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2022 – Study Question
Patentability of Diagnostic Methods

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I. Current law and practice

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

1) Are Diagnostic Methods⁹ generally patentable subject matter in your jurisdiction? Please answer YES or NO.
Yes, with the exception of diagnostic methods applied to the body of a human being or an animal.

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.

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

Yes, with the exception pointed out above.

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

Yes, with the exception pointed out above.

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

Yes, with the exception pointed out above.

(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, with the exception pointed out above.

(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.

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

No.

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

No.

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

Yes. According to the Italian patent law and case law the exception to the patentability of diagnostic methods applies in the case of the application to or treatment of human or animal body.

- 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?

Yes. Diagnostic methods carried out in vitro can be patented.

- 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?

Yes. There is no specific case law on this topic in Italy. Hence, assuming that an Italian court would follow the EPO approach we may refer to G1/04 and believe that the method would likely not be considered a diagnostic method.

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. Our current law and practice regarding the patentability of Diagnostic Methods are adequate and harmonized with the EPO law and practice.

- 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, with the exception of diagnostic methods applied to human or animal body.

- 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, with the exception of diagnostic methods applied to 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, with the exception of the use of such a finding for diagnostic methods applied to human or animal body.

- (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, with the exception of the use of this correlation for diagnostic methods applied to human or animal body.

- (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, with the exception of the use of such a threshold for diagnostic methods applied to human or animal body.

- (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.

- (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?

Yes. We agree that the exception concerning the patentability of diagnostic methods applies in the case of the application to or treatment of human or animal body.

- 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?

Yes. We believe that diagnostic methods carried out in vitro should be patentable.

- 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?

Yes. We are in line with decision G1/04 of the Enlarged Board of Appeal of the EPO: the method would likely not be considered a diagnostic method.

- 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.

We are not aware of such cases.

- 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?

No other policy considerations and/or proposals.

III. Proposals for harmonisation

- 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, harmonization is desirable.

- 15) Should Diagnostic Methods be patentable subject matter? Please answer YES or NO.

Yes, Diagnostic Methods should be patentable subject matter.

- 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, with the exception of diagnostic methods applied to 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, with the exception of the use of such a finding for diagnostic methods applied to human or animal body.

- (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, with the exception of the use of this novel correlation for diagnostic methods applied to human or animal body.

- (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, with the exception of the use of such a threshold for diagnostic methods applied to human or animal body.

- (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.

- (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.

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

Yes. We believe that the exception concerning the patentability of diagnostic methods should apply in the case of the application to or treatment of human or animal body.

- 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?

Yes. We believe that diagnostic methods carried out in vitro should be patentable.

- 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?

Yes. We believe that the approach maintained by the Enlarged Board of Appeal of the EPO in their decision G1/04 – according to which the method in re would likely not be considered a diagnostic method – should be followed.

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

Yes.

- 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.

No further comments.

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

Pharmaceuticals