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Software and Medical Device Guidance: A Global Perspective

I. Introduction

Innovation in medical technology plays a crucial role in the advancement of patient well-being around the world. Over the past several decades, software has accelerated the pace of innovation in medical technology, delivering new therapies, improving care outcomes, and lowering costs of care. To bring these new innovations to patients and physicians, many companies, non-profit organizations, and individual inventors have continued to make significant investments in R&D, clinical research, and commercialization.

Patent protection for medical technology is an important component of intellectual rights to continue advancing the state-of-the-art. Clear and predictable patent rights are essential not only to recoup investments in R&D and commercialization but also to incentivize future investments in new innovations. As software innovations continue to play a greater role in medical technology, patent protection for software will also take on greater significance for investors, innovators, and ultimately, physicians and patients.

This paper seeks to analyze patent systems around the world in order to provide a better understanding of how these patent systems are alike and different. By comparing and contrasting these patent systems with a focus on the current application of patent law in various jurisdictions, this paper highlights opportunities, risks, and tradeoffs associated with seeking patent protection for inventions that use software as or part of a medical device. Where

[1] This article was prepared through a collaboration of members on the IPO's Software-Related Inventions Committee. Statements in this article may not reflect the positions or policies of the firms, corporations, or clients affiliated with the authors.

possible, this paper seeks to provide practical strategies that can improve the likelihood of obtaining and enforcing patent rights for software inventions that relate to medical technology.

In Part II of this paper, the patent systems of China, Japan, the European Patent Office, France, and the U.S. are analyzed with a particular focus on software inventions that relate to medical technology. These national patent systems, in addition to the US patent system, have influential roles in the development and ongoing evolution of global patent policy for software and medical technology. In Part III of this paper, the similarities and differences of laws for the jurisdictions covered in Part II are summarized for quick reference. Through this rigorous treatment of the patent laws in the various jurisdictions of Part II, this paper seeks to equip applicants and practitioners with strategies that can aid in drafting of patent applications for software inventions that relate to medical technology and securing enforceable patent rights.

II. Software and Medical Device Guidance: A Global Perspective

A. China (John Kind)

The China National Intellectual Property Administration (CNIPA) has two sets of guidelines that are potentially relevant to inventions that use software as or part of a medical device. Specifically, CNIPA has guidelines for applications relating to *Computer Programs* and *Diagnosis or Treatment of Diseases*. The former do not typically present significant challenges for protecting software medical devices, but the latter introduce explicit challenges to Chinese practice.

Under CNIPA's guidelines, algorithms, mathematical rules, and computer programs *per se* are considered ineligible mental processes. *See* CNIPA Computer Program Guidelines, 2(1). This includes a computer program recorded in a computer-readable medium. *Id.* However, the guidelines provide broad exceptions for any invention that solves a technical problem. *Id.* at 2(2). Significantly for medical device applications, a computer program is considered to solve a technical problem where it is used to perform a measurement or test process. *Id.* Thus, most if not all medical device applications should have little trouble in being found to address a technical problem and thus not fall into the mental processes exclusion.

The Guidelines for Diagnosis or Treatment of Diseases require more careful consideration, ideally at the drafting stage. As a matter of policy, CNIPA does not consider methods of diagnosis or treatment of diseases to be inventions. *See* CNIPA Diagnosis or Treatment of Disease Guidelines. The guidelines provide distinct frameworks for evaluating whether methods are diagnostic or for treatment. *Id.*

Regarding potential diagnostic methods, the guidelines provide a two-part test for determining whether the exclusion applies. *Id.* Specifically, a method is ineligible for patent protection if: (1) it is practiced on a living human or animal; and (2) its immediate purpose is to obtain the diagnostic result of a disease or health condition. *Id.* The exclusion applies even if the diagnostic test is performed in vitro on a sample collected from a living subject. *Id.* Conversely,

a device or system that performs a diagnostic method or a method that provides an intermediate result that requires further analysis before a diagnosis is reached is patent eligible.

The two-part framework provides a roadmap for protecting many diagnostic innovations. First, kit claims that include the software, as well as data collection elements or chemical reagents, fall outside of the exclusion. Similarly, claims to the devices used to perform diagnostic methods are outside the scope of the exception. However, these workarounds are often not practical where the applicant provides diagnostic services based on data collected by a third party. But where possible, the applicant should include explicit support in their specification for kit and device claims.

Second, patent protection may be obtained for methods that achieve intermediate results that do not lead directly to a diagnosis. Thus, it is in applicants' interests to identify novel portions of their end-to-end diagnostic processes and ensure their specifications have support for those novel portions being practiced in isolation from each other.

With regard to treatment methods, the exceptions are significantly narrower. Those that are potentially relevant to medical devices are limited to making prosthetics, non-invasive cosmetic treatments, and techniques for killing microbes outside of the body.

B. Japan (Ryan Phelan)

The Japanese Patent Office (JPO)'s *Examination Handbook* includes a section dedicated to the field of software-related inventions. *See* JPO Examination Handbook, *Computer Software-Related Inventions*. The JPO defines a "software-related invention" as "an invention that uses software to carry out the invention." *Id.* at 1. As is common for all fields for Japanese applications, an invention (including software-related inventions) under Japanese law must be sufficiently enabled and have clarity. *Id.* The software-related invention must also possess eligibility, novelty, and an inventive step. *Id.*

The JPO Examination Handbook provides an example of a software medical device (e.g., a "file search system"). The example illustrates that software-related inventions that claim a "normal creation" activity of a person of ordinary skill can lack an inventive step, and, thus, are unpatentable. The JPO refers to this as "an exhibition of normal creation capabilities of a person skilled in the art." *Id.* at 31.

In the example, a "file search system" is used to create "a medical information search system by applying means (specific configuration for searching) whose function or action is common." *Id.* This example "falls under exhibition of normal creation capabilities of a person skilled in the art." *Id.* In particular, the JPO Examination Handbook explains that "[a] procedure or means used in a software-related invention related to a specific field … often [has] a common function or action irrespective of an applied field." *Id.* Because of this, "when the function or action is common, an attempt to apply a procedure or means of a software-related invention related to a specific field to another specific field falls under exhibition of normal creation

capabilities of a person skilled in the art." *Id.* Thus, the example "file search system" lacks inventive step. *Id.*

The JPO's recent publication on AI-related technologies provides further medical software-related examples. In particular, in 2019, the JPO released a set of case examples for AI-Related Technologies. See *Newly Added Case Examples for AI-Related Technologies* (the "JPO AI-Related Technologies guidelines"). The JPO AI-Related Technologies guidelines are designed to provide practitioners with an overview of AI-related technologies and also to allow practitioners to understand how the JPO will review AI-related inventions under its guidelines.

In an overview section, the JPO AI-Related Technologies guidelines remind practitioners that AI-related technologies, just as for other technical fields, must satisfy conventional Examiner Guidelines regarding (1) enablement; (2) support (*i.e.*, written description); and (3) inventive step. That is, the JPO AI-Related Technologies guidelines provide that AI-related technologies must include "a detailed explanation of the invention shall be clear and sufficient as to enable any person ordinarily skilled in the art to which the invention pertains to work the invention" (enablement).

Further, the JPO AI-Related Technologies guidelines provide that the "scope of a claimed invention should not exceed the extent of disclosure in the description" (support).

Finally, the JPO AI-Related Technologies guidelines provide that the examiner should look for factors that show the existence of an inventive step, e.g., advantageous effects and/or obstructive factors, such as where the combination of one prior art reference with another would obstruct the purpose of one of the references.

The JPO AI-Related Technologies guidelines add 11 new examples to the JPO guidelines that focus on various industries and technical fields that utilize AI. These range from autonomous vehicle technology to visual processing, and business methods.

Two examples highlight inventions related to software medical devices. The first example describes an AI-based apparatus that lacks a sufficient inventive step; the second example describes a different AI-based apparatus that includes a sufficient inventive step.

The first medical software device example (Example 33) describes a "Cancer Level Calculation Apparatus." The related claim recites "a cancer level calculation unit that calculates a possibility that a subject person has cancer." The cancer level calculation unit includes a neural network trained to calculate an estimated cancer level in response to the input of measured values of an "A marker" and a "B marker." The values of the markers are determined via blood analysis of a subject person.

Example 33 instructs that it is well-known in the art of machine learning to determine the possibility that a subject person has a certain disease based on input data of a subject person and the use of a trained neural network. For example, training data used to train a neural network would contain input data that has been collected from multiple people, each of which

consists of a prescribed set of input data (biological data, etc.) on each person, where the neural network is trained to output a possibility that a person has the disease.

In view of the well-known art, the JPO states that the claim for the Cancer Level Calculation Apparatus, even though reciting a "neural network," nonetheless lacks an inventive step. This is because, according to the JPO AI-Related Technologies guidelines, both the well-known art and the claim relate to mere estimation of the possibility of illness. In addition, both share a common problem to be solved. That is, it is merely the execution of ordinary creativity of a person skilled in the art to systemize an estimation method carried out by a doctor in the medical field using a computer or the like. Because of this Example 33 is not patentable.

A second medical software device example (Example 36) describes a "Dementia Stage Estimation Apparatus." The Dementia Stage Estimation Apparatus is configured to detect varying stages of dementia in a patient (i.e., a "respondent") based on the patient's speech. The apparatus uses a neural network trained on speech-to-text character input that was captured during question-and-answer sessions between the patient and a doctor (e.g., a "questioner"). The neural network is also trained on a question topic asked by the doctor, where both the question topic, and the speech-to-text character input, are associated with each other as training data for the training of the neural network.

According to the JPO, the claim of Example 36 possess a sufficient "invention step" under Japanese law because the claimed invention "brings about a significant effect, that is, a highly accurate dementia stage estimation by specifying a question topic by a questioner and a response by a [patient] respondent (corresponding character string) to the question topic in an associated manner with each other." Moreover, the claimed neural network effectively learns the know-how of a doctor from training data and can apply this know-how to test the various stages of dementia in a patient.

C. EPO (**Nikesh Patel**)

Statistics published by the EPO in 2020 show that medical technology was the leading field for inventions in terms of volume. In 2021, the EPO statistics show that the top three technical fields for filings at the EPO are digital communication, medical technology, and computer technology. The statistics also show that in both 2020 and 2021 the United States was the geographic origin for the highest number of European patent applications. It is therefore clear that US companies are seeking protection at the EPO for computer and medical technology. However, not all software-related inventions are patentable at the EPO. Below, we summarize the approach adopted by the EPO to assess such inventions.

The EPO assesses the patentability of inventions according to the European Patent Convention (EPC). The most relevant articles of the EPC that will apply to software in the medical device field are Articles 52, 53, 54, and 56 EPC. The EPC does not provide a *positive* definition of "invention" nor does it prescribe statutory categories (compared to e.g. 35 U.S.C. 101 - 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 to the *conditions and requirements of this title*). Art. 52(2) EPC provides a *non-exhaustive* list of "non-inventions," but they are excluded from patentability only when claimed, "as such." It should also be noted that although the term “technical” is used frequently by the EPO when commenting on patentability, the term is not defined in the EPC. The legislator has left the task of construing the legal concept of "invention" and “technical” to the case law of the EPO Boards of Appeal so as to allow for developments in technology to still be taken into account when assessing patentability.

The EPO adopts a “two-hurdle” approach for assessing inventions that may include a mix of technical and non-technical features. Typically, where an invention uses software it may be considered to be such a mixed-type invention or a computer-implemented invention (CII).

The EPO two-hurdle approach to assess patentability for “mixed-type inventions” – considering Articles 52, 54, 56 EPC

Hurdle 1

- ***Is the claimed invention an invention under Article 52 EPC***

Mathematical methods, schemes, rules and methods for performing mental acts, presentations of information, and programs for computers (as well as other exclusions identified in Article 52(2) EPC) are not regarded as inventions if claimed *as such* in the application.

This first hurdle can be overcome relatively easily by referring to any technical means in the claims. For example, one may choose to refer to a computer-implemented method or refer to technical means for carrying out steps of a method (where there is a basis in the original patent specification to do so). This assessment is normally performed without reference to any prior art. However, the mere reference to any technical means may not be enough to address the second hurdle explained below.

This hurdle may be considered similar to Steps 1 and 2A, first prong, of the US Subject Matter Eligibility Test.

Hurdle 2

- ***Is the claimed invention novel and inventive under Article 54 & 56 EPC?***

All features contributing to the technical character are taken into account for assessment of inventive step of an invention in the field of CIIs.

The second hurdle can be more challenging to address and it is recommended to show that the steps of the claim alleged to be non-technical by the EPO actually contribute to the technical character of the claimed invention. One may argue or amend a claim to link the novel features to a technical effect provided by the claimed invention. At this stage of the assessment, prior art may be taken into account and it can be helpful to show that the novel features contribute to solving a technical problem.

This hurdle may be closer to Step 2A, Second Prong of the US Subject Matter Eligibility Test.

A medical device implemented software invention may be covered by claims that include mathematical method steps or features. This is particularly true for inventions that may involve artificial intelligence solutions utilizing mathematical algorithms. To help decide whether claimed mathematical method features that would normally be excluded from patent protection under Article 52 contribute to the technical character of the invention (and therefore to the inventive step), the EPO looks at two independent indicators:

(a) **by the application to a field of technology**; or

(b) **by being adapted to a specific technical implementation**

Should the claimed features relate to at least one of these indicators, it is very likely they will be considered to contribute to the technical character of the invention and taken into account in the assessment of inventive step of the claimed invention.

The EPO Guidelines for Examination is a document used by EPO examiners to help with examination of European applications. It is a useful legal resource and includes detailed commentary on the EPO approach of assessing patentability. According to the Guidelines (Part G-II 3.3), the following are considered examples of indicator (a) **technical applications** (only a subset of applications relevant to this paper is shown):

- controlling a specific technical system or process, e.g. an X-ray apparatus or a steel cooling process;

- digital audio, image or video enhancement or analysis, e.g. de-noising, detecting persons in a digital image, estimating the quality of a transmitted digital audio signal;

- determining the energy expenditure of a subject by processing data obtained from physiological sensors; deriving the body temperature of a subject from data obtained from an ear temperature detector;

- providing a genotype estimate based on an analysis of DNA samples, as well as providing a confidence interval for this estimate so as to quantify its reliability;

- providing a medical diagnosis by an automated system processing physiological measurements.

The claims need to be functionally limited to the technical application and this can be achieved by linking relevant claim features to the application via inputs and outputs. For example, the final feature / output of the claim may be linked to a technical application.

The second indicator (b) relates to the claim being directed to a **specific technical implementation** of the mathematical method and the mathematical method is particularly

adapted for that implementation in that its design is motivated by technical considerations of the internal functioning of the computer system or network. One may be able to show that there is a technical improvement in the way the mathematical method is implemented on a medical device, e.g,. improvement in processing speed but not merely because the mathematical method is being implemented on a computer which inherently will be faster than doing something manually but perhaps due to interactions taking place with the hardware, or improved memory management.

The above example relates to the mathematical method exclusion which may be considered similar to the abstract idea non-eligibility in the US. The claimed invention will also be analyzed to check if it is not excluded under the other exclusions such as a presentation of information. This may be relevant to the medical devices field where data is displayed on a display device following some processing. A similar two hurdle approach will be taken and the claimed features will be assessed on whether another exclusion from patentability applies to the claimed invention. If another exclusion from patentability applies to the claimed invention, the EPO will also consider whether the relevant claimed features contribute to the technical character of the claim despite the features being prima facie excluded or non-technical.

Exceptions from patentability – Article 53 EPC

Under Article 53(c) of the EPC, European patents shall not be granted in respect of:

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Therefore, method claims that relate to treatment of the human or animal body and diagnostic methods practised on the human or animal body will not be patentable at the EPO. Note that device claims will not be excluded.

Example claim based on EPO Board of Appeal case T0598/07 where there is a mix of technical and non-technical features that was found allowable (not excluded, was patentable, not a diagnosis method):

28. A heart monitoring method comprising the steps of:

receiving an electrocardiograph signal from a patient during a monitoring phase;

preprocessing the electrocardiograph signal to suppress the noise and to analyse the shape of each pulse of said electrocardiograph signal to obtain a plurality n of values representative of the shape of each pulse of said electrocardiograph signal; and

using Kohonen neural network means (11) during the monitoring phase to initially read a stored first set of n dimensional reference vectors defining an n dimensional Kohonen feature map for the identification of distinctive irregular heartbeats which are spurious

with regard to monitoring heart conditions, each said n dimensional reference vector comprising a plurality n of values representative of the shape of each pulse of a distinctive irregular heartbeat, to define an irregular heartbeat n dimensional volume in n dimensional space using the first set of reference vectors and threshold ranges around the first set of reference vectors, to receive said plurality n of values for each pulse, to form an n dimensional vector from said plurality n of values for each pulse, and to compare the formed n dimensional vector with the irregular heartbeat n dimensional volume to determine if said n dimensional vector lies within or outside said irregular heartbeat n dimensional volume to identify the distinctive irregular heartbeats; and subsequently to read a stored second set of n dimensional reference vectors defining an n dimensional Kohonen feature map for monitoring regular heartbeats, each said n dimensional reference vector comprising a plurality n of values representative of the shape of each pulse of a regular heartbeat, to define a regular heartbeat n dimensional volume using the second set of reference vectors and threshold ranges around the second set of reference vectors, to compare the n dimensional vector formed from a regular heartbeat which does not include a distinctive irregular heartbeat with said regular heartbeat n dimensional volume, and to output an indication if it is determined that said n dimensional vector formed from said regular heartbeat is within or outside said regular heartbeat n dimensional volume.

The Board decided that since the method claim did not include a step relating to diagnosis for curative purposes that represents the deductive medical or veterinary decision phase, the method was found not to fall within the exclusion provisions of Article 53(c) EPC. It seemed key for allowance of this claim that the wording does not need to incorporate the deductive decision phase of establishing a diagnosis for curative purposes.

In terms of novelty and inventive step, the Board found a number of differences compared to the prior art including in relation to the data processing carried out by the Kohonen neural network means. It was found that the technical effect obtained by the distinguishing features is to allow the second comparison with the regular heartbeat n dimensional volume to be carried out only for *n*-dimensional vectors formed from a regular heartbeat which does not include a distinctive irregular heartbeat. This in turn improved the signal to noise ratio and thereby reduced the number of false identifications of novel electrocardiograph signals as explained in the original application. It was helpful that the original application included an explanation of the technical advantages of the novel features.

Sufficiency of description – Article 83 EPC

The specification of a European application must include sufficient information for the invention to be worked by a skilled person or team. This requirement is particularly important for AI inventions and should be borne in mind when drafting medical device cases that use machine learning, for example, particularly if the alleged novel and inventive features relate to the use of the machine learning. In May 2020, the EPO Boards of Appeal issued a decision that found an insufficient description under Article 83 EPC in case T161/18, by rejecting an application that related to the use of an artificial neural network to transform a blood pressure

curve measured at a periphery into an equivalent aortic pressure. The alleged inventive step was limited to the claimed use of an artificial neural network (the claim – translated from the German language proceedings - stated that "the transformation …is performed with the help of an artificial neural network whose weighting values are determined by learning"). With regard to the training of the neural network according to the invention, the present application was alleged to only disclose that the input data is intended to cover a wide range of patients of different ages, sex, constitution type, state of health and the like. The EPO concluded that the application did not disclose which input data is suitable for training the artificial neural network of the invention, or at least one data set suitable for solving the technical problem. Therefore, the invention was found to not be sufficiently disclosed. It was also found that there was no inventive step in the claim's reference to use of a neural network and weighting values determined by learning.

D. France (Charlotte Leleu and Anne Lejeune)

1.1. Recent evolution of French law regarding patentability criteria

A first specificity of French patent law that can be relevant for software and medical devices is that the requirements for patentability, in particular for software, depends on the filing date of the application due to a recent change of the law.

Indeed, paragraphs 4, 5 and 7 of Article 612-12 of the French Intellectual Property Code, listing the grounds for rejection of a patent application for lack of novelty, patentability or subject-matter excluded from patentability, has been amended as follows pursuant to the PACTE Act no. 2019-486 of 22 may 2019:

"A patent application shall be rejected, in whole or in part, if:

[…]

4. "its subject matter is an invention that is ~~clearly~~ not patentable pursuant to Articles L.611-16 to L.611-19" (see Section C, Chapter VII, point 2);

5. "its subject matter ~~clearly~~ cannot be considered an invention, pursuant to the second paragraph of Article L.611-10" (see Section C, Chapter VII, points 1 and 3);

7. "~~it has not been amended following a formal notice, even though the search report clearly showed a lack of novelty~~ its subject matter is not patentable […]" (see Chapter VII, point 4);

Thus, before implementation of the PACTE law, lack of inventive step of the invention was not a ground of rejection of the patent application. Moreover, the former writing of Article 612-12 required a **clear** (in French: manifest) lack of novelty or patentability for an application to be rejected.

Thus, the PACTE Act considerably “raised the bar” regarding patentability requirements, and brought the French practice closer to the European practice.

1.2. Software related dispositions

The convergence of French and European practices applies particularly to software which, according to Article L611-10 of the French patent law, cannot be considered an invention, when the patent application concerns a software “as such.”

Similarly to the European practice, a computer program may be considered an invention if it produces a further technical effect beyond the standard technical effects involved in operating the computer.

The Guidelines of the French Patent Office provides the following examples of technical effects:

- Control of an industrial process,
- Processing of data representing physical entities,
- Impact in the internal functioning of the computer itself.

Accordingly, a software developed for medical purposes, comprising either the processing of data representing physiological quantities, or the control of a medical device, may be considered an invention. The same applies to artificial intelligence methods which, when applied to medical data such as medical imaging, are considered technical.

The same notion of technicity also arises when assessing inventive step, since only the features contributing to the technical character of the invention shall be taken into account in the assessment of inventive step. On that matter, the French Guidelines do not provide examples and the change in patent law is too recent to have significant case law, but one can consider if a software is considered technical and not excluded from patentability, its features will also be considered technical and taken into account for assessment of inventive step.

1.3. Exclusion of therapeutic, surgical and diagnostic methods from patentability

Article 53(c) EPC has its counterpart in the French patent law: Article L611-16 of the Code de la Propriété Industrielle provides that: “*Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be patentable. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods*.”

If the terms of the exclusion are strictly the same as those of Article 53(c) EPC, it may happen that the outcome of implementation of the texts differs, because French practice can be peculiar on some aspects of, in particular, therapeutic or surgical methods.

<u>Surgery</u>

“Surgical” describes an intervention on the animal or human living body, which can be invasive or non-invasive. What defines the presence of a surgical step is not the purpose of the act, but its nature. Furthermore, it is sufficient that a single step in a multi-step process is to be deemed surgical to exclude the whole method from patentability.

While the European practice admits that

- even if the act is invasive, a possible routine character or performance on uncritical body parts generally carried out in a non-medical environment, or
- uncritical methods involving only a minor intervention and no substantial health risks,

may allow to escape unpatentability, the Guidelines of the French Patent Office does not envision such arrangements. This is in line with the perceived appreciation that French practice appreciates the surgical nature of an intervention, rather strictly.

Regarding the particular case of methods enabling the functioning of devices, applied to medical devices, the Guidelines of the French Patent Office explicitly provide that if a functional relationship exists between the step carried out for the functioning of the device and the surgical effect exerted on the animal or human body by the said device, then the surgical effect is deemed not dissociable of the steps for carrying out the process of functioning of the device and patentability will not be accepted. For example:

- A claim on a method for assisting the manipulation of an instrument using a device for assisting the manipulation of said instrument, with a co-manipulation of the instrument/surgical tool by both a robot and a human operator in the context of a surgical intervention, or
- A claim on a method for directing a device for assisting the positioning, by reference to an organ of a patient, of a medical instrument inserted in a natural or artificial orifice of a patient, or
- A claim on a method for controlling the rotation of a file of a dental treatment device, with a step of repeated determination of the distance of the file with respect to a reference position defined on a body part, in order to avoid hurting the tooth by stopping the device by security before it can damage the tooth,

are all indicated to be susceptible of being unallowable. Computer-assisted surgical methods may therefore be challenged on this ground.

Therapy

The same type of consideration regarding a strict implementation of the texts, also applies to therapeutic methods.

The Guidelines the French Patent Office explicitly exclude methods for treating the animal or human living body at a distance, e.g., by radiotherapy, from patentability (as being a therapeutic method applied to the animal or human living body).

Therefore, depending upon claim formalism, a process that makes use of a medical device relying on such a type of effect may face objections in this respect.

Of note, as in Europe, the rationale according to which the products for use in such therapeutic methods are not excluded from patentability only applies to compounds and composition products, and does not apply to devices.

The Guidelines of the French Patent Office also state that a claim relating to a procedure for the operation of a device used for therapeutic purposes on the animal or human living body shall be excluded from patentability if the therapeutic effect is considered to be indissociable from the steps involved in the implementation of the procedure.

The following are thus likely to be rejected:

- claims for a method of checking the functioning of an anesthetic and/or respiratory assistance device which uses patient-specific measured data during treatment to rectify the functioning of the device;

- claims for a method of controlling an apparatus for supplying breathing gas to improve the lung properties by increasing the volume of breathing gas supplied at least intermittently compared to the volume provided in assisted breathing.

Therefore, if there is a functional relationship between the steps carried out in the course of the operation of the device and the therapeutic effect achieved by the latter on the body, the argument that measured parameters may only be physical parameters, would not allow escaping an objection that the claimed subject-matter falls within the methods of treatment claims, which are excluded from patentability.

The above emphasizes that French practice may be seen as even stricter than the EPO practice regarding these matters.

E. US (**Christopher George**)

A prior *paper* published from this subcommittee in 2021 analyzed a series of U.S. court decisions impacting medical device-related software inventions. Innovations related to medical device technology, medical data processing, output generation, etc., can be patentable but face a high level of scrutiny as related to both software (*Alice*) as well as medical diagnostics (*Mayo*). Claims directed to guiding human actions or reflecting laws of nature are very difficult to find patent eligible. If a computer is involved as a tool to merely leverage generic computing capabilities in a well understood, routine, and conventional manner, then such claims are likely ineligible. In contrast, providing a high degree of specificity in the claim and using the computer

to perform a particular action could be patent eligible. Similarly, simply observing, measuring, gathering, and/or storing data using general computer processing functionality is likely ineligible.

However, careful, clear definitions of terms, functions, and benefits can change such a claim to be subject matter eligible. Further, if data processing results in an improvement to a physical process or other physical system, such a claim is likely patent eligible. Merely displaying results of data processing is likely insufficient, while creation of a physical output is likely eligible subject matter. Improvements to a physical device itself are most often patent eligible, as long as the claims are directed specifically enough to the improvement. Unconventional or unexpected results can also provide a path to subject matter eligibility of software-as-a-medical device (SaMD), software-in-a-medical device (SiMD), and/or other software-related medical device claims under 35 U.S.C. § 101.

Subject Matter Eligibility

Some recent cases, at the Federal Circuit and district court levels, continue to develop guideposts for SaMD, SiMD, and other software-related medical innovation. At the district court level, subject matter eligibility questions under 35 U.S.C. § 101 remain important, even at the early stages of a motion to dismiss. For example, Judge Alan Albright, a frequent arbiter of patent disputes in the Western District of Texas, recently rendered an opinion on subject matter eligibility in the medical technology space in *Health Discovery Corp. v. Intel Corp.*, Case No. 6:20-cv-00666-ADA, 2021 WL 6116891 (W.D. Tex. Dec. 27, 2021). In *Health Discovery*, the court notes the blurring of the steps of the *Alice* analysis and inconsistency in Federal Circuit opinions, but finds that the key is a determination of "the relevant technology", which then guides the analysis of whether the claims are directed to a "specific means or method that improves [that] relevant technology." *citing McRO, Inc. v. Bandai Namco Games America, Inc.*, 837 F.3d 1299, 1314 (Fed. Cir. 2016).

The district court in *Health Discovery* notes that merely directing a claim to a physical device may not be sufficient to satisfy the *Alice*-driven threshold of 35 U.S.C. § 101. Additionally, just because the claimed device analyzes health-related data should also not be dispositive. The court found that the relevant technology is machine learning technology, specifically recursive feature elimination with a support vector machine. The court held that this construct was a mathematical concept and determined that, as a result, the claims were directed to a mathematical concept, which is an abstract idea under *Alice*'s first step. In evaluating *Alice*'s second step, the court found that the patentee did not allege an inventive concept, and none was found by the court in its own analysis. The court noted, however, that it would have been willing to find the claims eligible at step two if the plaintiff could "plausibly allege[] innovation in the non-abstract application realm." *citing SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1169 (Fed. Cir. 2018). A particular field of use or specificity in the steps of the algorithm is not sufficient to satisfy step two of the *Alice* analysis. As a result, the court granted defendant's motion to dismiss under 35 U.S.C. § 101 (without prejudice, allowing plaintiff to potentially reframe the allegations).

Obviousness

Subject matter eligibility under 35 U.S.C. § 101 is not the only issue facing software-related patents in medical technology. The Federal Circuit recently opined on obviousness issues in relation to robotically-assisted surgical technology. *Auris Health, Inc. v. Intuitive Surgical Operations, Inc.*, Case 2021-1733 (Fed. Cir. 2022). The focus in this case was on the motivation to combine, and the Patent Trial and Appeal Board (PTAB) had determined that, while all elements of the claims were found in the art, "great skepticism" would have precluded any motivation to combine the elements across references to arrive at the claimed invention.

The Court found that proper focus should be on the motivation of the skilled artisan, not generic skepticism in the industry. In this case, expert testimony of what a skilled artisan would do was provided by the accused infringer to the PTAB, but not rebutted by the patentee beyond the statement of general skepticism. The lack of substantive rebuttal proved fatal to the patentee here, allowing the Federal Circuit to find the likely motivation to combine based on one side's expert testimony. The Federal Circuit sent the case back to the PTAB to reconsider that motivation to combine with reasonable expectation of success. As such, the importance of presenting a complete case and not relying on general, thinly supported statements looms large here. Of note, where the Appellant did not provide such expert testimony, the Federal Circuit affirmed the PTAB's holding of patentability of those claims.

III. Comparison Chart (**All authors**)

The below chart provides a reference comparing the similarities/differences of laws of the above countries.

	Patent Eligibility / Industrial applicability	**Inventive Step / Obviousness**
China	Methods of diagnosis are not allowable	Identify the technical problem solved and evaluate whether the claimed technical solution is inventive over the prior art
Japan	Inventions of methods of surgery, therapy, or diagnosis of humans do not comply with the industrial applicability requirements. *See* JPO Guidelines, Section 3.1; However, a medical device or a medicine is a product, and is not considered to be a "method of surgery, therapy, or diagnosis of humans." *See id.* at 3.2.1.	"normal creation" activity of a person of ordinary skill can lack an inventive step
EPO	Computer programs and mathematical methods, for example, are excluded from patentability when claimed as such.	Only features contributing to a technical effect are considered for the assessment of inventive step.

	Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body are excluded from patentability under Article 53(c) EPC. A medical product such as a device is not considered to be encompassed by this exclusion.	
France	Software claimed as such are not considered inventions but software involving a technical effect (e.g., such as processing of medical images or command of a medical device) is eligible. Methods for treatment of the living human or animal body by surgery or therapy and diagnostic methods are excluded from patentability. This does not apply to substances and compositions for use in such methods, but similarly to the EP practice, products such as devices are not encompassed by such a provision. Guidelines regarding acceptable claims may be stricter than before the EPO.	Only features contributing to a technical effect are considered for the assessment of an inventive step.
U.S.	Software medical device inventions must meet both the statutory requirements of 35 U.S.C. § 101 (falling into one of four statutory categories) and those described by the Supreme Court in ***Alice Corp. v. CLS Bank International***, 573 U.S. 208 (2014), holding that a software-related invention must not be "directed to" an abstract idea without significantly more (i.e., without an "inventive concept").	Under 35 U.S.C. § 103 (obviousness), a claimed invention cannot be previously recited in a combination of prior art references, where one skilled in the art would have had some motivation to combine those references in the same manner as claimed.