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The Conundrum of Patentable Subject Matter

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Relating to “[i]nventions patentable,” 35 U.S.C. § 101 was enacted in 1952 and Congress has not amended the section since. The section provides that “[w]hoever 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,” a mere 36 words.¹ Indeed, the language of the current statute has impressive historical roots because the comparable statute from 1790 provided that a patent could be granted:

[U]pon the petition of any person or persons to the Secretary of State, the Secretary for the department of war, and the Attorney General of the United States, setting forth, that he, she, or they, hath or have invented or discovered *any useful art, manufacture, engine, machine, or device*, or any improvement therein not before known and used. . . .²

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APPROACHES TO STATUTORY INTERPRETATION

Statutes frequently require interpretation. Consideration of legislative intent is one such approach. Perhaps the most relevant example is that of *Diamond v. Chakrabarty* where the U.S. Supreme Court stated that “[t]he Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”³ Many of the Court’s tests require consideration of legislative intent.⁴ However, this approach to statutory interpretation has fallen out of favor at least at the federal level.

The jurisprudence of the late Antonin Scalia drastically changed the Court’s approach to statutory interpretation. Justice Scalia was famously dismissive of the value of legislative history and professed to follow a textualist approach.⁵ According to Justice Scalia, “[t]he meaning of terms on the statute books ought to be determined . . . on the basis of which meaning is (1) most in accord with context and ordinary usage . . . , and (2) most compatible with the surrounding body of law into which the provision must be integrated. . . .”⁶

Some very recent civil cases follow the late Justice’s lead. For example, Justice Gorsuch, interpreting the Atomic Energy Act in 2019, wrote that “[i]n this, as in any field of statutory interpretation,

it is our duty to respect not only what Congress wrote but, as importantly, what it didn't write"⁷ while Justice Thomas, interpreting the Fair Debt Collection Practices Act later in 2019, wrote that "[i]t is a fundamental principle of statutory interpretation that 'absent provision[s] cannot be supplied by the courts.'"⁸ Interpreting the Lanham Act in 2020, Justice Gorsuch wrote: "Nor does this Court usually read into statutes words that aren't there."⁹ And interpreting the Civil Rights Act also in 2020, Justice Gorsuch wrote: "Nor is there any such thing as a 'canon of donut holes,' in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception." He continued: "[W]hen Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule."¹⁰

From these cases, we may derive a general rule that, under the Court's recent jurisprudence, there are no implicit exceptions to the language of civil statutes. Indeed, Justice Alito seems to take the position that the general rule applies to patent statutes.¹¹

With the language of 35 U.S.C. § 101 and the cited cases in mind, one might think that a claim reciting a process, machine, manufacture, or composition of matter – the very language of the current statute – would necessarily recite patentable subject matter in accordance with the general rule. But this seemingly reasonable position is incorrect. Rather, "[t]he Court has long held that [35 U.S.C. § 101] contains an important implicit exception," namely that "[l]aws of nature, natural phenomena, and abstract ideas' are not patentable."¹²

Moreover, the Court "ha[s] interpreted § 101 and its predecessors in light of this exception for more than 150 years."¹³ These exceptions to the general rule have played out in four recent cases.

BILSKI, MAYO, MYRIAD, AND ALICE: THE FOUR HORSEMEN OF THE APOCALYPSE?

In *In re Bilski*, the U.S. Court of Appeals for the Federal Circuit held that "[a] claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."¹⁴ The Federal Circuit was not so sure and reversed, holding that "[t]he machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible 'process.'"¹⁵ In *Mayo*, the

Supreme Court held that "[l]aws of nature, natural phenomena, and abstract ideas' are not patentable."¹⁶ In *Myriad*, the Supreme Court held that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated...."¹⁷ However, *Alice* sets forth the Court's current approach to assessing patentable subject matter, namely that in step one "we determine whether the claims at issue are directed to one of [the] patent-ineligible concepts" set forth in *Mayo*.¹⁸ "We have described step two of this analysis as a search for an "inventive concept" – *i.e.*, an element or combination of elements is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'"¹⁹

CLAIMS DIRECTED TO LAWS OF NATURE AFTER ALICE

In *Mayo*, "[t]he claims purport[ed] to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side effects."²⁰ And in *Myriad*, the Association for Molecular Pathology (the "Association") successfully challenged patents relating to genetic testing.²¹ One might imagine that invalidating these and similar patents would render the claimed genetic tests cheaper.

Indeed, the Association has found this to be the case but not necessarily to the extent desired. Specifically, in a survey of physicians and doctoral-level respondents involved in medical testing, the Association reported that "[a]ll types of respondents rated reimbursement for the analysis, interpretation, and reporting process to be *generally insufficient*. . . ."²²

Another recent dispute invoking the Court's "law of nature" jurisprudence is *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*.²³ There, a claim recited "[a] method for manufacturing a shaft assembly of a driveline system . . . comprising: providing a hollow shaft member; *tuning a mass and a stiffness of at least one liner*, and inserting the at least one liner into the shaft member. . . ."²⁴ "[B]oth parties' witnesses agree[d] that Hooke's law undergirds the design of a liner so that it exhibits a desired damping frequency pursuant to the claimed invention."²⁵ According to the majority, but without citing any authority, "Hooke's law is a natural law that mathematically relates the mass and/or stiffness of an object to the frequency with which

that object oscillates (vibrates).²⁶ The majority held that the claim was invalid as directed to unpatentable subject matter.²⁷ The decision was controversial with a leading scholar reporting the decision under the memorable title *Hey Mechanical Engineers: Your Patents are Also Ineligible*.²⁸

On rehearing before the same panel, the majority again held that the claim was not directed to patentable subject matter.²⁹ However, the majority upon rehearing described Hooke's law somewhat differently than did the majority in the original decision but only cited the appellate record in support of their description.³⁰ Judge Newman, writing in dissent of a denial of a petition for rehearing of the original decision en banc, saw Hooke's law differently and cited the *Encyclopædia Britannica* in support of her position.³¹ Arguably, the majority in the original decision and upon rehearing viewed Hooke's Law as a law applying generally – the mass of an object is related in some way to the frequency at which the object oscillates – whereas Judge Newman in viewed Hooke's Law more specifically, namely that the force applied to an object directly correlates with the displacement of that object.

The patentee in the *American Axle* cases submitted a petition for certiorari and various amici submitted briefs.³² Of note was that submitted by the New York City Bar Association ("NYCBA"). For example, the majority upon rehearing stated that the patentee "insist[ed that] the process of tuning a liner according to natural laws may involve extensive computer modelling, including finite element analysis ('FEA'), and experimental modal analysis (that is, trial and error). . . ." ³³ In response, the NYCBA stated that "[i]f the method of [the] claim [at issue] is . . . a mere application of a natural law such as that in *Mayo*, one wonders why extensive computer modeling is needed."³⁴ Subsequently, the Court sought the views of the Acting Solicitor General as to whether to grant the petition, suggesting that the Court may be interested in granting the petition at issue.

CLAIMS DIRECTED TO NATURAL PHENOMENA AFTER ALICE

While *American Axle* has pushed the envelope of the Court's jurisprudence regarding laws of nature, patents claiming natural phenomena have also been challenged. For example, the patent at issue in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, related to prenatal

testing for genetic abnormalities.³⁵ Before the patent's disclosure, physicians had to use techniques such as amniocentesis to sample fetal cells. While amniocentesis is still used today in some cases, it is well known that the technique is associated with risks such as loss of pregnancy.³⁶ The patent discloses that fetal DNA is found in maternal blood free from cellular association. This DNA is known as cell-free fetal DNA ("cffDNA") and is capable of amplification and detection clinically and the patentee's claims broadly recited as much.³⁷ However, "[i]t [was] undisputed that the existence of cffDNA in maternal blood is a natural phenomenon."³⁸ And "[b]ecause the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful."³⁹ Therefore, while the claimed subject matter in *Ariosa* was a significant step forward from the state of the art, the claim at issue was nevertheless not directed to patentable subject matter.

The Federal Circuit denied a petition for rehearing *Ariosa* en banc.⁴⁰ However, Judge Lourie wrote an interesting concurrence to the denial. He suggested that "[t]he claim to this invention, then, might have been better drafted as a so-called Jepson claim, which recites what is in the prior art and what is the improvement." He continued: "Such a claim might read, perhaps with more details added: 'In a method of performing a prenatal diagnosis using techniques of fractionation and amplification, the improvement consisting of using the noncellular fraction of a maternal blood sample.'" ⁴¹ However, the preamble of a Jepson claim can be taken as an implied admission that the subject matter of the preamble is prior art.⁴² Because such an implied admission can be damaging, U.S. practitioners have typically disfavoured Jepson claims. But *Alice* may make such claims worth the risk.

Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals, Int'l Ltd. may also offer some additional assistance.⁴³ There, the claim at issue recited:

A method for treating a patient with iloperidone . . . comprising . . . :

determining whether the patient [has] a CYP2D6 poor metabolizer [genotype] . . . ; and

if the patient has a CYP2D6 poor metabolizer genotype, then internally administering

iloperidone to the patient in an amount of 12 mg/day or less, and

if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day,

wherein [the method relates to] a risk of QTc prolongation. . . .⁴⁴

The Federal Circuit held that the claim recited patentable subject matter at step one of *Alice* without reaching step two.⁴⁵ According to the court, “[t]he inventors recognized the relationships between iloperidone, CYP2D6 metabolism, and QTc prolongation, but . . . [t]hey claimed an application of that relationship.”⁴⁶ In the court’s view, the claim at issue was “‘a new way of using an existing drug’ that is safer for patients because it reduces the risk of QTc prolongation.”⁴⁷ The court concluded that “the claims here are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome.”⁴⁸

Subsequently, the U.S. Patent and Trademark Office (the “Office”) issued a memorandum stating that “‘method of treatment’ claims that practically apply natural relationships should be considered patent eligible. . . .”⁴⁹ Thereafter, a small study revealed “an allowance rate of 84.2% for patent applications with a rejection citing *Mayo* where the applicant responded to [Office] action[s] with arguments and amendments based on *Vanda*, and for which there is a final disposition.”⁵⁰ Other patentees have followed *Vanda*. For example, claim 1 of U.S. Patent No. 10,234,464 B2 recites:

A method of treating a human patient having heart failure comprising:

- (a) combining a serum or plasma sample from a patient with an antibody . . . ;
- (b) detecting the antibody/biomarker complex . . . ;
- (c) comparing the level of the at least one marker to a respective reference level;
- (d) identifying the patient as more likely to respond to a therapy . . . ; and

- (e) administering a statin to the identified patient.⁵¹

The relationship between the level of the at least one marker with the respective reference level is reminiscent of the relationship claimed in *Mayo* that the Court found patent ineligible.⁵² While addition of the language set forth in step (e) resulted in allowance, one wonders whether the patentee here pushed the *Vanda* envelope too far. Is a generic administration of a generic statin “a specific method of treatment . . . using a specific compound at specific doses to achieve a specific outcome”?⁵³

CLAIMS DIRECTED TO PRODUCTS OF NATURE AFTER ALICE

In *Myriad*, the Court held that claims directed to an isolated natural product, without more, are not patent eligible merely because the natural product has been isolated.⁵⁴ However, it is well known that many common drugs such as aspirin and penicillin are natural products. Indeed, isolating penicillin in the 1940s was worthy of the Nobel Prize.⁵⁵ While previously uncharacterized natural products are disclosed regularly,⁵⁶ the disclosing parties might not wish to commercialize such products without meaningful patent protection.

There are options, though. In a recent case handled by my firm, the claim at issue was directed to a composition of bacterial proteins. The Office alleged that a composition of naturally occurring bacterial proteins was not patentable subject matter, citing *Mayo*. The independent claim was amended to be directed to a composition of bacterial proteins and an adjuvant. It was argued that the presence of the adjuvant renders the bacterial proteins immunogenic, which is a marked difference from the composition of bacterial proteins without the adjuvant.

Additionally, it was noted that the Office had taken the position that, while the components of gunpowder are naturally occurring but are not themselves explosive, the assembly of such components in a particular manner forms gunpowder that is explosive upon ignition. In other words, gunpowder is associated with a marked difference with respect to the individual components thereof.⁵⁷ Because the subject matter of the amended claim and gunpowder are both associated with a marked difference, the amended claim was on all fours with an exemplary claim that the Office had acknowledged

is patent eligible. Therefore, the amended claim is directed to patentable subject matter.

While it remains to be seen whether these arguments will ultimately persuade the Office, the approach taken is an example of how patentable subject matter rejections might be addressed.

CLAIMS DIRECTED TO ABSTRACT IDEAS AFTER ALICE

Alice led to the invalidation of many software-implemented patents.⁵⁸ *Yu v. Apple Inc.* is another example of the extent to which alleged infringers have pushed the principles of *Alice*.⁵⁹ Set forth below is a simplified and emphasized version of the claim at issue in *Yu*:

An improved digital camera comprising:

a first and a second image sensor, said first image sensor producing a first image and said second image sensor producing a second image;

two lenses . . . ;

an analog-to-digital converting circuitry . . . ;

an image memory . . . ; and

*a digital image processor, coupled to said image memory and receiving said first digital image and said second digital image, producing a resultant digital image from said first digital image enhanced with said second digital image.*⁶⁰

While methods were the subject matter at issue in *Mayo* and *Alice*, for example, the subject matter at issue in *Yu* is a physical object. One would imagine that a person skilled in the art could easily remove the back from such an object and identify the italicized components. However, it is the underlined language that led to the claim's demise.

The Federal Circuit initially noted that “[t]he district court granted Defendants’ motion to dismiss on the basis that the asserted claims were invalid under 35 U.S.C. § 101.” This is an important consideration: Unlike issues of lack of novelty and obviousness that typically require claim construction and expert testimony, a court can dismiss a claim as not directed to patentable subject matter very early in proceedings and at relatively low cost for the alleged infringers.

At step one of *Alice*, the *Yu* court held that the claim “is directed to the abstract idea of taking two pictures (which may be at different exposures) and using one picture to enhance the other in some way.” The court also noted that “the idea and practice of using multiple pictures to enhance each other has been known by photographers for over a century.” The court continued: “The claim’s remaining limitations undercut Yu’s contention” that the claim “is directed to a patent-eligible application of this idea as opposed to just the idea itself.” In this regard, the Federal Circuit was forthright: “Only conventional camera components are recited to effectuate the resulting ‘enhanced’ image . . . ,” “it is undisputed that these components were well-known and conventional,” “as claimed, these conventional components perform only their basic functions,” and “[w]hat is claimed is simply a generic environment in which to carry out the abstract idea.”⁶¹

In step two of *Alice*, the court concluded that the claim “does not include an inventive concept sufficient to transform the claimed abstract idea into a patent-eligible invention.”⁶² Moreover, “even if [the claim] recites novel subject matter, that fact is insufficient by itself to confer eligibility.”⁶³ Rather, “[t]he main problem that [Yu] cannot overcome is that the *claim* – as opposed to something purportedly described in the specification – is missing an inventive concept.”⁶⁴ Therefore, the Federal Circuit affirmed the district court’s finding that the claim recited unpatentable subject matter.⁶⁵

Judge Newman, in dissent, saw the claim at issue differently. “This camera is a mechanical and electronic device of defined structure and mechanism; it is not an ‘abstract idea.’”⁶⁶ She continued: “A device that uses known components does not thereby become an abstract idea, and is not on that ground ineligible for access to patenting.”⁶⁷ Judge Newman neatly summarized the issues arising from the current state of the law to patentable subject matter: “Although today’s Section 101 uncertainties have arisen primarily in the biological and computer-implemented technologies, all fields are affected.”⁶⁸

Yu also illustrated an oddity that arises from the Court’s patentable subject matter jurisprudence. For example, it is well settled that if the subject matter of a claim is nonobvious, the subject matter of any claim depending therefrom is also nonobvious.⁶⁹ But this is seemingly not the case for patentable subject matter. For example, if the claim

set forth above *lacked* the language “producing a resultant digital image from said first digital image enhanced with said second digital image,” the claim would recite patentable subject matter, although novelty and non-obviousness would be a different matter. However, if a dependent claim recited that language, such a dependent claim would not recite patentable subject matter. Therefore, the fact that an independent claim can be directed to patentable subject matter while a dependent claim may not be so directed is inconsistent with other areas of settled law.

CONCLUSION

The Court’s recent forays into patentable subject matter have caused considerable uncertainty that seems to be increasing as time goes on. Perhaps the strangest aspect of the Court’s approach is to read into a statute that is clear and unambiguous on its face language that is not present as such an approach is seemingly impermissible in connection with other civil statutes. In this regard, one wonders whether the Court’s recent jurisprudence has implicitly overturned *Alice* and its predecessors. There are also serious concerns about investment strategies in some industries resulting from *Alice*-induced uncertainty. Perhaps Jepson claims, which have long been disfavored in U.S. patent practice, may be a way forward in some cases.

Additionally, reference to *Vanda* and the Office’s examples of patentable subject matter may be of assistance where appropriate. At bottom, however, there are fundamental questions: When is a claim “directed to” a law of nature (*American Axle*)? When is a claim “directed to” an abstract idea (*Yu*)? It will be interesting to see if the Court grants certiorari in connection with *American Axle* to resolve some of these important questions.

Notes

1. 35 U.S.C. § 101 (2018).
2. 1 Stat. 109–10 (1790) (emphasis added). Remarkably for the 18th century, the statute is gender neutral.
3. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82–1979, at 5 (1952) and H.R. REP. NO. 82–1923, at 6 (1952)).
4. See, e.g., *Selective Serv. Sys. v. Minn. Pub. Interest Research Grp.*, 468 U.S. 841, 852 (1984) (citing *Nixon v. Adm’r of Gen. Servs.*, 433 U.S. 425, 473, 475–76, 478 (1977)) (bills of attainder).
5. See, e.g., *Zedner v. U.S.*, 547 U.S. 489, 511 (2006) (“Because the use of legislative history is illegitimate and ill advised in the interpretation of any statute – and especially a statute that is clear on its face – I do not join this portion of the Court’s opinion.”) (Scalia, J., concurring in part and concurring in the judgment).
6. *Green v. Bock Laundry Mach. Co.*, 490 U.S. 504, 528 (1989) (Scalia, J., concurring).
7. *Va. Uranium, Inc. v. Warren*, 139 S.Ct. 1894, 1900 (2019) (Gorsuch, J.); see also *Lomax v. Ortiz-Marquez*, 140 S.Ct. 1721, 1725 (2020) (“[T]his Court may not narrow a provision’s reach by inserting words Congress chose to omit.”) (Kagan, J.) (citing same).
8. *Rotkiske v. Klemm*, 140 S.Ct. 355, 361–62 (2019) (Thomas, J.) (quoting ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 94 (2012)) (alteration in original); see also *Little Sisters of the Poor Saints Peter & Paul Home v. Pa.*, 140 S.Ct. 2367, 2381 (2020) (citing same).
9. *Romag Fasteners, Inc. v. Fossil Grp., Inc.*, 140 S.Ct. 1492, 1495 (2020) (Gorsuch, J.).
10. *Bostock v. Clayton Cnty., Ga.*, 140 S.Ct. 1731, 1747 (2020) (Gorsuch, J.).
11. See *Minerva Surgical, Inc. v. Hologic, Inc.*, 141 S.Ct. 2298, 2311 (2021) (Alito, J., dissenting) (citing *Romag*, 140 S.Ct. at 1495).
12. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012) (Breyer, J.) (citing *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).
13. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014) (Thomas, J.).
14. *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008) (emphasis added) (en banc).
15. *Bilski v. Kappos*, 561 U.S. 593, 605 (2010).
16. *Mayo*, 566 U.S. at 70 (citing *Diehr*, 450 U.S. at 185).
17. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013).
18. *Alice*, 573 U.S. at 217.
19. *Id.* at 217–18 (alteration in original) (citing *Mayo*, 566 U.S. at 72–73).
20. *Mayo*, 566 U.S. at 72.
21. *Myriad*, 569 U.S. at 576.
22. ASS’N FOR MOLECULAR PATHOLOGY, *Analysis of Effort in Molecular Test Interpretation*, https://www.amp.org/AMP/assets/File/advocacy/AMP_MDx_Interpretation_Quant_Survey_Report.pdf?pass=2 at 32 (Mar. 16, 2021) (emphasis added).
23. *American Axle* has a complex procedural history before the Federal Circuit. *Axle I* was the original decision. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 939 F.3d 1355 (Fed. Cir. 2020). The court subsequently granted a petition for rehearing of *Axle I* and withdrew that opinion. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 966 F.3d

- 1294, 1295 (Fed. Cir. 2020) (per curiam) (“*Axle II*”). On the same day, the court denied a petition for rehearing en banc. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 966 F.3d 1347, 1348 (Fed. Cir. 2020) (per curiam) (“*Axle III*”). *Axle IV* replaced *Axle I*. See *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285 (Fed. Cir. 2020) (“*Axle V*”).
24. *Axle I*, 939 F.3d at 1359 (emphasis added).
 25. *Id.* at 1362.
 26. *Id.* (citing no authority).
 27. *Id.* at 1368.
 28. Dennis Crouch, *Hey Mechanical Engineers: Your Patents are Also Ineligible*, PATENTLYO (Oct. 3, 2019), <https://patentlyo.com/patent/2019/10/mechanical-engineers-ineligible.html>.
 29. *Axle IV*, 967 F.3d at 1292.
 30. *Id.* at 1291 (“Hooke’s law is an equation that describes the relationship between an object’s mass, its stiffness, and the frequency at which the object vibrates.”) (citing appellate record).
 31. *Axle III*, 966 F.3d at 1359 (citing ENCYCLOPÆDIA BRITANNICA, <https://www.britannica.com/science/Hookes-law> (last visited Dec. 8, 2021)) (Newman, J., dissenting).
 32. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, No. 20-891 (Dec. 28, 2020) (“*Axle V*”).
 33. *Axle IV*, 967 F.3d at 1294.
 34. Brief for New York City Bar Ass’n at 11, *Axle V*. The author was on the brief.
 35. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015).
 36. See, e.g., MAYO CLINIC, Amniocentesis, <https://www.mayoclinic.org/tests-procedures/amniocentesis/about/pac-20392914> (last visited Dec. 8, 2021).
 37. See *Ariosa*, 788 F.3d at 1373.
 38. *Id.* at 1376.
 39. *Id.* at 1377.
 40. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1284 (Fed. Cir. 2015) (per curiam).
 41. *Id.* at 1286 (Lourie, J., concurring).
 42. See generally U.S. PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE § 2129(III) (2020).
 43. *Vanda Pharms. Inc. v. West-Ward Pharms. Int’l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018). *Vanda* is an interesting case in that the Federal Circuit called a number of line balls fair.
 44. *Id.* at 1121.
 45. See *id.* at 1134.
 46. *Id.* at 1135 (emphasis added).
 47. *Id.* (citing *Mayo*, 566 U.S. at 87).
 48. *Id.* at 1136 (emphasis added). The Court denied a petition for certiorari. *Hikma Pharms. USA Inc. v. Vanda Pharms Inc.*, 140 S.Ct. 911 (2020).
 49. ROBERT W. BAHR, U.S. PAT. & TRADEMARK OFF., RECENT SUBJECT MATTER ELIGIBILITY DECISION: *VANDA PHARMACEUTICALS INC. v. WEST-WARD PHARMACEUTICALS* 2-3 (2018) (emphasis in original omitted).
 50. Mateo Aboy et al., *One Year After Vanda, Are Diagnostics Patents Transforming into Methods of Treatment to Overcome Mayo-Based Rejections?*, 38 NATURE BIOTECHNOLOGY 279, 279 (2020).
 51. U.S. Patent No. 10,234,464 B2 at cl. 1 (emphasis added).
 52. *Mayo*, 566 U.S. at 72.
 53. *Vanda*, 887 F.3d at 1136 (emphasis added).
 54. *Myriad*, 569 U.S. at 580.
 55. See, e.g., NOBEL PRIZE OUTREACH AB, *The Nobel Prize in Physiology or Medicine 1945*. <https://www.nobelprize.org/prizes/medicine/1945/summary/> (last visited Dec. 8, 2021).
 56. See, e.g., Hamed Mossel et al., 72 MOLECULAR CELL 263 (2018).
 57. U.S. PAT. & TRADEMARK OFF., EXAMPLES 1-36, 21 (2016), https://www.uspto.gov/sites/default/files/documents/101_examples_1to36.pdf.
 58. See, e.g., *In re TLI Commc’ns LLC*, 823 F.3d 607, 609 (Fed. Cir. 2016) (“[T]he patent-in-suit claims no more than the abstract idea of classifying and storing digital images in an organized manner. . .”). However, software-related claims directed to an improvement to computer functionality have a significantly higher chance of being found patent eligible. See, e.g., *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1336 (Fed. Cir. 2016) (“In this case, however, the plain focus of the claims is on an improvement to computer functionality itself, not on economic or other tasks for which a computer is used in its ordinary capacity.”).
 59. *Yu v. Apple Inc.*, 1 F.4th 1040 (Fed. Cir. 2021).
 60. See *id.* at 1042 (emphasis added).
 61. *Id.*
 62. *Id.* at 1045.
 63. *Id.* (citing *Two-Way Media Ltd. v. Comcast Cable Commc’ns, LLC*, 874 F.3d 1329, 1338 (Fed. Cir. 2017) (“Eligibility and novelty are separate inquiries.”)).
 64. *Id.* (alteration in original) (citing *Two-Way Media*, 874 F.3d at 1338).
 65. *Id.* at 1046.
 66. *Id.* (Newman, J., dissenting).
 67. *Id.* at 1048.
 68. *Id.* at 1049.
 69. See, e.g., *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (“Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious.”) (citing *Hartness Int’l, Inc. v. Simplimatic Eng’g Co.*, 819 F.2d 1100, 1108 (Fed. Cir. 1987), *In re Abele*, 684 F.2d 902, 910 (C.C.P.A. 1982), and *In re Sernaker*, 702 F.2d 989, 991 (Fed. Cir. 1983)).

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