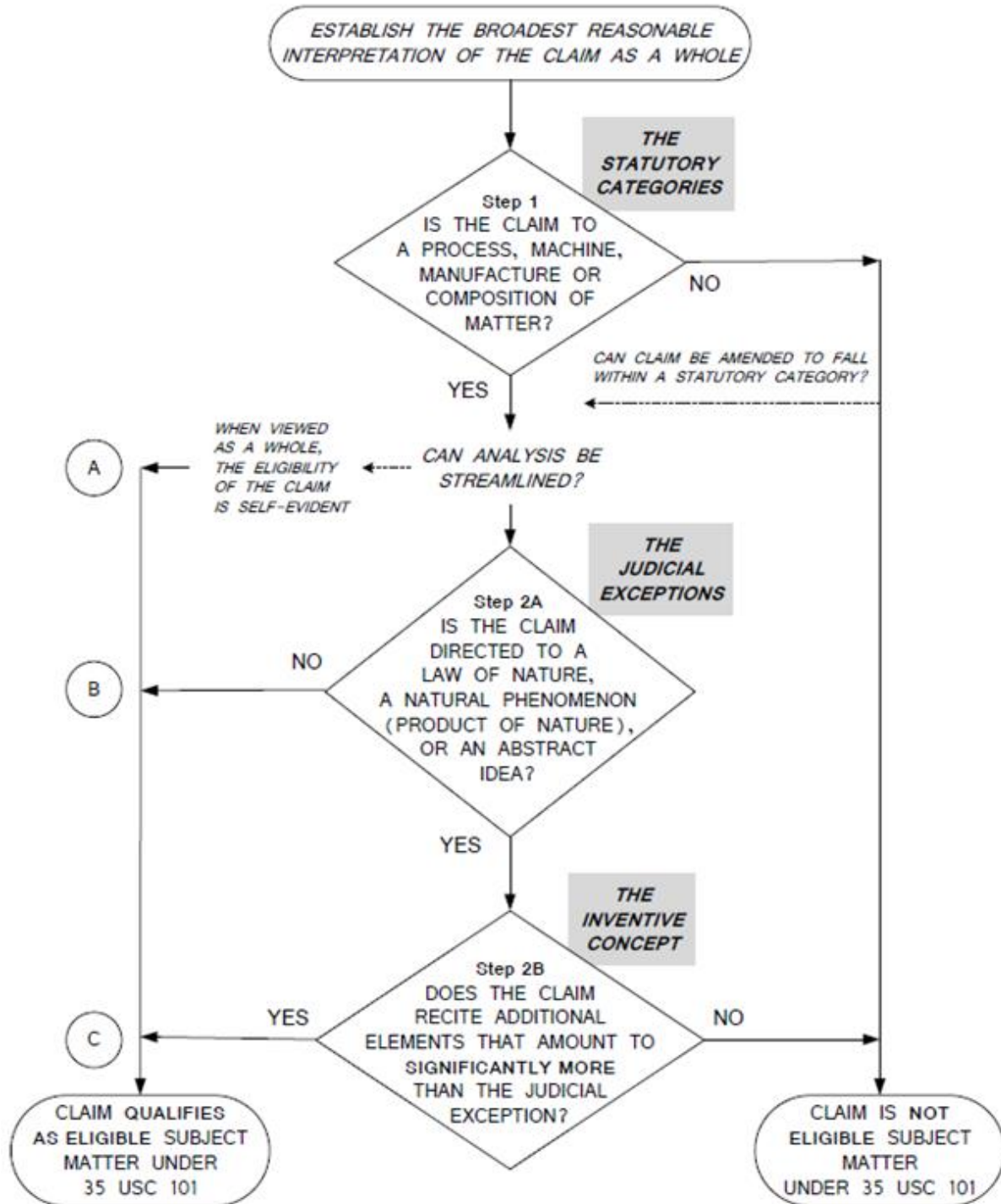


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**SUBJECT MATTER ELIGIBILITY TEST FOR PRODUCTS AND PROCESSES**



(A) (B) (C) → THE PATHWAYS TO ELIGIBILITY

The cases we report on here deal with the bold phrases in the chart above — i.e., the statutory categories, the judicial exceptions and the inventive concept.

- The practical application — Step 2A Prong 2; and
- The significantly more — Step 2B — pathways to patent subject matter eligibility.

## **Allaway**

The first case, the May 19 Ex parte Allaway decision,[2] concerned an appeal of a patent eligibility rejection for claims directed to a method of screening food products to detect increases in blood levels of a molecule in a cat to prevent disease.[3]

Specifically, Claim 1 recited:

[A] method of screening a foodstuff comprising: (a) preparing a foodstuff comprising [a list of potential molecules] ... as fed or dry matter basis; (b) feeding a cat the foodstuff, and (c) measuring the level of margaric acid in a blood sample from the cat before and after feeding the foodstuff."[4]

The PTAB evaluated whether the claim was directed to a patent-ineligible concept.[5] First, the PTAB determined that the invention claimed a "new and useful process"[6] — Step 1 — because Claim 1 recited a method, which, per the USPTO's revised guidance,[7] is within a statutory category of a process.

Next, the PTAB assessed if the claim (1) recited a judicial exception of an abstract idea or law of nature, and (2) integrated that exception into a practical application — Revised Step 2A.[8]

The PTAB found Claim 1 recited a judicial exception of a law of nature — Step 2A Prong 1 — and because the answer was no to Step 2A Prong 2, as seen in the discussion below, the PTO next applied Revised Step 2B.

For this step, the PTAB determined whether the claim (1) added anything beyond the judicial exception that is not "well understood, routine, and conventional in the field," or (2) "simply append[ed] well-understood, routine, conventional activities ... at a high level of generality, to the judicial exception."[9]

Applying the analysis to Claim 1, the PTAB found that this was a method patent, which sufficiently cleared Step 1.[10]

Moving to Step 2A Prong 1, the examiner asserted Claim 1 recites a mental process concept, which falls within the category of an abstract idea, because two levels of molecules were being measured. The applicant argued this claim did not fall under the "mental process" category because "comparing" and "judging" were not used in the claim language.[11]

The PTAB disagreed and decided there was an inherent comparison — a mental process — between the molecule sample pre-feeding and post-feeding to create a measurement.[12] The PTAB then went further to state that Claim 1 recited a law of nature; an observed increase in a blood molecule before and after feeding is a molecular process similar to the claim in Mayo.[13]

Moving to the revised guidance Step 2A Prong 2,[14] the applicant argued that feeding the foodstuff to a cat, along with measuring margaric acid, sufficiently integrated the judicial exception into a practical application.

In this specific case, the PTAB found that the foodstuff and the blood molecule were both commonly known in the art because the specification admitted that both margaric acid and the foodstuff were conventionally used in the field and, therefore, did not integrate the abstract idea into anything practical.[15]

Next, the PTAB then turned to Step 2B, which is satisfied when the claim limitation involves significantly more than well-understood and conventional activities known in the industry.[16]

Applying this standard to the specific allegations in Claim 1, the PTAB found that the foodstuffs were "made by [a] method known in the art," and prior art overlapped with the cat food ranges in Claim 1.[17] The PTAB determined that the applicant merely applied routine methods to reach the alleged invention, which was conceded in the specification as being routine.[18]

In this case, there was no additional element to surpass Step 2B since there was nothing "significantly more" than the judicial exception with "well understood, routine, or conventional" activities known in the industry.[19]

As such, the PTAB found Claims 1-6 directed to a patent-ineligible concept.[20] This finding would not be applicable in instances where the claims recite "unconventional step[s] that [are] more than a mere instruction to 'apply' ... (the exception)."[21]

## **Kravitz**

The June 10 Ex parte Kravitz decision[22] concerned an appeal of a patent eligibility rejection for claims directed to a method for perfusing one or more organs to a monitor, sustaining the viability of these organs and for transporting and storing the organs.[23]

The rejected independent claims under appeal were generally drawn to a method of determining parameters for maintaining viability of a liver or a kidney comprising:

- Procuring an organ;
- Forming a data record of the organ and donor;
- Selecting biomarkers;
- Perfusing the organ with a solution of selected biomarkers; and
- Using a processor to help keep the organ alive.

The PTAB found that the application was directed to a method, clearing Step 1. The PTAB proceeded to Step 2A Prong 1, to determine if the claims were directed to a judicial exception. The examiner asserted that the claims recited abstract ideas of data manipulation performed in the human mind.[24]

The applicant conceded that the claimed methods included abstract ideas but argued that the claims required "procuring a donor [organ]" and other steps that were incapable of being performed in the mind.[25]

The PTAB found that the claims recited abstract ideas and that these additional elements (i.e., "procuring," or "perfusing the donor [organ]") did not nullify an abstract idea determination.[26]

While examining Step 2A Prong 2,[27] the examiner asserted that all of the steps in the claims were computational steps that were not used in any technological environment.[28] The PTAB disagreed. In viewing the claims as a whole, all of the abstract ideas sufficiently integrated the judicial exception into a practical application meant to maintain viability of a donor organ.[29]

The PTAB made the comparison to the October 2019 guidance update 13[30] to note that "consideration of improvements is relevant to the integration analysis" and further that the U.S. Court of Appeals for the Federal Circuit held a method of preserving hepatocytes could be patent eligible as well.[31]

The PTAB determined that the steps of "procuring and perfusing an organ" were insignificant on their own to integrate the judicial exception into a practical application, but all elements of the claim did more than procuring and perfusing an organ. The applicant also claimed "[a] method of determining parameters [to maintain] viability of a liver or kidney." When viewed as a whole, the intended result of the claimed invention was to maintain viability of a donor organ.[32]

The PTAB went further to state the claimed invention provided a method of obtaining data from a donor organ, evaluating the data, and providing a solution from that data to maintain viability of the organ.[33] The PTAB overturned the examiner and held that Claim 1 sufficiently provided a practical application to the abstract ideas and brought the claim into patentable subject matter.[34]

## **Janevski**

The 2021 Ex parte Janevski decision[35] concerned an appeal of a patent eligibility rejection for claims generally drawn to the field of bioinformatics and specifically directed to forming novel signatures of biological data on multiple signatures of data.

The examiner rejected Claims 1 and 5 under Section 101.

Claim 1 is representative of Claim 5 and principally recites: "A computer readable storage medium comprising: (1) generating a set of data from patients; (2) forming matrixes for signature assessment; and (3) ranking those signatures for a diagnostic assay." [36]

The PTAB agreed with the examiner in characterizing Claim 1 as containing mathematical relationships and mental steps, i.e., "generating a set of multiple signatures," "forming a first [and second] matrix," "forming a vector," "sorting each value" and "computing" which are designated "abstract ideas." [37]

However, the applicant contended that Claim 1 may recite abstract ideas, but additional elements integrate the judicial exception into a practical application.[38] The PTAB agreed and restated the applicant's argument in its own decision:

The claim "focus[es] on the treatment of disease[,] which falls under the practical applications of the second Prong of Step 2A," because the claim recites that the data assessed by the claimed programming "is based on biological samples gathered from a plurality of patients," and "[t]he multiple molecular biological signatures of biological data

generated by the system assists a physician in reaching a diagnosis or in treating a patient," i.e., are implemented in "a diagnostic assay." [39]

The PTAB asserted that the data collecting, manipulation, and calculation steps, individually, would not meet the standards of Prong 2, but when the claim was viewed as a whole, these steps improve upon the relevant technological field by providing assessments of a meaningful diagnostic outcome. [40]

The PTAB reasoned that collecting a patient's data, then assessing the data for trends in signatures, and using the results in "a diagnostic assay," together sufficiently integrated the abstract idea into a practical application. [41]

The practical application in this instance allowed biological data to be used in a diagnosis of novel signatures derived from the patient data. [42]

The PTAB cited two Federal Circuit cases in its decision, *Enfish* and *Bascom*. [43]

Both cases found claims sufficiently added to generic computer components in specific combinations to result in a patent-eligible concept. In the present case, the PTAB determined that the claim recited generic computer functions, but nevertheless, the claim integrated the generic operations using bio-data of patients in tandem with new ways of sorting and organizing that data. [44]

The PTAB found that the applicant was able to integrate an abstract idea into a new and useful diagnostic method and consequently overturned the examiner's rejection and held that the claim was directed to patent-eligible subject matter. [45]

## **Conclusion**

When drafting claims directed to diagnostic methods and materials, practitioners should consider the possible characterization of this subject matter as a patent-ineligible abstract idea.

If a claim recites an expected outcome for diagnostic purposes, *Allway* suggests that this limitation will probably not be enough to overcome a patent-eligibility rejection, depending on the facts of the specific case.

Instead, integrating several abstract ideas as a whole, with a practical therapeutic objective, may support a patent-eligible finding, similar to *Kravitz* and *Janevski*.

In both of those cases, the claims included additional elements that integrated the "abstract ideas" into a practical application. For *Kravitz*, this practical application was integrating known functions in a novel application used to keep organs alive, which was a sufficient practical application.

In *Janevski*, the claims included known computer methods, but those computing methods were applied in a new way to solve patient-oriented diagnostics and bioinformatics assays. In both cases, the claims were read as a whole and helped the applicants overcome their respective patent eligibility rejections.

Accordingly, should a practitioner be in a position where their facts necessitate an argument to overcome Step 2A Prong 2 or Step 2B, then, in that instance, they will need to show that (1) the claim integrates the abstract idea into a practical application, or (2) the elements

when read as a whole do significantly more than recite an expected outcome.

*Correction: A previous version of this article misstated the patent eligibility requirements in the initial description of Step 2A Prong 1. The error has been corrected.*

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[1] This phrase refers to the combined January 2019 Revised Patent Subject Matter Eligibility Guidance and the October 2019 Update to it.

[2] Ex parte Allaway, No. 2021-002898 (P.T.A.B. May 19, 2022).

[3] Id. at 1.

[4] Id.

[5] Id. at 3.

[6] 35 U.S.C. § 101.

[7] Revised Guidance, 84 Fed. Reg., 50-57 (2019).

[8] Id. at 52-65.

[9] Id.

[10] Allaway, No. 2021-002898, at 3.

[11] Id. The applicant contended these words appeared in the Revised Guidance and were invocative of an "abstract idea." As noted by the PTAB in this case, the words are not required per se to make a claim fall in the mental process category.

[12] Id.

[13] Id. at 3-4 (citing [Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.](#), 566 U.S. 66, 78-79 (2012)).

[14] Revised Guidance, 84 Fed. Reg. at 54-56.

[15] Id. at 4-5.

[16] Id. at 5 (quoting [Alice Corp. v. CLS Bank Int'l](#), 573 U.S. 208, 217-18 (2014)); see also [Berkheimer v. HP Inc.](#), 881 F.3d 1360, 1367 (Fed. Cir. 2018).

[17] Id.

[18] Id. at 6.

[19] Id.

[20] Id.

[21] See Subject Matter Eligibility Examples: Life Sciences, U.S. Patent & Trademark Off. (Dec. 15, 2016) [https://www.uspto.gov/sites/default/files/documents/101\\_examples\\_1to36.pdf](https://www.uspto.gov/sites/default/files/documents/101_examples_1to36.pdf) (Example 29, Claim 3, discusses using a porcine antibody in an unconventional therapeutic effect as patentable subject matter).

[22] Ex parte Kravitz, No. 2021-004398 (P.T.A.B. June 10, 2022).

[23] Id. at 2.

[24] Id. at 11-12.

[25] Id. at 12.

[26] Id.

[27] See Revised Guidance, 84 Fed. Reg. at 54-55.

[28] Kravitz, No. 2021-004398, at 13.

[29] Id.

[30] Revised Guidance, 84 Fed. Reg. at 55.

[31] Kravitz, No. 2021-004398, at 14; see also [Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.](#), 827 F.3d 1042 (Fed. Cir. 2016).

[32] Kravitz, No. 2021-004398, at 13.

[33] Id. at 14.

[34] Id. at 15.

[35] Ex parte Janevski, No. 2020-002614 (P.T.A.B. Mar. 2, 2021).

[36] Id. at 3.

[37] Id. at 7.

[38] Id.

[39] Id.

[40] Id. at 7-8.



[41] Id.

[42] Id. (relying on the specification to note the improvement over prior patient-data systems where prior art was unable to meaningfully use such data).

[43] [Enfish, LLC v. Microsoft Corp.](#), 822 F.3d 1327 (Fed. Cir. 2016); [Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC](#), 827 F.3d 1341 (Fed. Cir. 2016).

[44] Janevski, No. 2020-002614 at 10.

[45] Id. at 11-12.