



## Study Guidelines

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### 2022 – Study Question Patentability of Diagnostic Methods

#### Introduction

- 1) This Study Question examines the issues of patentability of inventions regarding the diagnosis of diseases or disorders. For the purposes of this Study Question, an invention regarding the diagnosis of diseases or disorders (further referred to in these Study Guidelines as "Diagnostic Method") may include:
  - (a) a novel diagnostic apparatus or machine for the collection of data;
  - (b) a novel biomarker combined with a finding that either the presence, absence, or deviation in level of the biomarker (as compared to a standard value) is linked to a disease state;
  - (c) a novel link between a previously known biomarker and a disease;
  - (d) a novel threshold for a previously known, previously linked biomarker and disease;
  - (e) a method for selecting biomarkers that are relevant for diagnosis of a determined disease;
  - (f) a method that involves a determined procedure or setting for sampling, preparing samples or preparing a person for sampling or testing certain conditions;
  - (g) a method of diagnosis that involves an act of a medical doctor based on results of a novel or known biomarker as well as
  - (h) any one of (a) to (g), combined with treatment or personalization of treatment parameters of the diagnostically determined disease.
  
- 2) TRIPs Articles 27(2) and (3) permit but do not mandate the exclusion from patentability of (i) inventions the commercial exploitation of which would be contrary to *ordre public* or morality and (ii) **diagnostic**, therapeutic and

surgical **methods** for the treatment of humans and animals and (iii) plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals.

### **Why AIPPI considers this an important area of study**

- 3) Accurate, rapid, local diagnosis of diseases and disorders has become increasingly important in light of the global COVID pandemic. Further, the development and evolution of personalized medicine has led to an increasing use of diagnosing disease or medical conditions.
- 4) Consistent and predictable treatment of Diagnostic Methods from a patentability standpoint is an important factor in growing investment in research and development in this important field of art.

### **Relevant treaty provisions**

- 5) Article 8 (1) of the TRIPs Agreement states:

*Members may, in formulating or amending their laws and regulations, adopt measures necessary to **protect public health and nutrition**, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.*

- 6) Further, Article 27 (2) and (3) of the TRIPs Agreement state:

*2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect **human, animal or plant life or health** or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*

*3. Members may also exclude from patentability:*

*(a) **diagnostic, therapeutic and surgical methods for the treatment of humans or animals;** (...)*

### **Previous work of AIPPI**

- 7) AIPPI has looked at patentable subject matter in related contexts, e.g. in the Resolution on Q202 ("The impact of public health issues on exclusive patent rights", Boston, 2008) and in the Resolution on Q238 ("Second medical use and other second indication claims", Toronto, 2014).
- 8) AIPPI had a panel discussion on the Patentability of Diagnostic Methods at its Annual Congress in London 2019 and the AIPPI Pharma Committee conducted an informal survey among its membership on the Patentability of Diagnostic Methods in 2019, which showed significant divergence in how this subject matter was treated in different jurisdictions.

### **Scope of this Study Question**

- 9) This Study Question shall focus on the patentability, strictly from a subject matter basis, of various types of inventions in the Diagnostic Method space. Novelty, inventive step, utility, and support requirements for Diagnostic Method claims are out of scope.
- 10) A question to be answered is whether the increased importance of Diagnostic Methods, for example in light of the global COVID pandemic, as well as the development and evolution of personalized medicine, should have an impact on the treatment of this subject matter as patent eligible.
- 11) In particular, it shall be examined whether, and if so how, medical practitioners are prevented or restricted at the point of care of a patient by such Diagnostic Method claims, and what is the appropriate balance between such restrictions on medical practitioners and the research and development incentives created by patent protection in this space.
- 12) In addition, it shall be examined whether, and at which point, a Diagnostic Method is merely a law of nature, an algorithm or mathematical equation, and what elements may be necessary for patentability of a Diagnostic Method claim.
- 13) Although consideration of the subject matter eligibility of methods of medical treatment is beyond scope, it may be useful to consider whether Diagnostic Methods are analogous, and whether they should be restricted to the same extent.

- 14) Further, it should be considered whether Diagnostic Methods should be treated as part of, or as initial steps in a method of medical treatment, or whether they are a different class of invention.

## Discussion

- 15) The restrictions on patentability for diagnostic and therapeutic methods are related to the concept that medical practitioners should not be prevented or restricted at the point of care of a patient by the concern that a treatment or Diagnostic Method may be protected by a patent. This is reflected e.g. in Article 53(c) of the European Patent Convention, which specifies that:

*“European patents shall not be granted in respect of (...) methods for treatment of the human or animal body by surgery or therapy and **diagnostic methods** practised on the human or animal body (...).”*

- 16) The EPO Enlarged Board of Appeal in its decision of G1/04<sup>1</sup> sets out the phases that must all be present in a method for it to relate to an excluded/non-patentable diagnostic method:
- (a) the examination phase, involving the collection of data,
  - (b) the comparison of these data with standard values,
  - (c) the finding of any significant deviation, i.e. a symptom, during the comparison, and
  - (d) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase (diagnosis for curative purposes).

In other words, to be excluded the method must include steps of obtaining and analysing the data, and must come to a diagnostic conclusion.

- 17) Also other jurisdictions have limited the patentability of diagnostic inventions. Article 25 (3) of the Chinese Patent Law – exceptions to patentability, explicitly states that no patent right shall be granted for methods for the diagnosis or for the treatment of diseases. This is interpreted in Part II, Chapter 1, Section 4.3.1.1 to mean that where a method involving diagnosis of a disease is (i) practiced on a living human or animal body (or in vitro samples from that body) and (ii) its immediate purpose is to obtain the diagnostic result of a disease or health condition, patent rights cannot be granted.

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<sup>1</sup> EPO Enlarged Board of Appeal 16 December 2005, ECLI:EP:BA:2005:G000104.20051216 (G1/04).

- 18) Likewise, the Brazilian Industrial Property Law states in Article 10 that operating or surgical techniques and therapeutic or diagnostic methods, for use on the human or animal body, are not considered to be inventions.
- 19) Article 49 of the Federal Law for the Protection of Intellectual Property in Mexico also excludes from being patentable diagnostic methods which are applicable to humans or animals. The criteria in Mexico exclude diagnostic methods directly applicable (invasive in any of their steps) to humans or animal bodies, but allow in vitro or ex vivo diagnostic methods.
- 20) In the U.S., the patentability of diagnostic inventions has been considered in several cases, including *Athena Diagnostics v. Mayo Collaborative Services*,<sup>2</sup> *Mayo Collaborative Services v. Prometheus Laboratories*,<sup>3</sup> *Association for Molecular Pathology v. Myriad Genetics*,<sup>4</sup> *Ariosa Diagnostics Inc. v. Sequenom, Inc.*,<sup>5</sup> *Illumina Inc. v. Ariosa Diagnostics, Inc., and Vanda*.<sup>6</sup> Generally, the subject matter eligibility of diagnostic methods uses the standard subject matter eligibility flow chart from MPEP 2106<sup>7</sup>.
- 21) In Japan, the Patent Act does not explicitly exclude diagnostic methods from patentable subject matter; however, according to the Tokyo High Court,<sup>8</sup> diagnostic methods are regarded as “*medical activity*” and thus lacking industrial applicability, so that such inventions do not satisfy the requirements set forth in Article 29 (1) of the Japanese Patent Act. According to the Japanese Patent and Utility Model Examination Guidelines, “*medical activity*” is defined as “*methods of surgery, therapy or diagnosis of humans*” that are normally practiced by medical doctors (or directed by medical doctors). On the other hand, 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.

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<sup>2</sup> *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC (“Athena I”)*, 915 F.3d 743 (Fed. Cir. 2019); reh’g en banc denied, 927 F.3d 1333 (Fed. Cir. 2019).

<sup>3</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

<sup>4</sup> *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

<sup>5</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), reh’g en banc denied, 809 F.3d 1282 (Fed. Cir. 2015).

<sup>6</sup> *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 967 F.3d 1319 (Fed. Cir. 2020).

<sup>7</sup> USPTO Manual of Patent Examining Procedure, see <https://www.uspto.gov/web/offices/pac/mpep/index.html>

<sup>8</sup> Tokyo High Court, case number Heisei 12 nen (Gyou-ke) No. 65.

***You are invited to submit a Report addressing the questions below.***

## **Questions**

### **I. Current law and practice**

*Please answer the below questions with regard to your Group's current law and practice.*

- 1) Are Diagnostic Methods<sup>9</sup> generally patentable subject matter in your jurisdiction? Please answer YES or NO.
  
- 2) Are claims to the following considered patent eligible from a subject matter basis, in your jurisdiction? Please answer YES or NO for each.
  - (a) a novel diagnostic apparatus or machine, whose only or primary purpose is diagnostic testing;
  - (b) a novel diagnostic technique or method, whose only or primary purpose is diagnostic testing;
  - (c) correlating the presence, absence, or deviation of expression of a novel biomarker to a disease state;
  - (d) a novel correlation of the presence, absence or deviation of expression of a known biomarker to a disease state;
  - (e) a novel threshold for the expression of a known biomarker as an indicator of a disease state, said biomarker previously already linked to the disease in the prior art;
  - (f) a novel diagnostic apparatus or machine with capacity of correlating data in order to diagnose and/or propose a determined treatment based on such diagnosis;
  - (g) a novel way of sampling or preparing a person for diagnosis;
  - (h) a Diagnostic Method that involves an act of a medical doctor based on results of a novel or known biomarker.

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<sup>9</sup> In this question and the questions below, "diagnostic method" has the meaning as explained in para. 1 of these Study Guidelines.

- 3) Do your answers to 2 (a) – (h), above, differ if the claim also contains a treatment step?
- 4) Do your answers to 2 (a) – (h), above, differ if the method is carried out separately from the human or animal body, e.g. by removing a tissue or blood sample and using the Diagnostic Method on the sample after it has been removed?
- 5) Do your answers to 2 (a) – (h), above, differ if the method does not include a step of the attribution of any specific measured or analyzed value to a particular clinical picture, i.e. does not come to a diagnostic conclusion?

**II. Policy considerations and proposals for improvements of your Group's current law**

- 6) According to the opinion of your Group, is your current law and practice regarding the patentability of Diagnostic Methods adequate and/or sufficient? Please respond by YES or NO and you may add a brief explanation.
- 7) According to the opinion of your Group, should Diagnostic Methods be generally patent eligible, from a subject matter basis under your law and practice? Please answer YES or NO.
- 8) Specifically, please answer YES or NO to each of the following questions:
  - (a) Should a novel diagnostic apparatus or, machine, whose only or primary purpose is diagnostic testing, be patentable subject matter?
  - (b) Should a novel diagnostic technique or method, whose only or primary purpose is diagnostic testing, be patentable subject matter?
  - (c) Should a finding correlating the presence, absence, or deviation of expression of a novel biomarker to a disease state, be considered patentable subject matter?
  - (d) Should a novel correlation of the presence, absence or deviation of expression of a known biomarker to a disease state, be considered patentable subject matter?

- (e) Should a novel threshold for expression of a known biomarker as an indicator of a disease state, said biomarker previously already linked to the disease in the prior art, be considered patentable subject matter?
  - (f) Should a novel diagnostic apparatus or machine with capacity of correlating data in order to diagnose and/or propose a determined treatment based on such diagnosis, be considered patentable subject matter?
  - (g) Should a novel way of sampling or preparing a person for diagnosis, be considered patentable subject matter?
  - (h) Should a Diagnostic Method that involves an act of a medical doctor based on results of a novel or known biomarker be considered patentable subject matter?
- 9) Should the answers to 8 (a) – (h), above, differ if the claim also contains a treatment step?
- 10) Should the answers to 8 (a) – (h), above, differ if the method is carried out separately from the human or animal body, e.g. by removing a tissue or blood sample and using the Diagnostic Method on the sample after it has been removed?
- 11) Should the answers to 8 (a) – (h), above, differ if the method does not include a step of the attribution of any specific measured or analyzed value to a particular clinical picture, i.e. does not come to a diagnostic conclusion?
- 12) Has the ineligibility of diagnostic claims in any jurisdiction acted as a deterrent to research and development in diagnostics in your jurisdiction? Provide concrete examples if possible.
- 13) Are there any other policy considerations and/or proposals for improvement to your Group's current law falling within the scope of this Study Question?

### **III. Proposals for harmonisation**

*Please consult with relevant in-house / industry members of your Group in responding to Part III.*



- 14) Do you consider harmonisation regarding the patentability of Diagnostic Methods as desirable in general? Please respond by YES or NO, and you may add a brief explanation.

*If YES, please respond to the following questions without regard to your Group's current law or practice.*

*Even if NO, please address the following questions to the extent your Group considers your Group's current law or practice could be improved.*

- 15) Should Diagnostic Methods be patentable subject matter? Please answer YES or NO.
- 16) Should claims to the following be considered patentable eligible from a subject matter perspective? Please answer YES or NO for each of the below.
- (a) Should a novel diagnostic apparatus or machine, whose only or primary purpose is diagnostic testing, be patentable subject matter?
  - (b) Should a novel diagnostic technique or method, whose only or primary purpose is diagnostic testing, be patentable subject matter?
  - (c) Should a finding correlating the presence, absence, or deviation of expression of a novel biomarker to a disease state, be considered patentable subject matter?
  - (d) Should a novel correlation of the presence, absence or deviation of expression of a known biomarker to a disease state, be considered patentable subject matter?
  - (e) Should a novel threshold for expression of a known biomarker as an indicator of a disease state, said biomarker previously already linked to the disease in the prior art, be considered patentable subject matter?
  - (f) Should a novel diagnostic apparatus or machine with capacity of correlating data in order to diagnose and/or propose a determined treatment based on such diagnosis, be considered patentable subject matter?

- (g) Should a novel way of sampling or preparing a person for diagnosis, be considered patentable subject matter?
  - (h) Should a Diagnostic Method that involves an act of a medical doctor based on results of a novel or known biomarker be considered patentable subject matter?
- 17) Should the answers to 16 (a) – (h), above, differ if the claim also contains a treatment step?
  - 18) Should the answers to 16 (a) – (h), above, differ if the method is carried out separately from the human or animal body, e.g. by removing a tissue or blood sample and using the Diagnostic Method on the sample after it has been removed?
  - 19) Should the answers to 16 (a) – (h), above, differ if the method does not include a step of the attribution of any specific measured or analyzed value to a particular clinical picture, i.e. does not come to a diagnostic conclusion?
  - 20) Should the patentability of Diagnostic Methods be restricted to the same extent as the patentability of methods of treatment?
  - 21) Please comment on any additional issues concerning any aspect of the subject matter eligibility of Diagnostic Methods that you consider relevant to this Study Question.
  - 22) Please indicate which industry sector views provided by in-house counsels are included in your Group's answers to Part III.