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Patent Eligibility of Software Inventions: An Overview of the Laws in Japan, Europe, and the United States – Part II

By Kamaram Munira

Despite attempts to harmonize patent laws worldwide, laws for determining the eligibility of software innovations vary from country to country. This two-part article describes and compares the patent eligibility laws of the United States, Japan, and the European Patent Convention to understand how the different patent eligibility laws influence patenting trends of software innovations. After a brief introduction, the first part, which was published in the May 2024 of the *Intellectual Property & Technology Law Journal*, reviewed the Japanese, European, and United States approaches. This conclusion compares the current Japanese, American and European approaches for examining eligibility of software patents and discusses patenting trends of software inventions in Japan, Europe, and the United States.

A COMPARISON BETWEEN THE CURRENT JAPANESE, AMERICAN, AND EUROPEAN APPROACHES FOR EXAMINING ELIGIBILITY OF SOFTWARE PATENTS

As the first part of this article highlighted, the Japanese, European, and American approaches for determining patent eligibility are similar in some parts while different in other parts. This section will go over the comparisons between each step of the American approach and the counterpart steps from the Japanese and European approaches.

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Comparison of Step 1 of the American Approach and European and Japanese Counterparts

Under step 1 of the American approach, the claimed invention must be to one of the four statutory categories defined in 35 U.S.C. §101 – a process, a machine, manufacturing of a matter, or a composition. For example, in an Office Action dated April 10, 2015, for U.S. Application No. 13/852,568, claim 14 was rejected for reciting a "computer product," which was defined in the specification as "tangibly embodied in an information carrier" that could include signals/carrier-waves.[1]

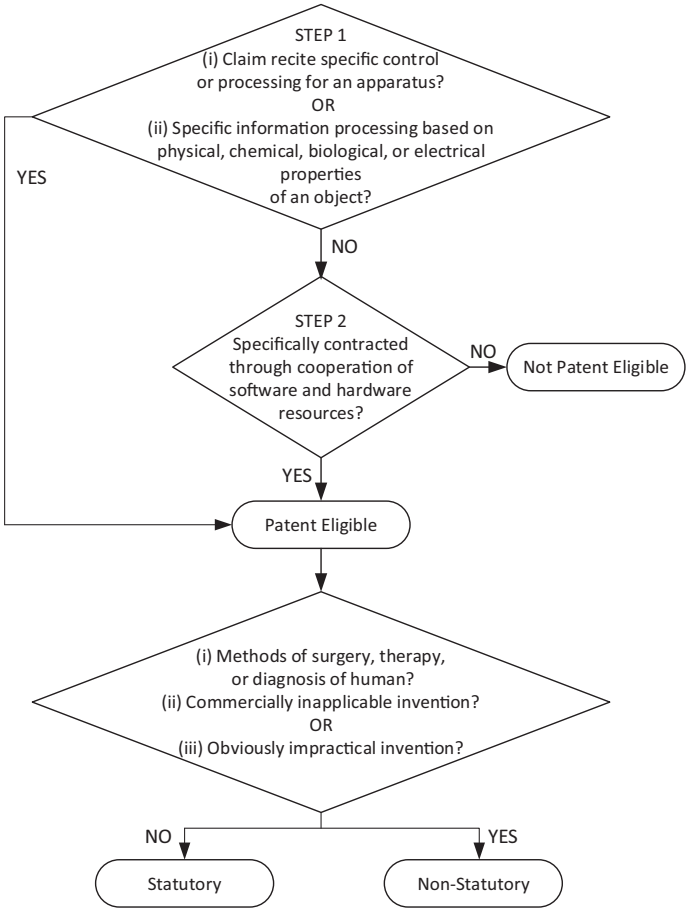
Under step 1 of the American approach, the claimed invention must be to one of the four statutory categories defined in 35 U.S.C. §101 – a process, a machine, manufacturing of a matter, or a composition.

The USPTO rejected the claim by alleging that signal/transitory media do not fall under any of the four statutory categories of 35 U.S.C. §101. In direct contrast, Article 29 of the Japanese Patent Act and Article 52(1) of the EPC takes a broader approach by requiring an "invention," which can comprise a computer product. Therefore, the USPTO rejected a claim that was allowed in counterpart European and Japanese applications by the EPO[2] and the JPO,[3] respectively.

Comparison of Step 2A, Prong I of the American Approach and European and Japanese Counterparts

Under Step 2A, Prong I of the American Approach, the claim is examined to evaluate whether any of the claim limitations recites an abstract idea, namely,

Figure 1- Framework for Determining Statutory Patents by the Japan Patent Office



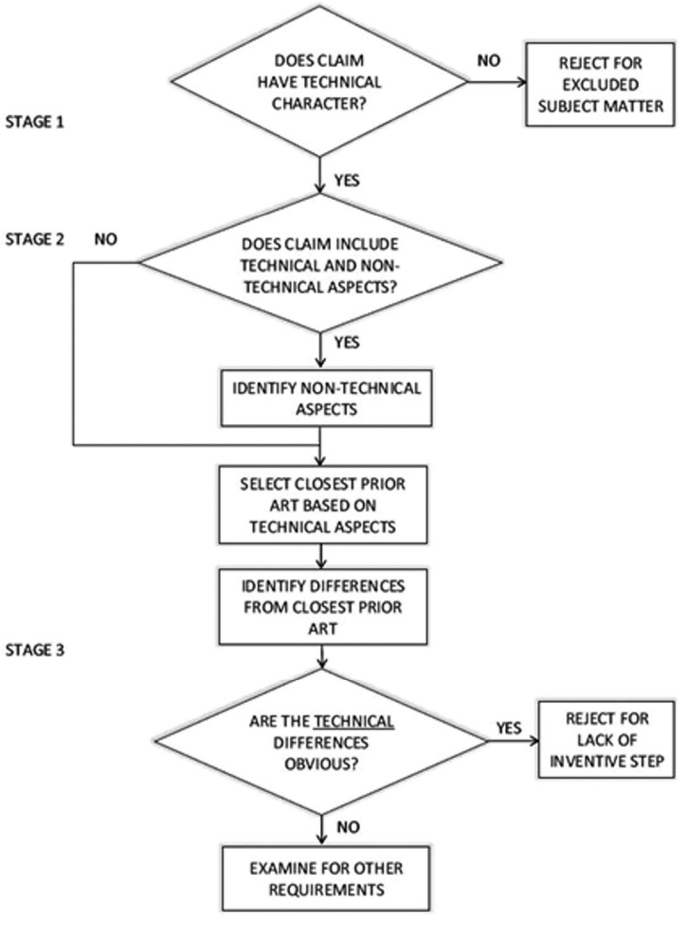
"mental processes," "mathematical concepts," [4] and "certain methods of organizing human activities."[5] Similar to the American approach, the Article 52(1) of the EPC lists subject matters that cannot be regarded as inventions, such as scientific theories (equivalent to laws of the nature in the American approach), discoveries (equivalent to natural phenomena in the American approach), and other subject matters that can be classified as abstract ideas in the American approach, such as mathematical methods, schemes, rules and methods for performing mental acts, and playing games or doing business.

However, the European approach does not have any step of identifying non-statutory subject matter like Step 2A, Prong I of the American approach. Rather, stage 1 of the European approach instructs the opposite by starting the patent eligibility examination to check whether the claim has any technical character. Only at stage 2 are the non-technical limitations separated from the technical limitations to continue examination with only the technical limitations at stage 3.

The European approach does not have any step of identifying non-statutory subject matter like Step 2A, Prong I of the American approach.

In its Examination Guidelines, Japan lists subject matters that can be classified as abstract ideas in the American approach, such as economic laws, rules for playing a game, mathematical formulas, mental activities of humans, and methods for businesses. However, the Examination Guidelines never attempt to identify the excluded subject matters.

Figure 2 - Framework for Determining Patent Eligibility by the European Patent Office



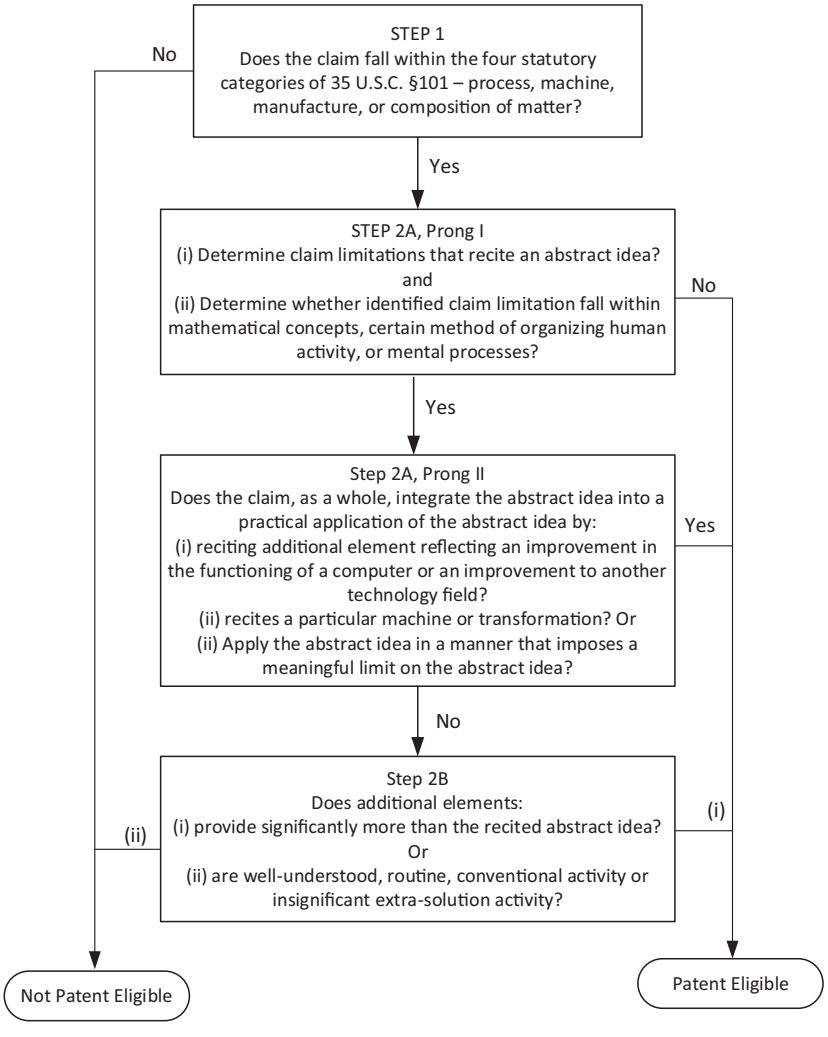
Comparison of Step 2A, Prong II of the American Approach and European and Japanese Counterparts

Under Step 2A, Prong II of the American approach, the claim is examined to determine if "the claim as a whole integrates the recited judicial exception into a practical application of that exception."[6] The claim "as a whole" means all limitations in the claim, including the claim limitations reciting abstract ideas (non-technical limitations in Europe) and additional limitations (technical limitations in Europe) that do not recite abstract ideas. A claim "as a whole" is integrated into a practical application if the claim reflects an improvement in the functioning of a computer, an improvement to another technology or technical field, recites a particular machine (other than a general computer), recites a particular transformation of an article to a different state or thing, or uses the abstract ideas in a manner that imposes a meaningful limit on the abstract ideas such that the claim is more than a drafting effort designed to monopolize the abstract idea.[7]

Like the American approach, steps 1 and 2 of the Japanese approach examine the claim as a whole.

The EPC looks for a technological improvement to determine whether the "technical character"[8] identified in stage 1 of the European approach produces a "further technical effect" when run on a computer.[9] The "further technical effect" is called

Figure 3 - Framework for Determining Patent Eligibility by the United States Patent and Trademark Office

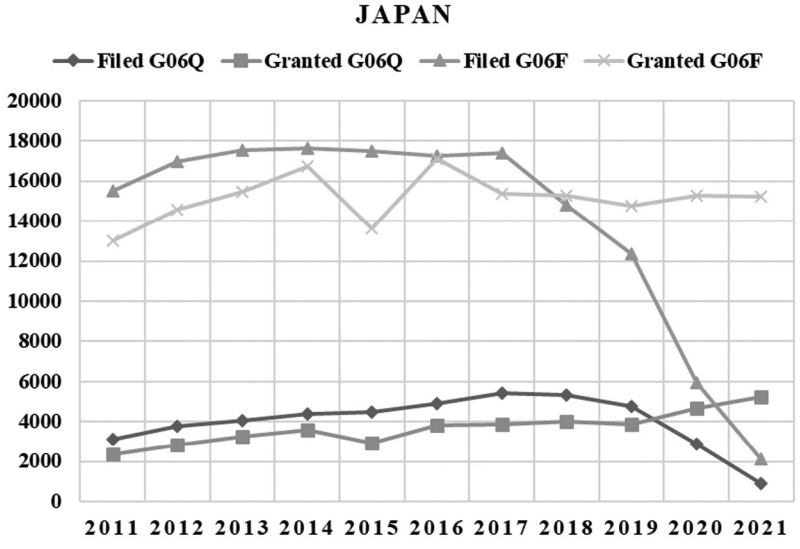


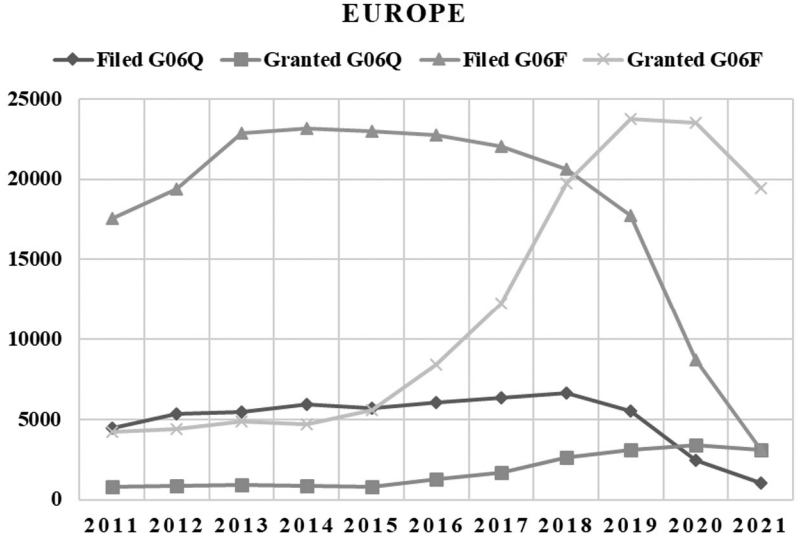
the "improvement in the functioning of a computer, or an improvement to other technology or technical field" by the USPTO such that the excluded subject matter is "practically applied."

However, in Japan, a skilled patent application draftsman would be able to overcome the patent eligibility hurdle by drafting claims taking the low bar requirements of steps 1 and 2 of the Japanese approach.

Like the American approach, steps 1 and 2 of the Japanese approach examine the claim as a whole. However, that is where the similarity ends. Rather than looking for a specific practical application like the one in the American Approach, the Japanese approach examines whether any specific device is being controlled, whether any technical properties of an object are being processed, or whether there is any coordination between the hardware and software in the claims. In the American approach, whether the claim is integrated into a practical application will depend on the technical details of the claimed invention. However, in Japan, a skilled patent application draftsman would be able to overcome the patent eligibility hurdle by drafting claims taking the low bar requirements of steps 1 and 2 of the Japanese approach.

Figures 4 & 5 - Patent Applications Filed in and Granted by the Japan Patent Office and the European Patent Office



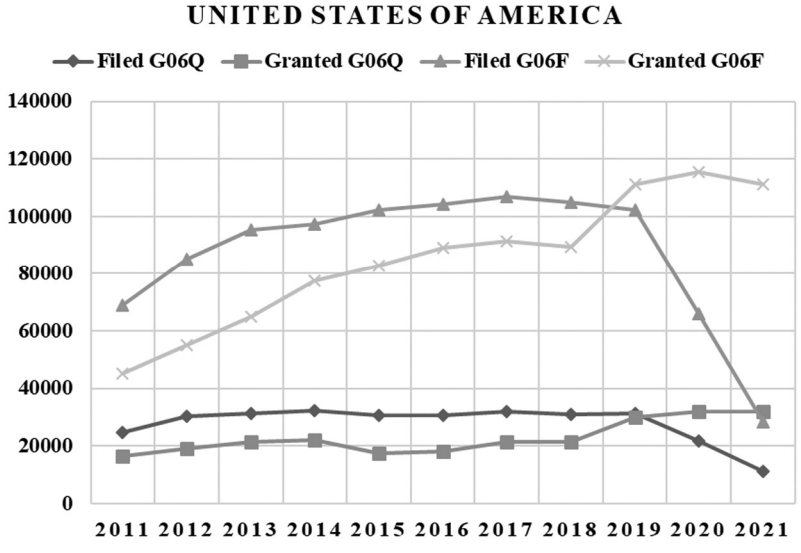


For example, when Japanese Patent Application No. 2014115682 was filed in 2014 (titled "Steak Delivery System"), claim 1 of the application recited:[10]

> A method of providing a steak comprising:
> guiding a customer to a table;
> determining an amount of steak from a customer;
> cutting the amount of steak found from a block of meat;
> baking the cut meat; and
> conveying baked meat to a customer table.

The above claim was rejected by the JPO as the claim did "not fall under the invention described in the main paragraph of Article 29 (1) of the Patent Act."[11] The claim was granted after the applicant amended claim 1 to recite "a weighing machine for weighing meat cut according to a request of the customer" and "a marking for distinguishing meat cut according to a request of

Figure 6 - Patent Applications Filed and Granted by the United States Patent and Trademark Office



the customer from other customers."[12] Following the grant of the patent, an opposition was filed against the patent, and the JPO held that grated claim 1 did not qualify for a patent under Article 2 of the Japan Patent Act.[13] However, the Japan Intellectual Property High Court rescinded the revocation on October 17, 2018, and justified the decision by stating that "the claimed invention . . . adopts a configuration including specific articles or equipment (devices) such as . . . a measuring device, and a sticker (mark)" and "adopting this configuration . . . prevent[s] confusion with meat for other customers is a solution to the problem of the claimed invention."[14] Just mentioning some articles such as a tag and a measuring device for weighting meat was enough for patent eligibility. However, such tags and measuring devices would fail to integrate the claim into a practical application under step 2A, prong I of the American approach.

Comparison of Step 2B of the American Approach and European and Japanese Counterparts

Under Step 2B of the American approach, the additional features (technical limitations in Europe) are examined to determine whether they amount "significantly more" than the identified abstract idea by being "unconventional in combination."[15] If the additional limitations just recite "well-understood, routine, conventional activity in the field" or "insignificant extra-solution activity," then the claim is not patent eligible.

Following the grant of the patent, an opposition was filed against the patent, and the JPO held that grated claim 1 did not qualify for a patent under Article 2 of the Japan Patent Act.

Japan does not have a corresponding step in its patent eligibility examination. However, Step 2B of the American approach is similar to the stage 3 of the European approach, where the closest prior art based on the identified technical features of the second stage are selected, and differences between the prior art and the identified technical features are identified to determine whether the identified technical features are non-obvious.[16] Claims are examined under Step 2B of the American approach if the claims fail to pass the Step 2A, Prong II requirement. However, the "inventive step" at stage 3 of the European approach is a required element for patent eligibility at the EPO.

PATENTING TRENDS OF SOFTWARE INVENTIONS IN JAPAN, EUROPE, AND THE UNITED STATES

This section will attempt to analyze how the developments of case law, policies, guidelines, and

statutes in these three jurisdictions affect the number of software patent applications filed in the three jurisdictions and the number of granted software patents. The data for the charts in Figures 4, 5, and 6 below have been extracted from *www.lens.org*.[17] As there is no precise definition of, or category for, software patents in these three jurisdictions, Figures 4, 5, and 6 represent the patent applications under the Cooperative Patent Classification (CPC)[18] codes G06F and GOQ, which are likely to be for software inventions. The CPC code G06F represents inventions that are drawn towards "electrical arrangements or processing means for the performance of any automated operation using empirical data in electronic form for classifying, analyzing, monitoring, or carrying out calculations on the data to produce a result or event."[19] The CPC class G06Q represents inventions that are drawn towards "data processing systems or methods, specially adapted for administrative, commercial, financial, managerial, supervisory, or forecasting purposes."[20]

Under Step 2B of the American approach, the additional features (technical limitations in Europe) are examined to determine whether they amount "significantly more" than the identified abstract idea by being "unconventional in combination."

While it might be expected that the number of granted patents change after a change of case law or patent policy that directly influences patent-eligibility requirements, the same consequences may not occur at the patent application level. Other factors may affect the number of filed patent applications. For example, the graphs in Figures 4, 5, and 6 clearly show fewer patent applications have been filed in 2020 and 2021, and the reason for the decreased filing may be the COVID-19 pandemic.[21] Still, the graphs in Figures 4, 5, and 6 may indicate trends in software patents from 2011 to 2021.

In Japan, the number of granted patents increases each year, in line with this "pro-software patent" stance of the Japanese patent law, the Japan Patent Office, and the Japanese courts. However, the number of patent applications filed in Japan has decreased since 2018 because the Japanese market for consumer electronics products has undergone significant technological and geographical disruption, with manufacturing and innovation markets moving to China and South Korea.[22] Europe has a stricter approach to the patent eligibility of software patents than Japan. In 2016, granted applications increased by 40% over 2015 in the EPO due to a series of reforms at the EPO for improving patent examination processes and efficiencies, which account for the upward swing of the grant rate of backlogged patent applications.[23] However, Figure 5 still indicates that granting software patents, at least those classified under CPC code G06Q, is stricter in Europe than in Japan.

This section will attempt to analyze how the developments of case law, policies, guidelines, and statutes in these three jurisdictions affect the number of software patent applications filed in the three jurisdictions and the number of granted software patents.

From 2010 to 2014, with *Bilski*,[24] *Mayo*,[25] and *Alice*,[26] the patent landscape partially changed as it became less easy to demonstrate patent eligibility, especially for software claims reciting abstract ideas, such as mental processes, business methods, and data processing. Figure 6 shows the effect of *Alice* with patent grants for CPC code G06Q (with claims drawn towards data processing for commercial, financial, managerial, supervisory, or forecasting purposes) decreasing by 20% from 2014 to 2015. However, the Alice decision did not substantially affect patent applications under CPC code G06F. The reason for this may be that patent applications under CPC code G06Q may be more prone to reciting abstract ideas than patent applications under CPC code G06F (with claims drawn towards electrical arrangements or processing for classifying, analyzing, monitoring, or carrying out calculations on data to produce a result or event). The data indicates that the standards of examination of patent eligibilities in the United States after the *Alice* decision, despite some uncertainties, have not been so difficult that they cannot be overcome, or the number of granted software patents would dramatically decrease.

However, the 2019 Guidance was issued by the USPTO in January 2019, followed by the 2019 Update in October 2019. As a result, the patent grant rates increased by 38% for G06F and 24.5% for G06Q from 2018 to 2019 and continued to increase in 2020 and 2021. The increased grants rates may be the result of the USPTO clarifying, for the first time since the *Alice* decision, confusion associated with the *Mayo-Alice* test. Therefore, the 2019 Guidelines improved consistency between patent eligibility examinations between different examiners.

CONCLUSION

Despite the rise of software-based technologies, the statutory basis, 35 U.S.C. §101, under which U.S. courts evaluate patent eligible subject matters, has remained unchanged since 1790. As a result, the U.S. Supreme Court and the CAFC have determined patent eligibility tests for software inventions without legislative input from the U.S. Congress. Most notably, the *Alice-Mayo* test from *Alice* has been criticized for its lack of clarity in determining patent eligibility. Fortunately, the 2019 Guidance from USPTO managed to clarify some of the confusions.

Despite the rise of software-based technologies, the statutory basis, 35 U.S.C. §101, under which U.S. courts evaluate patent eligible subject matters, has remained unchanged since 1790.

Unlike the United States, Japan has had clear guidelines for determining patent eligibility of software inventions since the early 2000s. However, Japan has a much lower bar for patent eligibility. Mere control of an apparatus, processing of technical properties, or some cooperation between hardware and software resources is enough to show patent eligibility. The European approach to determining patent eligibility is closest to the American approach after the issuance of the 2019 Guidance by the USPTO.

Although the 2019 Guidance was a step in the right direction, the federal courts are not bound by the 2019 Guidance by the USPTO.[27] Nevertheless, the straightforward analysis provided in the 2019 Guidance has already motivated Congress to consider amending 35 U.S.C. §101. The Patent Eligibility Restoration Act of 2023 has been proposed to clarify the statute and codify the exceptions identified by the U.S. Supreme Court.[28]

However before introducing the Patent Eligibility Restoration Act, the U.S. Congress, along with the USPTO, called from comments from the public weighing in on how the state of patent eligibility law in the United States has affected various industries and technologies in 2021.[29] The request drew in sharply divergent responses, including comments from giant software technology companies, such as IBM[30] and Google,[31] and prominent professional intellectual property organizations, such as the American Intellectual Property Law Association (AIPLA)[32] and the Intellectual Property Owners Association (IPO).[33]

IBM, argued that eligibility rulings by the federal courts "unnecessarily generate wide uncertainty" about the validity of software patents.[34] IBM further commented that "innovators are less likely to file patent applications in the United States and are less likely to enforce their patents in the U.S." because of the current confusion in the patent eligibility case law.[35] AIPLA commented that the *Mayo-Alice* test is causing "detrimental results" and "the current jurisprudence has narrowed the pipeline for inventions that are patent eligible under U.S. law, while applicants in other key jurisdictions, specifically China and Europe, are obtaining patent protection on applications claiming the same inventions."[36]

American businesses and innovators are divided about the state of the current laws for patent eligibility for software patents.

In direct contrast, Google commented that the current "patent law in particular strikes the right balance to protect true technological advances while making sure that abstract ideas do not hinder follow-on research."[37] Google further commented that *Alice* did not make it more difficult for Google to obtain patents on emerging technologies, because Google ensured that it provided enough detail in its patent applications.[38] The Internet Association, whose members include Amazon and Microsoft,

argued that the Supreme Court's patent eligibility test "leads to sound, predictable outcomes in the courts" and "there is no need for any alteration or abrogation of patent eligibility jurisprudence."[39] The High Tech Inventors Alliance, which includes Intel, Samsung, and Adobe, commented that its member "unanimously and unequivocally reject the suggestion that there has been a significant diminution in the availability of appropriate patent protection for software-related inventions" and claims critics of the *Alice* ruling as "speculative, overblown or simply inaccurate."[40]

The comments show that American businesses and innovators are divided about the state of the current laws for patent eligibility for software patents.

The comments show that American businesses and innovators are divided about the state of the current laws for patent eligibility for software patents. However, Google made a good point about drafting better applications with adequate technical details. The most affected software patents, especially in the federal courts or post-grant proceedings at the USPTO, where the software patents are put under stricter scrutiny, are poorly drafted or have superficial disclosures without many technical details. Carefully drafted applications and claims with adequate technical details can successfully get past the difficulties in the examination procedure of patent eligibility.

Notes

1. U.S. Patent Application Serial No. 13/852,568, ¶ [0072] (filed March. 3, 2013).
2. EP Patent No. 2976719A4.
3. JP Patent No. 6470735B2.
4. MPEP §2106.04(II)(1).
5. 2019 Guidance at 51-52.
6. 2019 Guidance at 53.
7. MPEP §2106.05(a-c),(e).
8. EPO Guidelines, sec. 2.
9. Id., sec. 3.6.
10. JP Patent Application Serial No. 2014115682, Claims (TRANSLATED) (filed Jun. 4, 2014), https://globaldossier.uspto.gov/#/details/JP/2014115682/A/126031.
11. Notice of Reasons for Refusal (TRANSLATED for) for JP Patent Application Serial No. 2014115682 (dated Sep. 9, 2015), https://globaldossier.uspto.gov/#/details/JClaimsP/2014115682/A/126031.
12. Written Amendment (TRANSLATED for) for JP Patent Application Serial No. 2014115682 (dated Nov. 26, 2015), https://globaldossier.uspto.gov/#/details/JClaimsP/2014115682/A/126031.
13. JPO revokes Ikinari steak's steak serve method patent, https://www.sakamotopat.com/en/news/357news.html.
14. See Intellectual Property High Court, October 17, 2018, p. 97, 2019 (Gyo-Ke) 102104.
15. 2019 Guidance at 56.
16. EPO Guidelines, sec. 5.4.
17. See O.A. Jefferson, D., Koellhofer, B. Warren, and R. Jefferson, The Lens MetaRecord and LensID: An open identifier system for aggregated metadata and versioning of knowledge artefacts (2019), https://doi.org/10.31229/osf.io/t56yh.
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22. Kenichi Nakajima, How pursuing patents in Japan has evolved over the past decade (June 19, 2020), https://clarivate.com/ip-asia-2020/how-pursuing-patents-in-japan-has-evolved-over-the-past-decade.
23. https://www.epo.org/about-us/annual-reports-statistics/annual-report/2016/statistics/granted-patents.html.
24. See Bilski, 561 U.S. at 612.
25. See Mayo Collaborative Servs., Inc., 566 U.S. at 73.
26. See Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. at 224.
27. See Cleveland Clinic Foundation v. True Health Diagnostics., 760 Fed. Appx. 1013 (Fed. Cir. 2019).
28. S.2140 - 118th Congress (2023-2024): Patent Eligibility Restoration Act of 2023, S.2140, 118th Cong. (2023), https://www.congress.gov/bill/118th-congress/senate-bill/2140.
29. Patent Eligibility Jurisprudence Study, 86 Fed. Reg. 36257 (Jul. 9, 2021).
30. See IBM 2021 Comments to USTPO on Eligibility (Oct. 2021), https://www.regulations.gov/comment/PTO-P-2021-0032-0078 (hereinafter IBM).
31. See AS SUBMITTED 10-15-21 Google Comment on USPTO Patent Eligibility RFI - Google Docs (Oct. 2021), https://www.regulations.gov/comment/PTO-P-2021-0032-0106 (hereinafter Google).

32. See AIPLA Comment USPTO on Section 101 Jurisprudence FINAL 101521 (Oct. 2021), https://www.regulations.gov/comment/PTO-P-2021-0032-0108 (hereinafter AIPLA).
33. See IPO Comments to USPTO on Patent Eligibility FINAL (Oct. 2021), https://www.regulations.gov/comment/PTO-P-2021-0032-0117.
34. IBM at 2.
35. Id. at 3.
36. AIPLA at 3.
37. Google at 2.
38. Id. at 3.
39. See Comments Submitted by Internet Association, 3, 9 (Oct. 2021) https://www.regulations.gov/comment/PTO-P-2021-0032-0083.
40. HTIA comments on USPTO patent eligibility, 12, 21 (Oct. 2021), https://www.regulations.gov/comment/PTO-P-2021-0032-0127.

Bipartisan Legislation Seeks to Clarify the Inventions That Are Patent Eligible

By Alicia Umpierre, Hin Au, Dawson Wong, Derrick D. Rowe and Chris W. McAndrew

The U.S. patent system is based upon a quid pro quo balance that incentivizes innovation via a time-limited patent exclusivity, while encouraging the dissemination of new ideas for public benefit and use upon expiration of the patented innovation. However, for some innovative technologies, such as personalized medicine, diagnostics, and artificial intelligence (AI), case law developed within the past decade has made obtaining patent protection increasingly difficult. This has led to a lack of clarity and incentive for some innovators to develop technologies that may not be eligible for patent protection.[1]

In an attempt to restore the balance of the patent system and provide clarity to innovators in these technologies, U.S. Senators Thom Tillis (R-NC) and Chris Coons (D-DE) have introduced the Patent Eligibility Restoration Act of 2023 (PERA).[2] The PERA has been referred to the Senate Judiciary Subcommittee on Intellectual Property, which recently held a hearing featuring witnesses largely in favor of patent eligibility reformation.[3] As discussed further below, passing of the PERA would reverse current patent eligibility case law and replace it with a framework for determining whether an invention is eligible for patent protection.

CURRENT PATENT ELIGIBILITY JURISPRUDENCE

The requirement for patent eligible subject matter is set forth in Section 101 of the Patent Act (Section 101). This section provides four statutory categories that are eligible for patenting: process, machine, manufacture, and composition of matter. Although not enumerated in the statute, the U.S. Supreme Court has held that these statutory categories contain an implicit exception for laws of nature, natural phenomena, and abstract ideas, referred to as "judicial exceptions."

To determine whether or not an invention is eligible based on the judicial exceptions, the Court set forth a two-step framework in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l* (2014) (*Alice* two-step framework). The first step requires determining whether or not the claimed invention is directed to one of the "judicial exceptions." If the answer is no, the claimed invention is patent eligible. If the answer is yes, the second step requires determining whether or not the elements of the claimed invention "transform the nature of the claim" into a patent-eligible application. Step two is described by the Court as a "search for an 'inventive concept'" to ensure the claimed invention is significantly more than a patent on the judicial exception itself. Claimed inventions that do not satisfy the second step are deemed patent-ineligible.[4]

The application of the *Alice* two-step framework has led to confusion among innovators, patent attorneys, and the courts. The uncertainty in determining patent eligible subject matter has prompted judges from the U.S. Court of the Appeals for the Federal Circuit (the appellate court with jurisdiction over patent matters) to explicitly request guidance with respect to the meaning of Section 101.[5] The U.S. Patent and Trademark Office (USPTO) has similarly acknowledged the lack of consistency, clarity, and the effect of the current framework on emerging innovations in the United States:

> [W]e need clear intellectual property laws that incentivize innovation, especially in key and emerging technology areas and from small to medium-sized enterprises, protect that innovation, and bring that innovation to impact including by incentivizing and protecting investment. This is critical for job creation, opportunity, economic prosperity and U.S.

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competitiveness. It is also necessary to incentivize our brightest minds and greatest companies to solve world problems.[6]

The USPTO Report to Congress also summarized comments from innovators and patent practitioners who expressed concern that the current framework "mak[es] patents less available and rights less predictable, inhibits investment in new technologies and companies." Start-up, small, and medium-sized companies indicated that the current framework "undermines innovation by decreasing the availability of private risk capital and works to concentrate markets in the hands of a few large, well-resourced incumbents." Proponents of the current framework argue that it enhances access to present medical technologies and reduces litigation.

The overall theme of the USPTO Report to Congress was that "stakeholders generally agreed that the law on patent eligibility needs to be clear, predictable, and consistently applied."

The overall theme of the USPTO Report to Congress was that "stakeholders generally agreed that the law on patent eligibility needs to be clear, predictable, and consistently applied."[7]

PATENT ELIGIBILITY RESTORATION ACT OF 2023

In view of the confusion and inconsistencies in applying the *Alice* two-step framework, U.S. Senators Tillis and Coons introduced the Patent Eligibility Restoration Act of 2023 (PERA). The PERA aims to incentivize innovation and provide clarity for innovative companies, while addressing concerns over the patenting of ideas and the discovery of what already exists in nature. The approach is to eliminate judicial exceptions, and instead provide a specific list of subject matter that is not patentable. The PERA would amend Section 101 as follows:

> *(a) In General.*—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 *only* to the *exclusions in subsection (b) and to the further* conditions and requirements of this title.

The term "useful" means that an invention or discovery has a specific and practical utility from the perspective of a person of ordinary skill in the art to which the invention or discovery pertains.

The exceptions to patent eligibility in subsection (b) are:

1. "[a] mathematical formula that is not part of a claimed invention in a category described in subsection (a)";

2. "a process that is substantially economic, financial, business, social, cultural, or artistic, even though not less than 1 step in the process refers to a machine or manufacture" unless "the process cannot practically be performed without the use of a machine or manufacture";

3. "[a] process that— '(i) is a mental process performed solely in the human mind'; or '(ii) occurs in nature wholly independent of, and prior to, any human activity'";

4. "[an] unmodified human gene, as that gene exists in the human body"; and

5. "[an] unmodified natural material, as that material exists in nature."

With respect to (2), the PERA clarifies that adding a nonessential reference to a computer by merely stating the use of a computer shall not confer eligibility. The PERA further clarifies that any process described in (2) shall be eligible if the process cannot practically be performed without the use of a machine (including a computer) or manufacture.

With respect to exceptions (4) and (5), the PERA clarifies that "a human gene or natural material shall not be considered to be unmodified" and thus not an enumerated exception to eligibility, if the human gene or natural material is "isolated, purified, enriched, or otherwise altered by human activity" or "otherwise employed in a useful invention or discovery."

The PERA also provides guidance as to how to evaluate a claimed invention for eligibility, stating that the claimed invention should be considered "as a whole and without discounting or disregarding any claim element" and without regard to:

(1) "the manner in which the claimed invention was made;"

(2) "whether a claim element is known, conventional, routine, or naturally occurring;"

(3) "the state of the applicable art, as of the date on which the claimed invention is invented;" or

(4) "any other consideration in [the other sections of the Patent Act:] section 102, 103, or 112."

Thus, the PERA not only replaces the current judicial exceptions for those enumerated in the bill, but also eliminates the search for an "inventive concept" in the second step of the *Alice* two-step framework. The "inventive concept" requirement is considered by many to conflate two separate requirements of the Patent Act: Section 101 (patent eligibility) and Section 103 (obviousness).

PATENT STRATEGIES FOR INNOVATORS

Supporters of the PERA argue that this bill brings much needed clarity to Section 101 that will instill the confidence innovators need to invest in areas such as medical diagnostics, personalized medicine, AI, and computing.[8] The PERA would also more closely align patent eligibility requirements in the U.S. with those standards adopted by many non-U.S. countries/jurisdictions for examining biotechnology inventions.

If the PERA is passed, diagnostic inventions will likely be afforded a significantly broadened scope of patent eligibility. For example, diagnostic methods that involve laboratory measurements will likely be patent-eligible, as such methods do not encompass a mental process performed solely in the human mind (exception (b)(C) in the PERA). Accordingly, in order to encompass patent-eligible subject matter, diagnostic claims would no longer require additional claim elements to satisfy step two of *Alice*, e.g., recite a combination of nonabstract steps that is not well-understood, routine, and conventional, such as administering therapeutic or prophylactic treatments, which can pose issues for proving patent infringement.

If passed, the PERA is also expected to have a significant impact on inventions relating to software, algorithms, business methods, and generally any computer-related or computer-implemented inventions, which are generally subject to heightened eligibility review under the current Section 101. Companies developing AI/machine learning (ML)-based inventions should consider that even if legislation were to be passed that grants a broader scope of eligibility under Section 101, AI/ML-based inventions are still subject to laws that require an inventor to be a person. Accordingly, an AI/ML-based invention that meets eligibility under Section 101, as well as the requirements under Sections 102, 103, and 112, may not be patentable if the AI/ML-based invention was generated by an AI model without a person providing substantial involvement or inventive contributions in the discovery process. While Section 101 eligibility and inventorship considerations have traditionally been two separate inquires, it is foreseeable that these issues may have intersecting roles to play in clarifying patentability of AI/ML-based inventions, which comes at a crucial time as AI/ML technologies and their applications grow exponentially. AI/ML innovators in various fields (including technology and life sciences) are advised to work with patent counsel to monitor Section 101 legislation and inventorship guidance, and to modify their patent strategies accordingly for optimal success in obtaining patents.

Although this bill is still pending in the Senate, companies should consider the PERA, and any amendments to the PERA, when evaluating their current patent portfolio, future innovations, and patent application filings. With respect to pending patent applications, companies who face current rejections under Section 101 (for example, medical diagnostic claims) may consider slowing examination and at least maintaining a pending

U.S. patent application should this bill pass into law. Similarly, companies that may face a potential challenge on patent eligibility may consider delaying litigation or selecting a venue with a longer disposition time.

Companies should also consider the impact this law may have on their freedom to operate strategies, since passage of this law (if passed in its current form) would likely lead to a significant number of inventions found eligible, and a corresponding increase in number of third-party patents in the fields that companies operate. With respect to future patent application filings, companies are advised to work closely with patent counsel to anticipate future modifications to Section 101, and to structure patent application filings (and claims) in anticipation of possible Section 101 modifications, e.g., by ensuring that inventions do not fall under any of the exceptions to patent eligibility as enumerated under the PERA, or current case law.

Notes

1. 2022 USPTO Report to Congress: Study by "Patent eligible subject matter: Public views on the current jurisprudence in the United States."
2. https://www.congress.gov/bill/118th-congress/senate-bill/2140/text.
3. https://www.judiciary.senate.gov/committee-activity/hearings/the-patent-eligibility-restoration-act_restoring-clarity-certainty-and-predictability-to-the-us-patent-system.
4. Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208 (2014).
5. https://crsreports.congress.gov/product/pdf/LSB/LSB10344/5.
6. 2022 USPTO Report to Congress: Study by "Patent eligible subject matter: Public views on the current jurisprudence in the United States."
7. Id.
8. https://www.judiciary.senate.gov/committee-activity/hearings/the-patent-eligibility-restoration-act_restoring-clarity-certainty-and-predictability-to-the-us-patent-system.

Patentability of Diagnostic Methods in the United States and Abroad – Part II

By Jacquelyn Pariseau, Hadia S. Ahsan, Haley S. Ball, Shoshana Marvin and Gaby L. Longsworth

In this two-part article, the authors summarize the current landscape for subject matter eligibility of diagnostic methods in the United States and abroad. In the first part, which was published in the May 2024 issue of the Intellectual Property & Technology Law Journal, *the authors discussed the Supreme Court's* Mayo/Alice *Test and explained that purely diagnostic claims continue to be held patent ineligible in the United States. In this conclusion, the authors explore the patentability of diagnostic methods in ex-U.S. jurisdictions.*

This article now provides parameters for subject matter eligibility of diagnostic methods in ex-U.S. jurisdictions, which may provide guidance for applicants and practitioners. Generally, many jurisdictions explicitly exclude diagnostic methods by statute, particularly in vivo diagnostic methods. However, some of these jurisdictions do provide exceptions. Namely, some jurisdictions permit in vitro and ex vivo methods and/or methods that merely provide intermediate results.

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PATENTABILITY OF DIAGNOSTIC METHODS IN NON-U.S. JURISDICTIONS

The intellectual property (IP) laws of some jurisdictions have drastically different approaches towards diagnostic methods, which can be challenging for applicants and practitioners. Israel, for example, allows diagnostic methods to be patented, subject to certain exceptions. By contrast, China, Europe, and Japan exclude diagnostic methods from patentability by statute. A nuanced understanding of ex-U.S. laws, along with carefully drafted claims, can help applicants protect their IP abroad.

Countries Where Diagnostic Methods Are Generally Patent Eligible

Australia

Under Australian law, an invention may be considered patentable subject matter if it is a manner of manufacture. In *National Research Development Corp. v. Commissioner of Patents (NRDC)*, the court laid out two general principles for establishing a manner of manufacture: (1) the invention must be an artificially created state of affairs, and (2) the invention must have economic utility.[1]

Up until 2015, the Australian Patent Office routinely permitted claims directed to isolated nucleic acid sequences. However, this changed as a consequence of the Australian High Court's decision in *D'arcy v. Myriad Genetics* (2015) (*Myriad Genetics*).[2] The claims at issue in *Myriad Genetics* were directed to an isolated nucleic acid comprising a mutated *BRCA1* gene (the presence of which is correlated with an increased likelihood of developing breast or ovarian cancer). In that

decision, the High Court held that naturally-occurring DNA sequences could not be validly made the subject of patent protection in Australia, even when extracted and isolated from a nucleus of a cell by human involvement.

Specifically, while formulated as claims to a product (a nucleic acid molecule), the High Court found the substance of the invention was the information embodied in the nucleotides of the molecule and that this information was an inherent part of the molecule and not created by human action. As such, claims directed to naturally occurring isolated nucleic acid sequences are no longer patent eligible. Notably, the High Court's decision was confined to naturally occurring isolated nucleic acid sequences, not all isolated naturally occurring substances (as in the U.S.). Therefore, claims directed to isolated protein sequences, for example, were not impacted. Likewise, claims to synthetic or modified nucleic acid sequences remain patent eligible, as do methods of detecting disease (e.g., cancer) using gene sequence information.

In reaching its decision, the Federal Court compared the claims at issue to those considered in *D'Arcy v. Myriad Genetics Inc.*

The Federal Court of Australia (equivalent to the U.S. Court of Appeals for the Federal Circuit) applied longstanding NRDC patent eligibility principles in *Ariosa Diagnostics, Inc. v Sequenom, Inc.*,[3] and affirmed the patentability of Sequenom's non-invasive pre-natal diagnostic method. The invention related to a method for detecting cffDNA in a serum or plasma sample of a pregnant woman. Ariosa contended that the claimed invention was not patent eligible because it involved using known methods and human interactions to detect natural phenomena. The Federal Court disagreed, finding that the substance of the invention was not the cffDNA itself, or the observation of the presence of cffDNA, but rather a new method for detecting fetal DNA without the need for invasive sampling. Accordingly, the Federal Court concluded that Sequenom's diagnostic method was patentable.

In reaching its decision, the Federal Court compared the claims at issue to those considered in *D'Arcy v. Myriad Genetics Inc.*[4] The Federal Court distinguished the claims in *Ariosa Diagnostics* as a method of diagnosis and the claims in *Myriad Genetics Inc.* as mere information that did not define a manner of manufacture. In sum, diagnostic methods that relate to the practical application of a natural phenomenon, e.g., a diagnostic that applies a method of detecting isolated nucleic acid sequences, rather than just the natural phenomena itself are patentable subject matter in Australia.

New Zealand[5]

Similar to Australia, the New Zealand Patent Office and courts consider an invention to be patentable subject matter if it is a manner of manufacture in accordance with the principles set out in *NRDC* (above). However, in contrast to Australia, the New Zealand Patents Act 2013 expressly excludes[6] from eligibility, claims directed to methods of medical treatment of humans by surgery or therapy – as well as claims directed to methods of diagnosis of humans. Methods performed on non-human animals, however, are not excluded. As such, procedures carried out in vitro, exclusively outside the body, or on a dead body, are not excluded. Methods of diagnosis performed on tissues or fluids that have been permanently removed from the body, therefore, are not excluded.

Under New Zealand law, a diagnostic method must attribute a "clinical picture" to a patient, which includes identifying the presence or absence of a disease state. Examples of diagnostic methods, which would generally not be excluded, are as follows:

- Methods of determining a person's general condition, such as their general state of fitness;
- Methods of imaging, such as CT scanning, without any step of identifying a disease or condition;
- Methods of measuring a parameter in a sample, such as blood glucose;
- Methods of assessing tissue viability by measuring total hemoglobin, oxygen saturation and hydration;
- Methods of determining ear temperature;

- Methods of imaging an artery in a patient using magnetic resonance imaging, without any step or identifying a disease or condition;

- Methods of measuring oxygen uptake in the lungs; and

- Methods performed in vitro or ex vivo on cells tissues or fluids permanently removed from the body, such as DNA testing.

For completeness, no New Zealand court (nor the New Zealand IP Office) has addressed whether genes or genetic sequences are patent eligible. Therefore, claims to isolated nucleic acids or isolated polypeptides continue to be patent eligible subject matter. A claim to a diagnostic method relating to the practical application of a natural phenomenon, such as an isolated nucleic acid sequence, may be patent eligible in New Zealand provided the method is not practiced on a human.

Canada

In Canada, diagnostic methods are generally patent eligible. Prior to 2020, the Canadian Intellectual Property Office (CIPO) drew a distinction between a diagnostic method that "solves a data acquisition problem" and one that "solves a data analysis problem," with only the former method being patentable. However, CIPO has broadened its interpretation of patent eligibility in the medical diagnostics field following *Choueifaty v. Canada (Attorney General)* (*Choueifaty*), wherein the Federal Court held that the "problem-solution" approach described earlier was improper when determining subject-matter eligibility.[7] The Federal Court emphasized that patent claims must be interpreted using established principles of purposive construction (i.e., claim construction) when assessing subject matter eligibility.

After *Choueifaty*, CIPO provided further guidance on determining subject matter eligibility via purposive construction and subject matter identification.[8] Purposive construction requires looking to the specification and (i) determining what a person skilled in the art would understand to be the nature of the invention, and (ii) identifying the "essential elements" of a claim. In purposive construction, examiners presume all claim elements are essential unless (i) established otherwise, or (ii) contrary to the claim language. Next, examiners determine whether the claimed subject matter falls into a category of patentable subject matter defined in Section 2 of the Patent Act. Per Section 2, an invention must be an art, process, machine, manufacture, or composition of matter, or an improvement in one of the foregoing, and must not be a mere scientific principle or abstract theorem.

A medical diagnostic method claim typically includes an element that correlates an analyte or medical test result with a disease. This correlation is generally considered to be an abstract idea, which is not patentable; however, an abstract idea that cooperates with other elements that (i) have a physical existence, or (ii) manifest a discernible physical effect or change, may constitute patentable subject matter.

In sum, diagnostic methods are generally patentable in Canada if the claims include a physical means for testing, identifying, detecting, measuring, or otherwise acquiring data. Whether computer-implemented inventions are patentable subject matter in Canada remains unanswered, however.[9]

Israel

Section 7 of the Israel Patents Law, 1967, states that "[n]o patent shall be granted for a method of therapeutic treatment on the human body." This provision's intent is to protect physicians from infringing patent claims for treating their patients. However, diagnostic methods are generally considered patentable because they do not constitute "treatment of the human body."[10]

For example, the following claim is patent eligible:

1. An assay for the diagnosis of a mental disorder in an individual, comprising:

    a) obtaining a sample from said individual, being a blood sample, a platelet-containing fraction thereof, or a fraction containing platelet-associated antibodies (PAA) shed from the platelets;

    b) contacting said sample with anti-human immunoglobulin antibody lacking the Fc domain (Fc-less anti-hIg antibody); and

    c) determining the degree of binding of said antibodies of to the PAA in said sample,

> a degree of binding above that found in normal individuals indicating that said individual has a high likelihood of having a mental disorder.[11]

According to the ILPTO's Examination Guidelines,[12] where a claim is directed to a multi-step process that includes one or more therapeutic steps, the intended purpose of the process and its essential features need to be examined. If the intended purpose of the process is diagnostic, rather than therapeutic, one or more therapeutic steps would not prejudice the patentability of the claimed process.[13] As an example, the ILPTO Examination Guidelines provide that the following claim would not contravene Section 7(1) of the Patents Law:

> A method of monitoring cancer therapy in a subject comprising the steps of (i) administering to a subject in need thereof at least one compound according to claims 1-19 in a diagnostic imaging amount in combination with therapeutically active compound of choice, and (ii) performing diagnostic imaging using PET by detecting a signal from said at least one compound to follow the course of cancer therapy.

Mexico

In vitro and ex vivo diagnostic methods are patentable in Mexico. However, Article 49, Section IV of the Federal Law for the Protection of Intellectual Property (FIPPL) excludes in vivo methods, i.e., diagnostic methods that directly affect or apply to human or animal bodies. Accordingly, eligible method claims cannot include a step of obtaining a body sample by an invasive procedure.[14]

However, in vivo methods that generate intermediate results that do not include a diagnostic step (e.g., a method of measuring blood glucose levels without correlating a diagnosis), are patent eligible, even if they are in vivo.[15] For example, the following claims describing methods of detecting ascorbic acid in urine samples of a subject are patent eligible:[16]

> 1. A method of detecting ascorbic acid in a urine sample from a subject, characterized in that it comprises: contacting at least a portion of the urine sample with a test strip comprising a reagent pad including one or more compounds configured to react with an analyte in the urine sample and thereby produce a change in an intensity of color on the reagent pad; detecting whether the analyte is present by measuring the intensity of color on the reagent pad, wherein an increase in the intensity of color in the reagent pad after the contacting relative to before the contacting indicates a presence of the analyte; and detecting whether ascorbic acid is present in the urine sample by measuring the intensity of color on the reagent pad, wherein a reduction in the intensity of color on the reagent pad after the contacting relative to before the contacting indicates a presence of ascorbic acid.
>
> 7. A method of detecting ascorbic acid in a urine sample with a test strip comprising a reagent pad including one or more compounds configured to react with an analyte in the urine sample and thereby produce a change in an intensity of color on the reagent pad, the method characterized in that it comprises: measuring, with electronics of an optical inspection apparatus, a first intensity of color from the reagent pad; contacting the test strip with at least a portion of the urine sample; measuring, with the electronics of the optical inspection apparatus, a second intensity of color from the reagent pad; detecting the analyte in the urine sample when the first intensity of color is less than the second intensity of color; and detecting ascorbic acid in the urine sample, the detecting comprising determining that the second intensity of color from the reagent pad is less than the first intensity of color.

In sum, (1) in vitro or ex vivo diagnostic method claims are patentable in Mexico, and (2) in vivo method claims are patentable in Mexico, if they exclude a diagnostic (interpretation) step.

Countries Where Diagnostic Methods are Generally Patent Ineligible

Brazil

The Brazilian Industrial Property Law states that diagnostic methods for use on the human or animal body are not considered inventions;[17] therefore, they are not patent eligible. According

to Brazilian Patent Application Examination Guidelines, diagnostic methods are not considered inventions if they: (i) directly apply to a human or animal body, and (ii) facilitate (1) conclusive determination of the patient's clinical condition, or (2) indicate probable clinical conditions.[18] As such, methods of obtaining data from a human or animal body are considered inventions if the collected data represents intermediate results that – alone – are insufficient for determining a clinical condition or probable condition.

The Brazilian Industrial Property Law states that diagnostic methods for use on the human or animal body are not considered inventions.

For example, methods for measuring blood pressure, X-ray, blood tests (except the step of collecting the blood sample), etc. are patentable. Methods of in vitro or ex vivo testing performed on samples removed from the body are also patentable, to the extent that they are not applied directly to the body or do not relate to the patient's clinical condition.

For example, the following claim directed to a method for detecting microsatellite instability and disease-related gene variations in patients based on next-generation high-throughput sequencing to provide clinical guidance on the risk control, treatment and/or prognosis of the patient or family was considered patent eligible for being applied to a plasma sample and therefore not applied directly to the human body:[19]

> 22. A method for detecting microsatellite instability and disease-related gene variations in patients based on next-generation high-throughput sequencing to provide clinical guidance on the risk control, treatment and/or prognosis of the patient or family, characterized in that it comprises the following steps: (1) detecting multiple microsatellite loci defined in claim 16 simultaneously; (2) determining the stability status of microsatellite loci in the sample according to the method defined in any one of claims 15 to 18; (3) obtaining the detection results of the one or more of disease-related genes according to the sequencing results; (4) providing clinical guidance on the risk control, treatment and/or prognosis of the patient or family by combining the results of the above steps (2) and (3).

China

The Chinese Patent Law explicitly states that no patent right shall be granted for methods for the diagnosis or treatment of diseases.[20] This applies where a method involving diagnosis of a disease is (i) practiced on a living human or animal body (or ex vivo samples from that body), and (ii) its immediate purpose is to obtain the diagnostic result of a disease or health condition.[21] Accordingly, methods of acquiring information from a living human or animal body or collected tissue and fluids as an intermediate result are patent eligible. Methods of processing that acquired information are also patent eligible if the processing does not involve a step to reach a diagnosis. Such patent eligible examples include, e.g.: a method of measuring the resonant frequency of a blood sample (CN101713775B) or a method of measuring nucleic acid concentration (CN101089196B).[22] Such methods do not directly diagnose a disease. They require at least one additional step to reach a diagnosis.

Although diagnostic methods are not patentable in China, the methods can be alternatively drafted as (i) a device claim that executes the diagnostic method steps, or (ii) a Swiss-type claim (e.g., use of a substance in the manufacture of a diagnostic reagent/kit/medicament for detecting/diagnosing/identifying/predicting a disease/responsiveness of a disease to a treatment). For example, if an invention is based on the discovery of a correlation between the expression of biomarker A and the responsiveness of disease B to treatment C, the discovery can be protected by the following hypothetical claim, "Use of an agent specifically binding to biomarker A in the manufacture of a kit for identifying a subject having disease B who may be responsive to treatment C."

A practical example can be observed in CN105659095B, where the following claim is patent eligible:

> 1. Use of a binding agent that specifically binds to the biomarker PLGF in the manufacture of

a kit for use in a method of identifying patients with heart failure as potentially responsive to treatment including inhibitors, wherein the method comprises: (a) measuring the level of the biomarker PLGF in a patient sample, and (b) comparing the level of the biomarker with a reference level.

In the context of Swiss-type claims, features pertaining to the "Inventive Concept" – as delineated by the *Mayo/Alice* test – may not be limiting elements in China. Swiss-type claims are typically characterized by three aspects:

(i) The structure or composition of the substance/medicinal product/kit;

(ii) The manufacture process; and

(iii) The intended use.

If a particular feature fails to provide limitation for any of these three aspects, it may be deemed non-limiting, thereby lacking the ability to distinguish the claimed use from prior art.

For example, the inventive concept of CN101918040B was the specific time interval between the step of administrating an imaging agent and the step of image collection; accordingly, a claim was drafted as below:

> 3. Use of a compound suitable for SPECT, capable of crossing the blood-brain barrier and associating with the dopamine transporter protein (DAT), in the manufacture of compositions for a diagnostic method in a single SPECT run, wherein the compound is selected from Technepine, Fluoratec, TROTEC-1, TRODAT-1, Altropane, Dopascan, and DaTSCAN, and the diagnostic method comprises at least the following steps: administering the compound to a human or animal; measuring the distribution of the compound in the brain using SPECT approximately 1-10 minutes after administration; measuring the association of the compound with DAT in the brain using SPECT approximately 15-45 minutes after administration; comparing the obtained results with appropriate controls; determining the presence of Alzheimer's disease, Lewy body dementia, and/or frontotemporal dementia.

The Re-examination Board stated that the above claim could not be distinguished from the prior art because the compound and the use were already known, and the steps comprised a diagnostic method that had no limiting effect on the structure of the compound or the manufacturing process of the compositions.

In contrast, in CN101918040B, the inventive concept was the use of a dopamine transporter (DAT) imaging agent that enables the simultaneous acquisition of perfusion and DAT information during a single imaging procedure, and the following claim was patentable:

> 1. Use of a compound labeled with 99mTc and/or 123I, suitable for SPECT, in the manufacture of a diagnostic composition *for the differential diagnosis of frontotemporal dementia with Lewy body dementia and Alzheimer's disease with frontotemporal dementia in a single SPECT run*, wherein the compound is capable of crossing the blood-brain barrier and associating with the dopamine transporter (DAT), and wherein the compound is selected from the group consisting of Technepine, Fluoratec, TROTEC-1, TRODAT-1, Altropane, Dopascan, and DaTSCAN, the differential diagnosis comprises at least the steps of: administering the compound to a human or animal; measuring the distribution of the compound within the brain using SPECT approximately 1-10 minutes after administration; and measuring the association of the compound with DAT within the brain using SPECT approximately 15-45 minutes after administration.

The Re-examination Board stated that the claimed use could be differentiated from the prior art by the emphasized feature "for the differential diagnosis of frontotemporal dementia with Lewy body dementia and Alzheimer's disease with frontotemporal dementia in a single SPECT run."

Accordingly, if features relating to "Inventive Concept" – as defined in the Mayo/Alice test – pertain solely to diagnostic procedures, these features tend to be non-limiting, and the claimed use cannot be distinguished from the prior art based on

such features. However, if these features are associated with a novel composition of the substance or a novel application, and the claim specifically recites the features related to this novel composition or application, then the claimed use can be distinguished from the prior art.

Lastly, it is worth mentioning the upcoming changes in Chinese patent practice. Effective January 20, 2024, a recent amendment to the Examination Guideline provides that methods of processing information will become patent eligible provided a device (e.g., a computer) executes all steps. This amendment may provide alternative patent protection for diagnostic methods if such methods are incorporated into device-executed information processes. As this amendment has not yet been fully implemented, practitioners will have to observe how the language and guidelines will be interpreted and applied during patent prosecution and invalidation procedures. The implementation of this amendment will clarify and potentially reshape the landscape of patentable subject matter within the domain of diagnostics in China.

Europe (European Patent Convention)

European law, as applied by Article 53(c) of the European Patent Convention (EPC), states that "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practi[c]ed on the human or animal body" are not patentable.[23] To be a diagnostic method claim, a claim must: (1) define a method, (2) be carried out on a human or animal body, and (3) include, explicitly or implicitly, all steps of: (i) collecting data; (ii) comparing the data with standard values; (iii) finding a deviation from normal (a symptom); and (iv) attributing that deviation/symptom to a clinical picture (i.e., a diagnosis).[24] A method falls within the ambit of diagnostic methods if the claim contains all steps. However, exclusion from patentability cannot be circumvented by omitting one of steps (i)-(iv) from a claim if its essentialness is unambiguously inferable from the patent application or patent as a whole, because such a claim would not comply with the requirements of Art. 84 EPC (i.e., clarity).

By contrast, per Article 53(c) EPC, products for use in a medical method, such as tools, devices, instruments, or apparatus – as well as substances or compositions – are patent eligible. For example, a method that employs a system or computer program to perform the method is patent eligible. According to the EPO's Guidelines for Examination,[25] a known substance or composition may be patented for use in a method referred to in Article 53(c) if the known substance or composition has not previously been disclosed for use for any such method. A claim to a known substance or composition for the first use in surgical, therapeutic, and/or diagnostic methods must be in a form such as, "Substance or composition X for use Y," wherein "use Y" may be, e.g., "for use as a medicament" or "for use in therapy/in vivo diagnostics/surgery." The EPO's guidelines also specify that "claims to medical devices, computer programs and storage media which comprise subject-matter corresponding to that of a method for treatment of the human or animal body by surgery or therapy or to that of a diagnostic method practiced on the human or animal body are not to be objected to under Art. 53(c), because only method claims may fall under the exception of Art. 53(c)."[26]

In vitro methods, wherein one of the steps is performed separately from the body, are also patent eligible.

In vitro methods, wherein one of the steps is performed separately from the body, are also patent eligible. Furthermore, methods that merely provide information or intermediate results, without an immediate diagnosis, are patent eligible. Similarly, methods for merely obtaining information (data, physical quantities) from the living human or animal body (e.g. X-ray investigations, MRI studies, and blood pressure measurements) are not excluded from patentability under Art. 53(c).[27] For example, the following claim is patentable:

> A method of imaging an artery in a region of interest in a patient using magnetic resonance imaging and a magnetic resonance contrast agent, the method containing the steps of: injecting the magnetic resonance contrast agent into a vein remote from the artery . . . and constructing an image of said artery, using the magnetic resonance image data, wherein the artery appears distinct from the adjacent veins and background tissue[28]

This claim was held to be patent eligible because the method was not found to include any "deductive phase" and only included "the preceding steps of gathering information which are constitutive for making the diagnosis."[29]

Conversely – "a claimed imaging method, in which, when carried out, maintaining the life and health of the subject is important and which comprises or encompasses *an invasive step* representing a *substantial physical intervention* on the body which requires *professional medical expertise* to be carried out and which entails a *substantial health risk* even when carried out with the required professional care and expertise" – is excluded from patentability as a method for treatment of the human or animal body by surgery pursuant to Article 53(c) EPC.[30] A claim that comprises a step encompassing an embodiment that is a "method for treatment of the human or animal body by surgery" within the meaning of Article 53(c) EPC cannot be left to encompass that embodiment. The exclusion from patentability under Article 53(c) EPC can be avoided by disclaiming the embodiment with it being understood that, to be patentable, the claim including the disclaimer must fulfil all the requirements of the EPC, and, where applicable, the requirements for a disclaimer to be allowable as defined in decisions G 1/03 and G 2/03 of the Enlarged Board of Appeal. Whether the claim language can be amended to omit the surgical step must be assessed based on the overall circumstances of the individual case under consideration.

Germany

With respect to patent eligibility of diagnostic methods, the European Patent Convention language is identical to the German Patent Act,[31] and the practice is similar. The following examples, according to German authorities, are patentable:

1. An examination procedure to determine a physical condition for purposes other than healing;

2. Examination procedures that enable non-therapeutic as well as therapeutic uses;

3. Suitability tests, determination of the stress limit, assessment of findings for cosmetic procedures;

4. A method for monitoring the respiratory function of living beings;

5. A method of storing signals in an implantable device where there is no connection between the method and the effect of the device on the human being; and

6. The evaluation of a sequence of discrete measured values of physical variables (e.g. electrocardiograms).

In view of the recent abolishment of the prohibition of double patenting, and the lower official fees, a parallel filing strategy in Germany and the EPC may be attractive.

Japan

In Japan, methods of surgery, therapy, or diagnosis of human**s** are not patentable. According to the Tokyo High Court, diagnostic methods are regarded as "medical activity" and thus lack industrial applicability. Therefore, such inventions do not satisfy the subject matter requirements set forth in the Japanese Patent Act.[32]

The Japanese Patent and Utility Model Examination Guidelines define "medical activity" as "methods of surgery, therapy or diagnosis of humans" that are normally practiced by medical doctors (or directed by medical doctors). Conversely, methods of collecting medical information and data by measuring and/or sensing, etc., for diagnostic purposes, may be patentable as long as "medical activity" is not involved. For example, a method of X-ray computed tomography (CT) imaging would not be patent eligible as a method of diagnosis, but a method of controlling the operation of an X-ray CT imaging device would be eligible because "medical activity" is not involved.[33]

Methods for gathering information from the human body by "measuring structures and functions of organs in the human body" are also not considered to be diagnostic and are therefore patentable. For example, the following claim is patentable: "[a] method for measuring the body temperature by inserting an electronic ear thermometer into the external ear canal."[34] Methods of testing extracted samples of blood, urine, hair, or tissue ex vivo are also patentable.

Although a method for diagnosing a human is unpatentable in Japan, there are ways to render such claims patentable. For example, a method of diagnosing cancer such as, "a method for diagnosing whether a patient has cancer" can be made patentable by reformulating the claims as, "a method for *assisting* diagnosing whether a patient has cancer." By adding the word "assist," the claim can be practiced by a non-medical worker. Such a claim amendment – i.e., adding the word "assist" – can be done, even if the specification as filed does not include the term "assist."

United Kingdom

In the United Kingdom, diagnostic methods are generally ineligible. According to Section 4A(1) of the UK Patents Act 1977, a patent cannot be granted for a method of diagnosis practiced on the human or animal body.[35] The scope of this UK standard is in line with the European Patent Office Enlarged Board of Appeal's decision in G 0001/04, where the Board characterized a number of steps for the process of diagnosis:

(1) Examination and collection of data;

(2) Comparison of the data with normal values;

(3) Recording any deviation from the norm; and

(4) Attributing the deviation to a particular clinical picture.[36]

Under Section 4A.06.01 of the UK Intellectual Property Office's Manual of Patent Practice, a practitioner should ask two key questions with any claim to a diagnostic method.[37] First, does the claimed method include both step 1 (the measurement step) and step 4 (the final deductive step), i.e. does it allow the disease or condition to be identified? Second, is step 1 practiced on the body? If the answer to both of these questions is "yes," then the practitioner should object to these claims as not patentable. However, if a method of diagnosis is performed on tissues or fluids that have been permanently removed from the body, then the method of diagnosis is not excluded from patentability. For example, a genetic or immunological test on blood or urine samples is patentable in the United Kingdom.

In *Illumina, Inc. v. Premaitha Health PLC*[38] – the United Kingdom's version of *Ariosa Diagnostics v. Sequenom* – the court held that Illumina's licensed patents from Sequenom were valid. The court stated that the licensed patents were not directed to information about the natural world, but rather to the practical process of a "detection method," which uses information about the natural world. The court further explained that the independent claim was directed to the detection of fetal DNA in a sample or plasma, and as such, the samples do not exist in the natural world but are artificially created, along with the method of detection. The court concluded that the claimed diagnostic method was directed toward patent eligible subject matter.

South Korea

In South Korea, diagnostic methods that include the human body as an essential element are patent ineligible. In 2019, the Korean Intellectual Property Office (KIPO) issued a revised version of the patent examination guidelines providing expanded protection for precision medicine, including dose and dosage regimen.[39] Additionally, the KIPO expanded the scope of patent eligibility to include diagnostic methods, as long as these methods are clearly interpreted as a method for processing information on a computer, and there is no clinical judgment by medical practitioners. The 2023 KIPO Patent Examination Guidelines provide several examples of patentable diagnostic methods:[40]

1. A method of detecting cancer marker A through antigen-antibody reaction based on a sample from a patient to provide a necessary information in testing colon cancer.

2. A method of measuring the concentration of A protein in a sample including detecting an antigen-antibody complex.

3. An analysis method including quantifying mitochondria DNA included in a sample from a human body and then comparing the quantity with mitochondria DNA of a control group.

4. A method of measuring blood glucose level based on collected blood.

Table 2. Summary of Patent Eligibility of Diagnostic Methods in Various Jurisdictions

Jurisdiction	Are Diagnostic Methods Permitted or Excluded by Statute?	Restrictions/Exceptions
Australia	Permitted	Natural phenomenon are not patentable. Methods including a natural phenomenon must have a practical application.
Brazil	Excluded	In vitro methods are patentable. A method in which the data collected represents an intermediate result is patentable.
Canada	Permitted	Scientific principles or abstract ideas are not patentable. A method that defines a combination of elements that cooperate together to form a single invention that includes physical means for testing, identifying, detecting, measuring, or otherwise quantifying the presence or quantity of an analyte is patentable.
China	Excluded	In vitro methods are patent eligible if they do not involve a diagnostic step (i.e., a method using an ex vivo sample with the immediate intention of making a diagnosis of the patient from whom the sample was taken may not be patent eligible). A method in which the data collected represents an intermediate result is patent eligible. Swiss-type claims are patent eligible – e.g., use of a substance in the manufacture of a diagnostic reagent/kit/medicament for detecting/diagnosing/identifying/predicting a disease/responsiveness of a disease to a treatment. Devices that execute diagnostic method steps are patent eligible. A method of processing information where all the steps are executed by a device such as a computer is patent eligible, effective on January 20th, 2024.
Europe (EPC)	Excluded	In vitro methods are patentable. A method that provides information or intermediate results is patentable. Products or apparatus used for a diagnostic method are patentable.
Israel	Permitted	Methods that include *treatment of a human body* are not patentable.
Japan	Excluded	Ex vivo methods are patentable. Methods of collecting medical information and data are patentable, if "medical activity" is not involved.
Mexico	Permitted	In vitro or ex vivo methods are patentable.
South Korea	Excluded	The human body cannot be an essential element of a diagnostic method. A method that can be clearly interpreted as a method for processing information via computer, without clinical judgment by a medical practitioner, is patentable.

United Kingdom	Excluded	Methods that involve a diagnosis on the human or animal body are not patentable. In vitro methods are patentable. Methods that merely provide information or intermediate results are patentable.
United States	Permitted	Methods cannot be directed toward a judicial exception. Claims that include an unconventional step are patentable. Claims that recite an inventive concept are patentable.

5. A method of detecting albumin from urine for diagnosing kidney disease.

6. A method of detecting cancer marker A through antigen-antibody reaction based on a sample from a patient by using a medical device to provide necessary information in diagnosing colon cancer.

7. A method of providing information for predicting cancer or predicting cancer by implementing AI algorithm in a medical device.

8. A method of providing information for diagnosing cancer by using X-ray diagnostic apparatus including a step in which a preprocessing module removes noise from X-ray image; a step in which an AI module is input with X-ray image that does not have noise and extracts information for cancer diagnosis.

9. A method of providing necessary information in diagnosing cancer including measuring methylation level of CpG island in the promoter region of gene A based on the biological samples of a subject.

10. A method of predicting sensitivity of a subject for stomach cancer, implemented in a computer including (a) inputting data of one or more stomach cancer antagonistic variations existing in a subject to a computer; (b) comparing the data with database stored in a computer including information on stomach cancer related to the variations and stomach cancer antagonistic variation; and (c) computing indicators determining the subject's vulnerability to stomach cancer based on the comparison.

11. A diagnostic method of a mammal except for a human being.

Practitioners should generally be wary of the patentability of in vivo diagnostic methods in most ex-U.S. jurisdictions.

Examples 1-10 cover diagnostic methods that do not include a clinical judgment and Example 11 covers a diagnostic method that does not apply to human beings.

CONCLUSION

Practitioners should generally be wary of the patentability of in vivo diagnostic methods in most ex-U.S. jurisdictions. However, for in vitro and ex vivo methods, practitioners should refer to guides – such as this one – and local counsel to determine the likelihood of patent eligibility. Additionally, or alternatively, practitioners should consider drafting claims directed to determining "intermediate results," rather than "conclusive" or "diagnostic" results since many ex-U.S. jurisdictions except such diagnostic method claims. A summary of the IP laws of each jurisdiction discussed is provided in Table 2.

Notes

1. Nat'l Rsch. Dev. Corp. v Comm'r of Patents (1959) 102 CLR 252 (Austl.).
2. D'Arcy v Myriad, [2015] HCA 35 (Austl.).
3. Ariosa Diagnostics, Inc. v Sequenom, Inc. [2021] FCAFC 101 (Austl.).
4. D'Arcy v. Myriad Genetics Inc. [2015] HCA 35 (Austl.).

5. A single body known as the Trans-Tasman IP Attorneys Board regulates the Australian and New Zealand IP attorney profession. Under an agreement between the two countries, Australian attorneys can act before the New Zealand IP Office, and New Zealand attorneys can act before the Australian IP Office. There has been suggestion that the IP regimes in both countries may by unified; however, this has not yet occurred. As such, IP practice and laws between the two countries maintain notable differences, despite their similarities. The former is particularly true for patent claims to methods of treatment and diagnosis.
6. Section 16(2) and (3) of the New Zealand Patents Act 2013, respectively.
7. Choueifaty v. Canada (Attorney General), 2020 FC 837.
8. Canadian Intellectual Property Office, Patentable Subject-Matter under the Patent Act (Nov. 3, 2020).
9. Benjamin Moore & Co. v. Canada (Attorney General), 2022 FC 923 attempted to provide guidance, but was vacated by the Court of Appeal, 2023 FCA 168.
10. Liad Whatstein et al., Life Sciences Commercialisation in Israel: Overview, Thomas Reuters PRACTICAL LAW (Mar. 1, 2023), https://uk.practicallaw.thomsonreuters.com/w-014-5548?transitionType=Default&contextData=(sc.Default)&firstPage=true.
11. Moshe Leimberg, From Patent to Drug, State of Israel, Ministry of Justice, Israel Patent Office, World Intellectual Property Organization (Oct. 24, 2011).
12. The ILPTO's Examination Guidelines reflect the ILPTO's understanding of the law; however, they are not binding either on the Commissioner of Patents or on the Israeli courts.
13. ILPTO Examination Guidelines, Appendix 3, Section 4.1.
14. Begoña, C., et al., Intellectual Property Rights in Mexico: Overview, Practical Law Country Q&A, 7-505-4664 (May 1, 2021).
15. Maqueda, J. and Arellano, F., Mexico: Treatment Methods and Their Patentability in Mexico – Overview, Mondaq (May 8, 2008).
16. Patent No. MX399562B.
17. Law No. 9279, May 14, 1996, Brazil Industrial Property Law [B.I.P.L.], May 15, 1996.
18. Resolution No. 169/2016, July 26, 2016, Block II, § 1.39-1.42, National Institution of Intellectual Property [INPI], July 15, 2016, (Braz.).
19. Patent No. BR 11 2021 005966 0.
20. Patent Law of the People's Republic of China, art. 25(3) (2008), World Intellectual Property Organization.
21. People's Republic of China, Guidelines for Examination (2006), Part II, Chapter 1, § 4.3.1.1.
22. Jennifer Che, China Patent Strategy: Diagnostic Claims in China, in Eagle IP (Jan. 9, 2020).
23. European Patent Convention, art. 53(c) (Nov. 2020).
24. European Patent Office, Boards of Appeal, G 0001/04 (Diagnostic methods) (Dec. 16, 2005).
25. Guidelines for Examination in the European Patent Office, Chapter II, 4.2.
26. Guidelines for Examination in the European Patent Office, Chapter II, 4.2.1.
27. Guidelines for Examination in the European Patent Office, Chapter II, 4.2.1.3.
28. European Patent Office, Boards of Appeal, T 0663/02, pg. 5 (Mar. 17, 2011).
29. European Patent Office, Boards of Appeal, T 0663/02, pg. 9 (Mar. 17, 2011).
30. European Patent Office, Enlarged Board of Appeal, G 0001/07, pg. 80 (Feb. 15, 2010).
31. German Patent Act, Article 2a I No 2 (Aug 30, 2021).
32. Japanese Patent Act, art. 29(1) (1959).
33. Japanese Patent and Utility Model Examination Guidelines § 3.2.1(2) (2015).
34. Japanese Patent and Utility Model Examination Guidelines § 3.2.1(3) (2015).
35. Patents Act 1977 (UK), § 4(A).
36. European Patent Office, Boards of Appeal, G 0001/04 (Diagnostic methods) (Dec. 16, 2005).
37. Intellectual Property Office, Manual of Patent Practice (MOPP), § 4A.06.01.
38. Illumina, Inc. v. Premaitha Health PLC, [2018] EWHC 615 (Pat).
39. Korean Intellectual Property Office, Patent Examination Guidelines (Mar. 2019).
40. Korean Intellectual Property Office, Patent Examination Guidelines (Mar. 2023).

U.S. Patent and Trademark Office Rejects "Contingent" Terminal Disclaimer

By David K. Barr and Kaitlyn M. Rodnick

The U.S. Patent and Trademark Office (USPTO) has rejected a "contingent" terminal disclaimer filed by Acadia Pharmaceuticals Inc. (Acadia) for a patent it owns that is being challenged in a pending litigation as invalid for obviousness-type double patenting. The USPTO ruled that terminal disclaimers could not be made contingent on the occurrence of a future event, in this case the outcome of a double patenting invalidity challenge to the subject patent.

BACKGROUND

By way of background, a terminal disclaimer filed under 35 U.S.C. § 253 is an accepted means of obviating double patenting by ensuring, among other things, that the challenged patent and the patent that formed the basis for the double patenting challenge (the reference patent) expire on the same date. However, to be effective, the terminal disclaimer must be filed before the expiration date of the reference patent.

Acadia had sued MSN Pharmaceuticals, Inc. and MSN Laboratories PVT. Ltd. (MSN) in the U.S. District Court for the District of Delaware under the Hatch-Waxman Act, based on its filing of an Abbreviated New Drug Application seeking Food and Drug Administration (FDA) approval to market a generic version of Acadia's Nuplazid® drug product before the expiration of patents Acadia had listed in the FDA's Orange Book.[1] One of the Orange Book-listed patents Acadia asserted in the litigation, U.S. Patent 7,601,740 ('740 patent), issued with 1,249 days of Patent Term Adjustment (PTA) under 35 U.S.C. § 154, based on USPTO delays in issuing the patent, and also had been granted 1,315 days of Patent Term Extension (PTE) under 35 U.S.C. § 156, based on FDA delays in the approval of the Nuplazid® product.

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THE LAWSUIT

In the litigation, MSN asserted as a defense that the '740 patent was invalid for obviousness-type double patenting based on Acadia's ownership of another Orange Book-listed patent from the same family, U.S. Patent 9,566,271 ('271 patent), which would expire earlier than the '740 patent because it had not been granted any PTA. The parties agreed that the claims of the '271 patent were not patentably distinct over the claims of the '740 patent.

MSN and Acadia cross-moved for summary judgment on double patenting, agreeing that the court could decide as a matter of law two independent issues:

- Whether under the Federal Circuit's recent *In re Cellect*[2] decision the PTA awarded to the '740 patent resulted in double patenting because of the earlier expiration of the '271 patent; and

- Whether a finding of double patenting was precluded under the Safe Harbor of 35 U.S.C. § 121.

While a decision on the summary judgment cross-motions was pending, on November 21, 2023, Acadia filed with the USPTO a "Contingent" Terminal Disclaimer, which sought to disclaim the term of the '740 patent, which extended beyond the impending January 15, 2024 expiration of the '271 patent because of the 1,249 days of PTA, but made the disclaimer contingent on the outcome of a decision on MSN's double patenting defense. Acadia's Contingent Terminal Disclaimer specified that if no claim of the '740 patent is found invalid for double patenting "in a final decision from which no appeal has been or can be taken," the "contingency has not been met" and no portion of the term of the '740 patent has been disclaimed.

Acadia also specified that if the Contingent Terminal Disclaimer "is declared impermissible and thus void" and if "one or more claims are held

invalid" for double patenting "in a final decision from which no appeal has been or can be taken," then the Contingent Terminal Disclaimer is "automatically converted nunc pro tunc into an effective non-contingent terminal disclaimer" and Acadia disclaims the terminal portion of the '740 patent that extends beyond the term of the '271 reference patent. Acadia also stated that it "*DOES NOT DISCLAIM any part of the patent term extension of the instant patent granted pursuant to 35 U.S.C. § 156.*"

Patent owners confronted with a double patenting challenge that remains unresolved at the time the reference patent is due to expire must decide whether to file a definitive, unconditional terminal disclaimer before that expiration date or risk an adverse decision invalidating the challenged patent rendered after the expiration of the reference patent.

Acadia also filed with the USPTO a petition for expedited consideration of its Contingent Terminal Disclaimer in view of the approaching expiration of the '271 reference patent on January 15, 2024.

THE DECISION

On December 13, 2023, the Delaware district court denied MSN's summary judgment motion of invalidity of the '740 patent and granted Acadia's cross-motion of validity of the '740 patent.[3] However, that decision was subject to appeal, and on January 23, 2024, MSN appealed to the Federal Circuit the district court's January 11, 2024 entry of judgment in favor of Acadia. Acadia's responsive brief is due May 29, 2024.

The USPTO's decision rejecting Acadia's proffered Contingent Terminal Disclaimer cites MPEP § 1490(V)(A), which "precludes acceptance of disclaimers which are conditional and/or contingent."[4]

Acadia filed a request for reconsideration of the USPTO decision, which was dismissed on May 2, 2024. Therefore, patent owners confronted with a double patenting challenge that remains unresolved at the time the reference patent is due to expire must decide whether to file a definitive, unconditional terminal disclaimer before that expiration date or risk an adverse decision invalidating the challenged patent rendered after the expiration of the reference patent.

Notes

1. Acadia Pharms. Inc. v. Aurobindo Pharma Ltd. et.al., C.A. No. 1:20-cv-00985-GBW (D. Del.).
2. In re Cellect, 81 F.4th 1216 (Fed. Cir. 2023).
3. Acadia Pharms., C.A. No. 1:20-cv-00985-GBW, Dkt. 275 (D. Del. Dec. 13, 2023).
4. The USPTO's decision quotes a portion of MPEP § 1490(VI)(A), which states, in pertinent part, "[i]t is further noted that the statute does not provide for conditional disclaimers (whether they are terminal disclaimers or statutory disclaimers). Accordingly, a proposed disclaimer that is made contingent on the allowance of certain claims or the granting of a petition, is improper and cannot be accepted." (emphasis omitted).

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