Intellectual Property & Technology Law Journal

Edited by the Technology and Proprietary Rights Group of Weil, Gotshal & Manges LLP

VOLUME 36 • NUMBER 6 • JUNE 2024

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.*

Jacquelyn Pariseau, Hadia S. Ahsan, Haley S. Ball, Ph.D., Shoshana Marvin, M.Sc., and Gaby L. Longsworth, Ph.D., associated with Sterne, Kessler, Goldstein & Fox P.L.L.C., may be contacted at jpariseau@sternekessler.com, hahsan@sternekessler.com, hball@sternekessler.com, smarvin@sternekessler.com and glongs@sternekessler.com, respectively. The following persons contributed to the preparation of this article on their respective jurisdictions of expertise: Australia and New Zealand: Chris Vindurampulle and Naomi Pearce, Pearce IP; Canada: Selena Kim and Sarah Raja, Gowling WLG; Israel: Noam Blei and Tal Band, S. Horowitz & Co.; Brazil: Luiza Cotia, Roberto Rodrigues, and Rafaella Oliveira, Licks Attorneys; China: James Zhu and Yejun Wang, JunHe LLP; Europe: Alessandra Antonucci, Paolo Di Giovine, and Mario Pozzi, Società Italiana Brevetti S.p.A.; Sabine Agé, Hoyng Rokh Monegier; Koen Bijvank, Brinkhof; and Tobias Alexander Popp, Meissner Bolte (and also Germany); Japan: Yoichi Watanabe, Seiwa Patent & Law; Hideki Kodera, Shimizu Patent Office; Mexico: Eunice Lewis Velasco, Arochi & Lindner; UK and Europe: Alexander Crew and Gwilym Roberts, Kilburn & Strode LLP; South Korea: Jay J. Kim, Kim & Chang IP.

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.

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.

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

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.

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.

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

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. 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]

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.

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.

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).