

Q280



National Group: Hungary
Title: **Patentability of diagnostic methods**
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Questions

I. Current law and practice

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

- 1) Are Diagnostic Methods¹ generally patentable subject matter in your jurisdiction? Please answer YES or NO.

YES.

- 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 proviso that at least one of the following criteria is met: a) the method is not practised on the human or animal body, b) the method does not come to a diagnostic conclusion.

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

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

YES.

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

YES.

(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.

(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;

YES.

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

YES.

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

YES – because therapeutic treatment methods (and also diagnostic methods comprising treatment steps) performed on the human or animal body are not patentable in Hungary.

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?

NO.

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?

NO.

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.

- 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.

- 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.

(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.

(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.

(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.

(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?

YES.

(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?

YES.

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

YES – because therapeutic treatment methods (and also diagnostic methods comprising treatment steps) performed on the human or animal body should not be patentable in Hungary.

- 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.

- 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.

NO, but the incentive of obtaining patents for such developments is now significantly lower because of important jurisdictions where said developments are not patentable.

- 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.

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.

YES - because according to present practice, e.g. in the US, important diagnostic developments are not patent eligible.

- 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.

(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.

(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.

(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.

(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?

YES.

(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?

YES.

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

YES – because therapeutic treatment methods (and also diagnostic methods comprising treatment steps) performed on the human or animal body should not be patentable in Hungary.

- 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.

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

Pharma, biotech.