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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 generally patentable subject matter in your jurisdiction? Please answer YES or NO.

YES. The exclusion to patentability is interpreted narrowly. According to Section 1(3) of the Finnish Patents Act, Diagnostic Methods are only excluded from patentability, if the examination phase of the method is performed on or requires the presence of a human or animal body. Finnish Patent Law has been harmonised with the EPC and the principles outlined in Decision G 1/04 of the Enlarged Board of Appeal of the EPO are followed. To be excluded from patentability the Diagnostic Method must include all the steps of obtaining and analysing the data and must come to a diagnostic conclusion. Moreover, all technical method steps must be practiced on the human or animal body.

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;

YES. A novel diagnostic apparatus or machine is patentable even if the primary purpose is diagnostic testing. Functional features relating to the device, may be excluded if a step of the method may be considered as a treatment by therapy or surgery or diagnostic method.

(b) a novel diagnostic technique or method, whose only or primary purpose is diagnostic testing;

YES, the novel diagnostic technique or method may be patentable, if at least one of the four steps identified in G 1/04 is omitted and none of the technical steps are performed in the presence of the human or animal body.

(c) correlating the presence, absence, or deviation of expression of a novel biomarker to a disease state;

YES. Correlating the presence, absence, or deviation of expression of a novel biomarker is generally patentable.

(d) a novel correlation of the presence, absence or deviation of expression of a known biomarker to a disease state;

YES. This scenario would be analogous to a "second medical use", and the general exclusion from patentability does not extend to a novel correlation assuming the novel correlation does not directly lead to the prescription of a medical treatment on a human or animal.

(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;

YES. Unless the examination requires the presence of a human or animal.

(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;

YES. Cf. the answer to question 2(a).

(g) a novel way of sampling or preparing a person for diagnosis;

NO. Assuming this method requires the presence of a human or animal body.

(h) a Diagnostic Method that involves an act of a medical doctor based on results of a novel or known biomarker.

NO. Assuming that this method requires presence of a human or animal body.

3) Do your answers to 2 (a) – (h), above, differ if the claim also contains a treatment step?

(a) The answer does not differ from the answer of 2 (a).

A method relating to the operation of a therapeutic device in contact with a living human being or animal may be patentable if there is no functional link between the method and the therapeutic effect of the device.

(b) A diagnostic method is patentable if the method does not include a measure performed directly on a human body. The answer differs from the answer of 2 (b) if there are several steps in the procedure, and the surgical or therapeutic treatment cannot be distinguished from other steps. In this case, the whole procedure is considered surgical or therapeutic. Therapeutic methods are not patentable. Both preventive and curative measures are defined as therapeutic treatments.

(c) The answer does not differ from the answer of 2 (c). The first medical use is a product claim linked to a medical use. Anyone who discovers that a substance or compound known in another context has diagnostic or surgical utility or therapeutic effect may, notwithstanding the novelty requirement, obtain a patent for such substance or compound, even if such substance or compound is previously known.

However, A claim in the format: "Use of substance or composition X for the treatment of disease Y..." is not accepted for patentability, as it is considered a method for treatment excluded from patentability.

(d) The answer does not differ from the answer of 2 (d). If the known substance or composition was previously disclosed for use in surgery, therapy or diagnostic methods practised on the human or animal body, a patent may still be obtained for any second or further use of the substance in these methods provided that said use is novel and inventive.

However, as noted above, if there are several steps in the procedure, but the surgical or therapeutic treatment cannot be distinguished from other steps, the whole procedure is considered surgical or therapeutic and methods of therapeutic treatment are not patentable.

(e) The answer does not differ from the answer of 2 (e).

However, as noted above, if there are several steps in the procedure, but the surgical or therapeutic treatment cannot be distinguished from other steps, the whole procedure is

considered surgical or therapeutic and methods of therapeutic treatment are not patentable.

(f) The answer does not differ from the answer of 2 (f).

According to the Finnish Patents Act methods for surgical or therapeutic treatment or diagnostic methods, practiced on humans or animals, shall not be regarded as inventions. This provision shall not, however, preclude the grant of patents for products, including substances and compositions, for use in any of these methods.

A method relating to the operation of a therapeutic device in contact with a living human being or animal may be patentable if there is no functional link between the method and the therapeutic effect of the device.

(g) The answer does not differ from the answer of 2 (g).

Diagnostic methods are patentable as long as the method used does not include a measure performed directly on a human body.

(h) The answer does not differ from the answer of 2 (h).

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?

(a) The answer does not differ from the answer of 2 (a). An *in vitro* Diagnostic Method using a tissue or blood sample after it has been removed from the human body is patentable, assuming that the removal step from the human body is excluded.

(b) A diagnostic method is patentable if the method does not include a measure performed directly on or requires the presence of a human body and is carried out using a tissue sample after it has been removed, assuming that the removal step from the human body is excluded.

(c) The answer does not differ from the answer of 2 (c). A diagnostic method is patentable if the method does not include a measure performed directly on or requires the presence of a human body and is carried out using a tissue sample after it has been removed, assuming that the removal step from the human body is excluded.

(d) The answer does not differ from the answer of 2 (d), assuming that the removal step from the human body is excluded.

(e) The answer does not differ from the answer of 2 (e), assuming that the removal step from the human body is excluded.

(f) The answer does not differ from the answer of 2 (f), assuming that the removal step from the human body is excluded.

(g) The answer differs from the answer of 2 (g), assuming that the removal step from the human body is excluded and it is carried out *in vitro*, without requiring the presence of the human body. Diagnostic methods are generally patentable as long as the method used does not include a measure performed directly on or requiring the presence of a human body.

- (h) The answer differs from the answer of 2 (h), assuming that the removal step from the human body is excluded and it is carried out *in vitro*, without requiring the presence of the human body. Diagnostic methods are generally patentable as long as the method used does not include a measure performed directly on or requiring the

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?

- (a) The answer does not differ from the answer of 2 (a). A Diagnostic Method which does not include a step of the attribution of any specific measured or analyzed value to a particular clinical picture, is patentable.
- (b) The answer does not differ from the answer of 2 (b). A Diagnostic Method is patentable if it does not include a step of the attribution of any specific measured or analyzed value to a particular clinical picture.
- (c) The answer does not differ from the answer of 2 (c). A Diagnostic Method is patentable if it does not include a step of the attribution of any specific measured or analyzed value to a particular clinical picture.
- (d) The answer does not differ from the answer of 2 (d). A Diagnostic Method is patentable if it does not include a step of the attribution of any specific measured or analyzed value to a particular clinical picture.
- (e) The answer does not differ from the answer of 2 (e). A Diagnostic Method is patentable if it does not include a step of the attribution of any specific measured or analyzed value to a particular clinical picture.
- (f) The answer does not differ from the answer of 2 (f). A Diagnostic Method is patentable if it does not include a step of the attribution of any specific measured or analyzed value to a particular clinical picture.
- (g) The answer does not differ from the answer of 2 (g). A Diagnostic Method is patentable if it does not include a step of the attribution of any specific measured or analyzed value to a particular clinical picture.
- (h) The answer does not differ from the answer of 2 (h). A Diagnostic Method is patentable if it does not include a step of the attribution of any specific measured or analyzed value to a particular clinical picture.

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.

YES. However, the need for patent protection should be reasonably balanced with the access to health as a human right and considerations relating to sustainability of the healthcare system at large.

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.

YES. The exclusion to patent eligibility should be interpreted narrowly in the context of Diagnostic Methods.

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?

YES.

(b) Should a novel diagnostic technique or method, whose only or primary purpose is diagnostic testing, be patentable subject matter?

YES, novel diagnostic technique or method should be patentable, if none of the technical steps are performed in the presence of the human or animal body.

(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?

YES. However, according to general patent eligibility requirements, a mere discovery as such should not be a 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?

YES. However, according to general patent eligibility requirements, a mere discovery as such should not be a 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?

YES. However, according to general patent eligibility requirements, a mere discovery as such should not be a 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?

YES.

(g) Should a novel way of sampling or preparing a person for diagnosis, be considered patentable subject matter?

NO. Clinical measures *as such* requiring the presence of a human body should not 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?

NO.

9) Should the answers to 8 (a) – (h), above, differ if the claim also contains a treatment step?

NO, should be the same.

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?

NO, should be the same.

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?

NO.

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.

Generally speaking, no, as the possibilities to patent Diagnostic Methods in many jurisdictions, especially in Europe are fairly flexible. However, the developments in the US have made more difficult to obtain patent protection for Diagnostic Methods.

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?

Access to health as a human right should be balanced with commercial interests and possibilities to obtain sufficient patent protection for innovations.

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.

YES. As general rule the exceptions to patentability should be interpreted narrowly and the overall rules relating to patentability of diagnostic methods should be clear and predictable.

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.

YES.

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?

YES.

(b) Should a novel diagnostic technique or method, whose only or primary purpose is diagnostic testing, be patentable subject matter?

YES. At least novel diagnostic techniques or methods performed *in vitro*, without requiring the presence of the human body should be patentable.

(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?

YES. However, according to general patent eligibility requirements, a mere discovery as such should not be a 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?

YES. However, according to general patent eligibility requirements, a mere discovery as such should not be a 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?

YES. However, according to general patent eligibility requirements, a mere discovery as such should not be a 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?

YES.

(g) Should a novel way of sampling or preparing a person for diagnosis, be considered patentable subject matter?

NO. Clinical measures *as such* involving the presence of a human body should not 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?

NO. Clinical measures as such involving a patient should not be considered patentable subject matter.

17) Should the answers to 16 (a) – (h), above, differ if the claim also contains a treatment step?

YES.

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?

NO.

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?

NO.

20) Should the patentability of Diagnostic Methods be restricted to the same extent as the patentability of methods of treatment?

NO.

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.

The rules relating to patentability of diagnostic methods, such as the *in vitro* vs. *in vivo* distinction is to some extent artificial and conservative and does not necessarily apply to emerging technologies. Moreover, global harmonization is needed to facilitate the possibilities to obtain patent protection for diagnostic methods in various jurisdictions. In addition, particularities concerning cross-border use of diagnostic methods, where different steps are carried out in different jurisdictions should be addressed.

22) Please indicate which industry sector views provided by in-house counsels are included in your Group's answers to Part III