AIPPI Nederland – Q280 Patentability of Diagnostic Methods

Conceptantwoorden AIPPI werkgroep Q280

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I. Current law and practice

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

YES.

Using the definition given in the Study Guidelines under paragraph 1, inventions that relate to the diagnosis of diseases or disorders are generally patentable. There is no legislation or case law in the Netherlands that prevents patenting of devices or methods suitable for diagnostic means as long as the treatment itself is not involved. The exception formulated in the EPC and the Dutch Patent Act ("**DPA**") is interpreted narrowly by the EPO and the Netherlands does not seem to deviate from this policy in any way. The patentability of technology aimed at diagnostic and therapeutic applications is generally accepted in the Netherlands. See for instance Court of The Hague, 9 December 2009 (341571 / HA ZA 09-2183), Intervet v Merial.

As stated, diagnostic methods as such are excluded form patentability (Art. 3(f) DPA and Art. 53(c) EPC, G1/04). However, in practice methods having a diagnostic character can be protected if the claim does not include any method step relating to all of the following phases of a diagnostic process:(i) the examination phase, involving the collection of data, (ii) the comparison of these data with standard values, (iii) the finding of any significant deviation, i.e. a symptom, during the comparison, (iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase (diagnosis for curative purposes *stricto sensu*). In other words, a method can only be considered a diagnostic method excluded from patentability if it contains <u>all</u> of the steps cited above.

Furthermore, steps (i) – (iii) should be performed on the human or animal body and only <u>technical steps</u> are taken into account for the assessment whether an invention is excluded from patentability. "On" the human or animal body should be interpreted as meaning that the steps each imply an interaction with the body in question, whereby physical presence is necessary. There is, however, no specific level of degree of invasiveness that is required. Any interaction will suffice, and not even direct contact is necessary: a method may also fall under the exception if the steps are performed at some distance.

A practical solution to be able to patent a certain method that includes one or more of the above steps would, for instance, be to omit step (iv), i.e. by only providing intermediate findings.

The exception regarding inter alia diagnostic methods relates only to those methods as such. Therefore, medical devices and medical aids, prostheses and implants, medicinal products, dressings etc. can generally be patented in full, although certain applications of such devices, as treatment or diagnostic methods, may of course be excluded from patentability.

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; the restriction only applies to methods and generally not to products for use in such a method (Art. 53(c) EPC, second sentence, Art. 3(f) DPA, second sentence).

As an exception to this general principle, for devices used in surgery or method of treatments, EPO caselaw however prescribes that a device which is defined with a functional feature that can only be obtained by surgery or a therapeutic step is excluded (T1731/12, T 775/97). A same reasoning may be applied to an apparatus defined (only) by a functional feature relating to the step of diagnosis.

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

YES, see answer under question 1 above.

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

YES, see answer under question 1 above.

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

YES, with reference to the answer under question 1 above and provided that said novel correlation is put into practical use in the claim, because otherwise the subject matter would be a mere discovery, which is unpatentable.

(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, see answers under (d).[1]

(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, see answers under in (a) and (d).

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

YES, the actual diagnosis (step iv) is lacking, and of course provided that this does not involve a surgical step, i.e. an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be caried out and which entails a substantial health risk even when carried out with the required professional care and expertise (exception on surgical methods, G1/07, headnote 1).

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

[1] One might even say that this is comparable to a new dosage regimen of a known substance for a known use, which is also patentable in the Netherlands.

YES, see the answer under questions 1 above and provided that

- the claim includes technical features; and
- the act of the medical doctor does not include a step of treatment of the human or animal body by surgery or therapy (see above).

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

YES, the answers for (b), (c), (d), (e), (g) and (h) could be different if the claim includes a step of treatment of the human or animal body by surgery or therapy, because a patent cannot be granted in respect of methods for treatment of the human or animal body by surgery or therapy. In that case the answer would be “no”.

For (a) and (f) this should not make a difference, provided that the device is not defined with a functional feature that can only be obtained by surgery or a therapeutic step (see answer under (a) above).[2]

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, the answers would be the same. All method steps of a technical nature belonging to phases (i)-(iii) must be "practiced on the human or animal body". If the method is not practiced on the human body, even an actual step of diagnosis (iv) is allowed in the claim (GL G-II, 4.2.1.3, G 1/04 r. 5).

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. (a) – (g) are already considered patentable when properly drafted, i.e., not including a step iv (the attribution of the deviation to a particular clinical picture). The answers would thus be the same for (b), (c), (d), (e) (g) and (h). For (a) and (f) relating to the devices, any functional features (see answer under (a) above) would be even less relevant.

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.

NO. The aim of the exclusion from patentability of diagnostic methods is to ensure that those who carry out diagnostic methods as part of the medical treatment of humans or veterinary treatment of animals are not inhibited by patents (see Enlarged Board of Appeal decisions G1/04 reasons 4), and that medical and veterinary practitioners are free to use their skills and knowledge of the best available treatments to achieve the utmost benefit for their patients

[2] During prosecution, these claims should be limited to exclude any such step. This could however lead to a lack of clarity due to missing essential features (which is not a nullity ground but can lead to lack of enablement, which is a nullity ground).

uninhibited by any worry that some treatment might be covered by a patent (see G1/07 reasons 3.3.6).

However, on the one hand the exclusions do not shield these practitioners from the realm of patent law when providing care to their patients. Medical and veterinary practitioners still need authorization to practice any inventions outside the excluded field yet required to diagnose the patient as part of the medical treatment. There is no general exclusion of infringement under Dutch law for the acts of medical practitioners when providing treatment to a patient, contrary to the US solution of 35 USC 287(c). As a consequence, medical practitioners can still be inhibited by patents when diagnosing the patient as part of the medical treatment.

In this respect, the group observes that a diagnosis of a patient's condition is the result of a sequence of successive steps taken by the medical and veterinary practitioner, of which the purely intellectual step of the diagnosis "strictu sensu" is the final step. According to the established case law a method claim which does not include the feature pertaining to the diagnosis "strictu sensu" is outside the excluded field. To diagnose a patient as part of a medical treatment though, the medical or veterinary practitioner will in most cases have to perform some of the preceding steps, which being outside the excluded field could be covered by a patent. If so, the practitioner would require a license from the patentee to perform those steps.

The group further observes that for most cases, effective patent protection for a diagnostic method can still be obtained by a claim to a device or kit suitable to perform this method. The use of a patented diagnostic device or use a patented kit for diagnosis is an act reserved to the patentee under art. 53(1)(a) Dutch patent act. (Under the Agreement on a Unified Patent Court expected to enter into force end of 2022, this would be an infringement under art. 25 (a)). The practitioner would therefore require a license from the patentee, in the absence of which the use of the device or kit constitutes an infringement with the associated liabilities on the practitioner. Hence, even in the excluded field the practitioners are not shielded.

On the other hand, the exclusion of diagnostic methods is an absolute one, independent from the person performing the method. This creates a protection gap because diagnostic methods performed without involvement of a medical practitioner or which are not for curative purposes are also excluded. For example, diagnostic methods completely performed by personal health devices or by wearables like smart watches which inform the device user of the outcome are excluded as well. This excludes a valuable type of protection in an area which is outside the aim of the exclusion.

The group further observes that the current exclusion can be detrimental to investments and research within the excluded field. Research in areas beneficial to society, e.g. to link a certain deviation to a particular clinical picture and therefore open effective treatment of illnesses, or to develop systems which improve the accuracy of the diagnosis by the medical or veterinary practitioner may be less attractive to invest in.

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, provided that:

(1) The acts of a medical or veterinary practitioner carrying out diagnostic methods as part of the medical treatment of humans or veterinary treatment of animals are excluded from being considered infringing acts.
The groups observes that such an exclusion should be narrowly tailored to immunize medical practitioners from liabilities resulting from diagnostics as part of medical or

veterinary treatment of a patient, and not cover commercial exploitation by medical practitioners or the provision of commercial services to medical practitioners.
The group further observes in this respect that both the Dutch patent act and the Agreement on a Unified Patent Court already contain a provision exempting the extemporaneous preparation by a pharmacy for an individual case in accordance with a medical prescription or acts concerning the medicine so prepared, thus ensuring for an individual case that the best medicine to treat the patient is available for that individual case. It seems consistent to extent this exemption to the diagnosis by the medical practitioner which precedes the prescription to make sure that the best diagnosis available can be made.

(2) The human body itself does not become subject to the exclusionary rights of the patentee.
(3) The diagnostic methods do not enter into a non-eligible category, like mental acts or discoveries and meet the other requirements for patentability like novelty and inventive step.

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

As a preliminary remark, the group observes that the answers below are subject to the comments to question 7 above.

(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

The group notes though that a claim to such a finding could be a purely mental act or just be a discovery, and be excluded from patentability on that ground.

In addition, the group notes that in such a case the contribution to the state of the art by the finding could be a purely intellectual one. This would lead to this de facto being non-eligible subject matter, because non-technical features are excluded for the purpose of assessing inventive step and the claim would therefore always fail to involve an inventive step.

(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.

The group notes though that a claim to such a correlation could be a purely mental act or just be a discovery, and be excluded from patentability on that ground.

In addition, the group notes that in such a case the contribution to the state of the art by the finding could be a purely intellectual one. This would lead to this de facto being non-eligible subject matter, because non-technical features are excluded for the purpose of assessing inventive step and the claim would therefore always fail to involve an inventive step.

(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.

The group notes though a claim covering this could be a purely mental act or just be a discovery, and be excluded from patentability on that ground.

In addition, the group notes that the contribution to the state of the art by determining what the threshold should be, could purely reside in an intellectual exercise. This would lead to this de facto being non-eligible subject matter, because non-technical features are excluded for the purpose of assessing inventive step and the claim would therefore always fail to involve an inventive step.

(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.

The group notes though that correlating data could be a purely intellectual exercise. In such a case the contribution to the state of the art by the apparatus or machine could be a non-technical one. This would lead to this de facto being non-eligible subject matter, because non-technical features are excluded for the purpose of assessing inventive step and the claim would therefore always fail to involve an inventive step.

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

YES, but only to the extent that this does not patent the human body or result in the human body being covered by the exclusionary rights of the patentee.

(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, but this should either be excluded from patentability to the extent that this results in:

1) patenting of the human body or
2) the human body becoming a product directly obtained with the method and hence being subject to patent rights.

With respect to medical or veterinary practitioners, the group believes that by excluding their acts of carrying out the treatment (or surgery) from being considered to be a patent infringement as indicated in the answer to article 7, allowing the treatment step would not limit their free choice of treatment and therefore achieving the aim sought by the exclusion without unduly excluding the protection of inventions beneficial to society.

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.

This would unduly focus on linguistics, where materially there is no difference because the diagnostic conclusion itself is a purely mental activity. The result would still be a patent with liabilities to a medical or veterinary practitioner.

The group observes that to the extent performed by a human being, it would be hard to see a technical contribution in solely in a diagnostic conclusion itself, since this is a purely mental activity. Although such a step may be needed to resolve issues of clarity or sufficiency of a claim, it would therefore a priory be immaterial to the aspects of patentability.

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.

Although we have no hard data, the group concludes from the reaction of the markets with a more than 20% drop in share price of Myriad Genetics (Nasdaq:MYGN) on the US Supreme Court's decision in Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013), that the question is relevant to investors and shareholders. Obviously, investors will not invest in research and development unless they can expect a return on investment, and therefore some protection from competitors free-loading by copying the results without having to make similar investments. Investors will thus be less likely to invest in R&D in the field of diagnostics in the absence of effective patent protection.

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?

See the answer to question 9 above, patent laws should have provisions excluding patenting of the human body or the human body being considered as a product directly obtained with the method and hence being subject to patent rights.

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.
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, it is desirable that the developers of the diagnostic method have a uniform potential market.

A harmonized practice provides transparency to users. It also allows for a common drafting and prosecution strategy, which makes obtaining patents for multiple jurisdictions more efficient. Limitations to patentability of diagnostic methods should be made narrow to only strictly serve its purpose.

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

YES, as long as the medical professional is allowed to diagnose a patient without having to worry about patent infringement. The development of a method requires significant investment, and apart from the expected benefit for general health hence it is desirable that there is an incentive for commercial parties. Hence, such an exclusion should only extend to methods that explicitly include the step of making a final diagnosis for the patient. The purpose of excluding diagnostic methods is to allow the medical professional to diagnose a patient without having to worry about patent infringement.

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. Comparable to other devices, all medical equipment should be patentable. An apparatus or machine, regardless of its purpose, does not constitute a diagnostic method. The medical professional remains free in how the information provided by the apparatus is used.

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

YES, but should not hamper medical practitioners to help patients as mentioned above. Hence, diagnostic testing provides information for the medical professional, but does not involve making a final diagnosis for the patient. The medical professional remains free in how the information provided by the technique or method is used

(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, provided that the correlation provides information for the medical professional, but does not involve making a final diagnosis for the patient. The medical professional remains free in how the provided information is used.

(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, although the correlation by itself should not be patentable, a method to measure the correlation or any other technical implementation could be patentable.

(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, although the threshold itself should not be patentable, a method to measure the threshold or any other technical implementation could be patentable, see also answer d above).

(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, could be patentable. An apparatus or machine, regardless of its purpose, does not constitute a diagnostic method. The medical professional remains free in how the information provided by the apparatus is used.

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

YES, this could be part of diagnostic method without being the medical treatment of a person. These methods relate to preparation only and do not involve making a final diagnosis for the patient. The medical professional remains free in how the information provided by the technique or method is used.

(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, provided that the medical doctor is free to perform this act without having to worry about patent infringement.

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

YES, if the treatment is not a medical treatment (eg a step to cure the person or to achieve another medical effect). The medical professional should be free to perform medical treatment steps without having to worry about patent infringement. Therefore, method claims involving a treatment step that necessarily needs to be performed by a medial professional should not be patentable. All apparatuses, machines and equipment of any type should be patentable.

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, would be the same.

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?

Not desirable since that leaves the patent claim open ended (missing essential features), subject to the nature of what is claimed in the patent

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

YES, the restriction should only serve the purpose of allowing freedom the medical professional to ensure proper diagnosis to restore health and wellbeing for his patients.

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.

Should not extend to disease categories that are not yet discovered, eg. generic method claim extending to diseases that were not investigated yet. Such generic claims give uncertainty to third parties and hamper the development of the actual diagnostic methods.

An important issue that is not addressed here is the definition of “diagnostic”. The basic concept, of course, is clear. However, for an exclusion to patentability the boundaries also need to be set. For example, does a consultation to determine a strategy for cosmetic surgery also amount to a diagnostic method?

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

Views are provided by in-house counsel working in the field of medical technology such as medical devices and supporting software.