900 W. 48th Place, Suite 900, Kansas City, MO 64112 • (816) 753-1000

July 2025

CAN YOU PATENT THAT? UNLOCKING THE SECRETS OF MEDICAL DEVICE PATENT ELIGIBILITY

AUTHOR

Jacek Wnuk
Electrical Engineering & Computer Science Patent Prosecution
Email | Bio
+1 415.248.2122

Patent eligibility under 35 U.S.C. §101 is a fundamental requirement for obtaining a patent in the United States. The statute defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." However, the Supreme Court has long recognized three judicial exceptions: laws of nature, natural phenomena, and abstract ideas.

The Supreme Court's decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012) and *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014), established the two-step framework now used to analyze patent eligibility. Under the *Alice/Mayo* test:

1. A court determines whether the claims are directed to a judicial exception to patent eligibility (e.g., a law of nature, a natural phenomenon, or an abstract idea).

2. If so, the court assesses whether the claim includes an “inventive concept” (also referred to as “something more”) that is sufficient to transform the judicial exception into a patent-eligible application.

Applying this framework, courts and the U.S. Patent and Trademark Office (USPTO) have examined patent eligibility for all kinds of technologies, including medical devices.

In 2019, the USPTO attempted to streamline patent eligibility analysis by adding an additional prong to the first step, inquiring “if the recited judicial exception is integrated into a practical application of that exception.” *See* MPEP § 2106.04(II)(A). However, courts are not bound by this additional prong. *See cxLoyalty, Inc. v. Maritz Holdings, Inc.*, 986 F.3d 1367 (Fed. Cir. 2021) (“We note that [the USPTO] guidance ‘is not, itself, the law of patent eligibility, does not carry the force of law, and is not binding

on our patent eligibility analysis.'... [a]nd to the extent the guidance 'contradicts or does not fully accord with our caselaw, it is our caselaw, and the Supreme Court precedent it is based upon, that must control.").

Supreme court decision, Federal Circuit decisions, and USPTO-provided examples are the best indicators of how patent eligibility applies to different types of medical device technologies. For instance, these sources provide clear guidance on best practices with regard to patent eligibility in spaces such as artificial intelligence (AI), diagnostics, therapeutics, and testing methodologies.

1. AI-Based Medical Technologies

AI-based medical innovations, such as those using machine learning or neural networks, have increasingly faced scrutiny under §101. The key issue is whether AI-based claims are merely directed to an abstract idea or a practical application with a technological improvement.

- ***Recentive Analytics, Inc. v. Fox Corp.***, 134 F. 4TH 1205 (Fed. Cir. 2025) concerns four patents about training machine learning models in the entertainment and broadcasting industries. The Federal Circuit dismissed the claims as directed abstract ideas and thus patent-ineligible, noting that "patents that do no more than claim the application of generic machine learning to new data environments, without disclosing improvements to the machine learning models to be applied, are patent ineligible under § 101" – even if "it can "perform a task previously undertaken by humans with greater speed and efficiency than could previously be achieved." The Federal Circuit does not entirely rule out patent eligibility of ML-based technologies, noting that "Machine learning [...] may lead to patent-eligible improvements in technology." Based on this decision, it may be beneficial to focus claims on aspects of a technology that could not have been done by human beings, such as sensors of a medical device.

- **USPTO Example 47** discusses use of an artificial neural network (ANN) to detect anomalous network behavior, and highlights that claims should either **(1)** provide structural details of a machine learning model and specific hardware (e.g., "neurons organized in an array, wherein each neuron comprises a register, a microprocessor, and at least one input" and "synaptic circuits, each synaptic circuit including a memory for storing a synaptic weight, wherein each neuron is connected to at least one other neuron via one of the plurality of synaptic circuits") or **(2)** provide "proactive remediation" such as by "dropping [...] malicious network packets in real time" and "blocking future traffic from [a specific] source address."

- **USPTO Example 48** involves a system that separates speech from multiple speakers using a trained neural network. The example emphasizes that eligibility may be found in steps that **(1)** help solve a specific problem (e.g., using "cluster assignments to correspond to the sources identified in the mixed speech signal" to "provid[e] a particular speech-separation technique that solves the problem of separating speech from different speech sources belonging to the same class, while not requiring prior knowledge of the number of speakers or speaker-specific training") or **(2)** improve a downstream technology (e.g., "use[] both

temporal and spatial features of the speech signal" to "help[] a downstream conventional speech-to-text system reduce the gap in transcription performance for accented speakers over traditional speech-to-text methods").

- **USPTO Example 49** involves an AI model that classifies a glaucoma patient as being at high risk of post-implantation inflammation (PI), and administering "an appropriate treatment." The example clarifies that specificity as to medical condition and/or treatment can help provide patent eligibility. The example notes that if claims identify a specific treatment (e.g., "the appropriate treatment is Compound X eye drops"), then the claims are patent eligible based on provision of a "particular treatment for a medical condition" and therefore a "practical application."

- **USPTO Example 39** is an older USPTO example concerning a method for "creating" two "training set[s]" of "facial image[s]" and "training a neural network for facial detection" in two stages using the two training sets. The USPTO identified this claim as "eligible because it does not recite a judicial exception" – however, similar language in newer USPTO Examples 47–49 is not treated as leniently by the USPTO.

2. Software-Driven Medical Devices

Medical devices that rely on software, such as diagnostic apps or monitoring systems, must demonstrate a specific technological innovation rather than a mere automation of mental processes.

- ***SRI International, Inc. v. Cisco Systems, Inc.***, 930 F.3d 1295 (Fed. Cir. 2019), upheld claims related to "detecting [...] suspicious network activity" and "generating [...] reports of said suspicious activity." The court emphasized that the claims are 'directed to a technological solution to a technological problem," namely "providing a network defense system that monitors network traffic in real-time to automatically detect largescale attacks." Based on this decision, it may be helpful to focus claims on proactive actions undertaken in real-time by a medical device in response to detecting or recognizing something.

- ***Core Wireless Licensing S.A.R.L. v. LG Electronics, Inc.***, 880 F.3d 1356 (Fed. Cir. 2018), upheld claims directed to a graphical user interface as "not directed to an abstract idea." The claims concern "display[ing] a limited list of at least one function offered within the first application [...] selectable to launch the first application and initiate the selected function." The court noted that the "claims are directed to a particular manner of summarizing and presenting information in electronic devices," "a specific manner of displaying a limited set of information to the user," "an improved user interface for computing devices," and an "improvement in the functioning of computers, particularly those with small screens." Based on this decision, it may be helpful to focus claims on interactive aspects of a user interface that make the user interface easier to use given certain restrictions of the hardware.

- ***Finjan, Inc. v. Blue Coat Systems, Inc.,*** 879 F.3d 1299 (Fed. Cir. 2018) upheld claims related to a "providing computer security by scanning a downloadable and attaching the results of that scan to the downloadable itself in the form of a 'security profile'" that "enables more flexible virus filtering and greater user customization." The court concluded that the claims at issue represent "a non-abstract improvement in computer functionality" because they are directed to "employ[ing] a new kind of file that enables a computer security system to do things it could not do before" and that "allows access to be tailored for different users and ensures that threats are identified before a file reaches a user's computer." Based on this decision, it may be helpful to focus claims on new types of files, data structures, or functions that allows a medical device to provide a technical improvement.

- ***CosmoKey Solutions GmbH & Co. KG v. Duo Security LLC***, 15 F.4th 1091 (Fed. Cir. 2021) upheld claims concerning "multifactor authentication" for "authenticating a user to a transaction" "with fewer resources, less user interaction, and simpler devices." The court concluded that the claims at issue "constitute an improvement that increases computer and network security, prevents a third party from fraudulently identifying itself as the user, and is easy to implement and can be carried out even with mobile devices of low complexity." Based on this decision, it may be helpful to focus claims on techniques used to maintain or improve security, accuracy, or other functionality, even with lower-complexity devices.

- ***McRO, Inc. v. Bandai Namco Games America Inc.,*** 837 F.3d 1299 (Fed. Cir. 2016) upheld claims concerning "automatically animating lip synchronization and facial expression" based on a "set of rules that define output morph weight." The court found the claims non-abstract and patent-eligible because they are "limited to a specific process for automatically animating characters using particular information and techniques and does not preempt approaches that use rules of a different structure or different techniques." Based on this decision, it may be helpful to focus claims on rules or other details of automation techniques.

3. Diagnostic and Testing Methods

Testing and diagnostic methods present significant challenges under §101, particularly when claims are based on natural correlations or biological laws of nature. Courts have frequently struck down claims in this area as being directed to natural phenomena. However, claims that integrate these discoveries into specific applications with concrete steps may be found eligible.

- ***Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int'l Ltd.,*** 887 F.3d 1117 (Fed. Cir. 2018), upheld claims for a method of "treating a patient" who "is suffering from schizophrenia" "with iloperidone" "in an amount" that changes depending on whether "the patient has a CYP2D6 poor metabolizer genotype" or not. The court found that "the claims are patent eligible" because they "are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome," and thus "recite more than the natural relationship between CYP2D6 metabolizer genotype and

the risk of QTc prolongation." Based on this decision, it may be helpful to use claims reciting specific medical conditions, treatments, and/or dosages.

- ***XY, LLC v. Trans Ova Genetics, LC***, 968 F.3d 1323 (Fed. Cir. 2020), reversed a district court's finding of ineligibility, holding that "the asserted claims [...] are directed to a patent-eligible improvement to a method of sorting particles using flow cytometry technology, not to an abstract idea." The court notes that "[t]hough the asserted claims employ formulas to improve classification and separation of individual particles, the formulas operate to achieve the improved result of the claimed method only when combined with the specific detectors and other flow cytometry limitations in the claims." Based on this decision, it may be helpful to recite how specific hardware is used to implement a technological improvement.

- ***Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.***, 919 F.3d 1347 (Fed. Cir. 2019) upheld claims directed to "measuring a creatinine clearance rate of the patient" and "orally administering" "oxymorphone or a pharmaceutically acceptable salt," with "dosage" dependent on the measured "creatinine clearance rate." The court upheld these claims as patent-eligible because they "are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome" much like *Vanda*, not just diagnostics.

- ***Ariosa Diagnostics, Inc. v. Sequenom, Inc.***, 788 F.3d 1371 (Fed. Cir. 2015) and ***Ariosa Diagnostics, Inc. v. Sequenom, Inc.***, 809 F.3d 1282 (Fed. Cir. 2015) both concern "detecting a paternally inherited nucleic acid" in a sample. The court found that these claims are not patent-eligible because "the claims at issue [...] are generally directed to detecting the presence of a naturally occurring thing or a natural phenomenon" without "additional features that [are] new and useful," as the claimed process amounted to "nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients." Based on these decisions, it is important to focus claims on how, technically, any analyses and detections are performed.

- ***Illumina, Inc. v. Ariosa Diagnostics, Inc.***, 967 F.3d 1319 (Fed. Cir. 2020) upheld claims directed to "preparing a fraction of cell-free DNA" for analysis, noting that "[t]he claims do not cover a method for detecting whether a cell-free DNA fragment in a previously-prepared sample is fetal or maternal based on the natural size distribution of cell-free DNA fragments; rather, the claimed methods exploit that natural size distribution *during* the sample preparation steps to remove some maternal DNA from the mother's blood." Based on this decision, it can be helpful to focus claims on processes used to prepare cells or compounds for later diagnostic analysis.

- ***Association for Molecular Pathology v. Myriad Genetics***, Inc., 569 US 576 (2013) noted that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated," even though "isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule." The Supreme

Court added that "cDNA is patent eligible because it is not naturally occurring." The Supreme Court noted that "there are no method claims before this Court," and that "an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes" could potentially be patent-eligible.

- **USPTO Example 31** expands on the Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics*, Inc., 569 US 576 (2013) with hypothetical method claims. The USPTO notes that merely "comparing the patient's genetic sequence with wild type genetic sequences" "could be performed by a human using mental steps" and was thus patent-ineligible. The USPTO notes that adding or reciting "unconventional ways of gathering data" such as "hybridizing a wild-type probe to a BRCA1 gene isolated from a sample" or "amplifying by Cool-Melt PCR all or part of a BRCA1 gene" makes the claims patent-eligible.

- **USPTO Example 29** discusses methods for detecting a JUL-1 disease marker for autoimmune disease Julitis in a patient. Example claims that detail specific diagnosis techniques are noted to be patent-eligible (e.g., "detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting resultant binding between JUL-1 and the antibody," "by contacting the plasma sample with a porcine anti-JUL-1 antibody and detecting binding between JUL-1 and the porcine antibody," or "by contacting the plasma sample with antibody mAb-D33 and detecting binding between JUL-1 and antibody mAb-D33"). Example claims that also recite administration of treatment are noted to be patent-eligible (e.g., "administering an effective amount of topical vitamin D," "administering an effective amount of anti-tumor necrosis factor (TNF) antibodies").

4. Therapeutic Treatments

Methods of treatment have historically been more successful in overcoming §101 challenges because they typically apply natural laws in a specific and practical manner.

- ***Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.***, 887 F.3d 1117 (Fed. Cir. 2018), again stands as a leading case in this area, emphasizing that claims "directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome" are patent-eligible.

- ***Natural Alternatives International, Inc. v. Creative Compounds, LLC***, 918 F.3d 1338 (Fed. Cir. 2019), upheld claims for administering specific amounts of beta-alanine to enhance athletic performance. The court found that, "[a]lthough beta-alanine is a natural product," the claims "are not directed to ineligible subject matter" because they "specify a patient population to be treated" and "particular results to be obtained," and thus "contain specific elements that clearly establish they are doing more than simply reciting a natural law."

- ***Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.***, 919 F.3d 1347 (Fed. Cir. 2019) is important in this area as well, emphasizing that the claims are patent-eligible

because they "are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome."

- **USPTO Example 43** specifies that claims for "calculating a ratio of C11 to C13 levels measured in a blood sample from a patient" and "administering a treatment to the patient" are not patent-eligible, but become patent-eligible when a limitation is added specifying what the treatment is (e.g., "a non-steroidal agent capable of treating NAS-3," "rapamycin," or "a course of plasmapheresis").

- **USPTO Example 44** specifies that claims for a "dosage unit comprising denveric acid in a container" is not patent-eligible because denveric acid is naturally-occurring, but become patent-eligible when limitations are added specifying a "wearable delivery device" with "particular specified components such as [a] dosage control button, [a] delivery valve, and [a] needle assembly" because these are "non-nature based product limitation[s]," are "not recited at a high level of generality" and "an integral part of the claim," and thus ultimately represent a "practical application."

- **USPTO Example 29**, as noted above, specifies that claims reciting administration of treatment are patent-eligible (e.g., "administering an effective amount of topical vitamin D," "administering an effective amount of anti-tumor necrosis factor (TNF) antibodies").

- **USPTO Examples 11, 12, 13, 14, 15, 16, and 17** concern specific treatments, including Amazonic acid (Example 11), purified proteins (Example 12), genetically modified bacteria (Example 13), bacterial mixtures (Example 14), nucleic acids (Example 15), antibodies (Example 16), and cells (Example 17). The takeaway from these examples is that processed substances are not patent-eligible if they do not have "markedly different characteristics" than the version of the substance found in nature – but derivatives with "markedly different characteristics," such as structural differences, are patent-eligible.

5. Hardware

Methods of treatment have historically been more successful in overcoming §101 challenges because they typically apply natural laws in a specific and practical manner.

- ***CardioNet, LLC v. InfoBionic, Inc.***, 955 F.3d 1358 (Fed. Cir. 2020) reversed a district court's finding of ineligibility, holding that claims directed to a "device" that monitors "beat-to-beat timing of cardiac activity" and "generate[s] an event when the variability in the beat-to-beat timing is identified as relevant to [...] atrial fibrillation [or] atrial flutter" are patent-eligible because they are "directed to an improved cardiac monitoring device and not to an abstract idea," an provide "technological improvements" such as "more accurately detect[ing] the occurrence of atrial fibrillation and atrial flutter [...] and allow[ing] for more reliable and immediate treatment of these two medical conditions."

- ***Thales Visionix Inc. v. US***, 850 F.3d 1343 (Fed. Cir. 2017) upheld claims directed to two "inertial sensor[s]," one "mounted on [a] tracked object" and the other "on [a] moving reference frame," and an "element adapted to receive signals from" the sensors and "to determine an orientation of the object relative to the moving reference frame based on the signals." The Federal Circuit concluded that the claim is not abstract because it uses an "unconventional utilization of inertial sensors" that "mitigates errors," "works with any type of moving platform," "is simpler to install than conventional systems," and "is also beneficially self-contained."

- **USPTO Example 19** concerns a "hip prosthesis" with several recited structural features (e.g., "femoral component," "acetabular cup") and a limitation indicating that "the outer convex surface is coated with hydroxyapatite." The USPTO notes that, while "hydroxyapatite is a naturally occurring mineral," the claim is patent-eligible because "the claim clearly does not seek to tie up the mineral" and is [i]nstead [...] focused on the assembly of the femoral component and the cup that together form the hip prosthesis."

- **USPTO Example 20** concerns a "robotic arm assembly" with a "robotic arm having an end effector," a "sensor that obtains movement information about the end effector," and a "control system that uses the movement information from the sensor to adjust the velocity of the end effector in order to achieve a smooth motion." The USPTO notes that, while "[t]he claim operates using certain mathematical relationships," the claim is patent-eligible because "the claim clearly does not seek to tie up these mathematical relationships."

- **USPTO Example 44**, as noted above, specifies that claims reciting "denveric acid in a container" are not patent-eligible, but become patent-eligible when limitations are added specifying a "wearable delivery device" with "particular specified components such as [a] dosage control button, [a] delivery valve, and [a] needle assembly."

6. Conclusion

Navigating patent eligibility under 35 U.S.C. §101 for medical devices requires careful claim drafting and an emphasis on technological improvements. By structuring claims to highlight specific, non-conventional technical improvements in medical technology, and steering closer to claim language that has been previously held to be patent-eligible through caselaw and USPTO examples, applicants can improve the chances of securing patent protection while avoiding pitfalls associated with abstract ideas and natural laws. Staying informed about recent caselaw and USPTO guidance is essential for ensuring robust and defensible patent protection in this evolving landscape.