AIPPI Q280 – Patentability of Diagnostic Methods

Report of the Swiss Group

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.

No.

Exclusion from patentability according to Art. 2(2)(a) Federal Act on Patents and Inventions (PatA)

> «2 Also excluded from patentability are:
>
> a. methods for treatment by surgery or therapy and diagnostic methods practised 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.
(Art 2(2)(a) PatA and Art 53(c) EPC, 2nd sentence, Art 1 EPC; Guidelines for the substantive examination 3.2.3)

b) a novel diagnostic technique or method, whose only or primary purpose is diagnostic testing;
Yes.
We understand that the subject-matter does not include the deductive medical decision phase.
Guidelines for the substantive examination 3.2.1

c) correlating the presence, absence, or deviation of expression of a novel biomarker to a disease state;
No.
(Art 1(1) PatA; Art 2(2)(a) PatA)

d) a novel correlation of the presence, absence or deviation of expression of a known biomarker to a disease state;
No.
(Art 2(2)(a) PatA. This response takes into account that a biomarker can be evaluated as a part of the human body.)

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;
No.
(Art 1(1) PatA: not deemed to be an invention)

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.
(Art 2(2)(a) PatA and Art 53(c) EPC, 2nd sentence, Art 1 EPC, Guidelines for the substantive examination 3.2.3)

g) a novel way of sampling or preparing a person for diagnosis;
No.
(Art 2(2)(a) PatA: can be considered a method of surgery, treatment practised on the human body that is excluded from patentability)

h) a Diagnostic Method that involves an act of a medical doctor based on results of a novel or known biomarker.
No.
The presence or the absence of a medical doctor is not relevant for the exclusion from patentability of the diagnosis method.

3.

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

Yes.

In this case the answers to 2 (a)–(h) are No. Guidelines for the substantive examination 3.2.2.

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The english translation of the summary is included on Swisslex and legalis only.

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, the answers to 2 (c) to (d), (g) and (h) are Yes..

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., in this case the answer to 2 (h) is Yes.

Comment: Concerning (c) and (d), it is our view that the step of correlating the presence, absence or deviation of expression of a known/novel biomarker to a disease state includes the step of attribution of any specific measured or analysed value to a particular clinical picture.

Guidelines for the substantive examination 3.2.2.

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., according to current law and practice it is still possible to protect an invention related to diagnostics that has a commercial value.

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.

No.

(To reach this conclusion, we have taken into consideration Art. 9(g) PatA that excludes from the effects of patents medical activities related to a medicinal product, but this Article does not exclude from the effects of patents medical activities related to a diagnostic method. Thus, based on current law and practice, if diagnostic methods were patentable, medical doctors could be held liable for infringing such patented diagnostic methods. We would suggest further discussion of this issue with the whole group.)

8.

Specifically, please answer YES or NO to each of the following questions:

Since our response to question 7) is No., we have concluded that our answers to question 8) (a)–(h) should not be different from our answers to question 2) (a)–(h) – Part I.

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, provided that the subject-matter does not include the deductive medical decision phase.

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?
No.

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?
No.

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?
No.

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?

No.

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.

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.

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.

No pharmaceutical can be marketed any longer without a specific companion diagnostic. R&D in diagnostics will therefore occur irrespective of the ineligibility of diagnostic claims in any jurisdiction. The Swiss group is of the opinion that IP protection for diagnostics is nevertheless an important upside, also under the freedom-to-operate aspect, but does not regard it as a deterrent of diagnostics R&D.

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?

The Swiss group would welcome a concept of acknowledging the patentability of diagnostics per se. The patentability of diagnostics nowadays appears to be a mere question of clever claim drafting to bypass existing limitations. Acknowledging patentability would in our view simplify patent practice in the various jurisdictions and lead to more certainty regarding patentability.

Legal privileges for medical practitioners (e.g. physician or pharmacist privileges, Art. 9(g) and (h) PatA) and their exemption form the effects of patents are seen as a better means to safeguard an unburdened medical practice. In addition, compulsory license models, such as in Art. 40(c) PatA, which set forth a kind of compulsory license for diagnostic tools, can be foreseen in cases of anticompetitive behaviour of a patent holder.

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.

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?**
No.
(if interaction with human body is involved)

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*?

No.

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*?

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

The Study Group is of the opinion that the aim of the diagnostic method exemption can be achieved through rules relating to patent enforcement, rather than patent eligibility. Patent law should allow diagnostic methods to be patented but foresee a regime under which medical practitioners are subject to a special regime of enforcement that guarantees full medical freedom for the benefit of patients' well-being.

22.

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

In vitro diagnostics

Zusammenfassung

Innerhalb der Schweizer Arbeitsgruppe wurden vielfältige Aspekte der Patentierbarkeit diagnostischer Methoden rege diskutiert. Während solche Verfahren nach schweizerischem Recht *per se* nicht patentfähig sind, bietet die geltende Gesetzgebung und Praxis unter bestimmten Umständen Zugang zur Patentierbarkeit. Insbesondere sind diagnostische Verfahren, die *in vitro* durchgeführt werden, nicht von der Patentierbarkeit ausgeschlossen. Gleiches gilt für diagnostische Instrumente im Allgemeinen, solange kein therapeutischer Schritt inbegriffen ist.

Die Gruppe ist der Ansicht, dass Forschung und Entwicklung auf dem Gebiet der Diagnostik nicht durch die Patentierbarkeit diagnostischer Verfahren als solcher behindert wurden. Erstens kann Patentschutz durch die Formulierung entsprechender Patentansprüche erlangt werden. Zweitens erfordern Pharmazeutika heutzutage die Entwicklung spezifischer Companion Diagnostics unabhängig von jeglichen IP-Aspekten.

Die Schweizer Arbeitsgruppe würde ein Regime der Patentierbarkeit von diagnostischen Verfahren *per se* begrüßen und empfehlen. Damit dieser Wandel sinnvoll umgesetzt werden kann, muss die Berufsfreiheit der Heilberufler und Ärzte gleichwohl gewährleistet sein. Dies könnte durch eine spezifische Regelung der Durchsetzung diagnostischer Patente erreicht werden, anstatt diagnostische Verfahren insgesamt von der Patentierbarkeit auszuschließen. Aus verschiedenen Gründen, nicht zuletzt zum Wohle der Rechtssicherheit, sollte auch eine internationale Harmonisierung der Regelungen zu Diagnoseverfahren gefördert werden.

Résumé

Un large éventail d'aspects concernant la brevetabilité des méthodes de diagnostic a été vivement débattu au sein du groupe de travail suisse. Alors que ces méthodes ne sont pas brevetables en soi en vertu du droit suisse, la législation et la pratique actuelles offrent un accès à la brevetabilité dans certaines circonstances. En particulier, tant qu'aucune étape de traitement n'est impliquée, les méthodes de diagnostic réalisées *in vitro*, ainsi que les instruments de diagnostic en général, ne sont pas exclus de la brevetabilité.

Le Groupe est d'avis que la recherche et le développement dans le domaine du diagnostic n'ont pas été entravés par l'inéligibilité au brevet des méthodes de diagnostic en tant que telles. Premièrement, la protection par brevet peut toujours être obtenue en rédigeant des revendications appropriées. Deuxièmement, les produits pharmaceutiques nécessitent aujourd'hui le développement de diagnostics compagnons spécifiques, indépendamment de tout aspect de propriété intellectuelle.

Le groupe de travail suisse saluerait et recommanderait un régime d'admissibilité au brevet des méthodes de diagnostic en soi. Pour que ce virage s'opère de manière sensée, la liberté d'exercice des professionnelles en soins et des médecins praticiens doit néanmoins être garantie. Cela pourrait être réalisé via une réglementation spécifique de l'application des brevets de diagnostic, plutôt que d'exclure complètement les méthodes de diagnostic de la brevetabilité. Pour diverses raisons, dont la sécurité juridique, l'harmonisation internationale des règles entourant les méthodes de diagnostic est également à encourager.