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Datasheet for the decision of 11 April 2014

Case Number: T 1016/10 - 3.2.02

Application Number: 07023740.9

Publication Number: 1913866

IPC: A61B3/117, A61B3/135

Language of the proceedings: EN

Title of invention:
Methods for diagnosing a neurodegenerative condition

Applicants:
The General Hospital Corporation
The Brigham and Women's Hospital, Inc.

Headword:

Relevant legal provisions:
EPC Art. 53(c), 112(1)(a)
EPC 1973 Art. 52(4)
Vienna Convention on the Law of Treaties (1969) Art. 31

Keyword:
Diagnostic method (yes)
Referral to the Enlarged Board of Appeal (no)

Decisions cited:
G 0001/04, G 0001/07, T 0385/86, T 0964/99, T 1197/02, T 0992/03 - Interlocutory Decision of 20 October 2006, T 0143/04, T 1255/06

Catchword:

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Case Number: T 1016/10 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 April 2014

Appellants: The General Hospital Corporation
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 26 November 2009 refusing European patent application No. 07023740.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: C. Körber
M. Stern

Summary of Facts and Submissions

I. On 26 November 2009 the Examining Division posted its decision to refuse European patent application No. 07023740.9 under Articles 53(c), 54, 84, 123(2) and 52(2)(c) EPC.

II. An appeal was lodged against this decision by the applicants by notice received on 26 January 2010, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 26 March 2010.

III. By communication of 27 January 2014, the Board summoned the appellants to oral proceedings and forwarded its provisional opinion.

IV. Oral proceedings were held on 11 April 2014. The appellants requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request, filed with letter dated 26 March 2010, or, in the alternative, one of the 1st to 5th auxiliary requests, filed during the oral proceedings.

V. The various requests comprise the following sets of claims:

Main request:

Independent claim 1 reads as follows:

"A non-invasive method of diagnosing an amyloidogenic disorder, or a predisposition thereto, in a mammal, said method being characterised by:

illuminating a mammalian ocular lens with an excitation light beam;
detecting light signals emitted from the supranuclear or cortical region of said lens; and
analysing said detected light signals by quasi-elastic light scattering (QLS), Raman spectroscopy or fluorimetry to detect protein aggregates in said supranuclear or cortical region;
wherein the presence or an increase in the amount of aggregates in said region as compared with a normal control value indicates that said mammal is suffering from or is at risk of developing an amyloidogenic disorder."

Claims 2 to 18 are dependent claims, with claims 17 and 18 reading as follows:

"17. A method as claimed in claim 1, wherein said amyloidogenic disorder is selected from Alzheimer's Disease (AD), Familial AD, Sporadic AD, Creutzfeldt-Jakob disease, variant Creutzfeldt-Jakob disease, spongiform encephalopathies, a Prion disease, Parkinson's disease, Huntington's disease (and trinucleotide repeat diseases), amyotrophic lateral sclerosis, Down's Syndrome (Trisomy 21), Pick's Disease (Frontotemporal Dementia), Lewy Body Disease, Hallervorden-Spatz Disease, a synucleinopathy, neuronal intranuclear inclusion disease, a tauopathy, Pick's disease, corticobasal degeneration, hereditary frontotemporal dementia and Guam amyotrophic lateral sclerosis/parkinsonism dementia complex."

"18. A method as claimed in claim 1, wherein said amyloidogenic disorder is Alzheimer's Disease."

1st auxiliary request:

Independent claim 1 reads as follows (changes over the main request highlighted in bold and strike-through):

"A ~~non-invasive~~ method ~~of~~ **useful in** diagnosing an amyloidogenic disorder, or a predisposition thereto, in a mammal, said method being characterized by:
illuminating a mammalian ocular lens**e** with an excitation light beam;
detecting light signals emitted from the supranuclear or cortical region of said lens**e**; and
analysing said detected light signals by quasi-elastic light scattering (QLS), Raman spectroscopy or fluorimetry to detect protein aggregates in said supranuclear or cortical region;
wherein the presence or an increase in the amount of aggregates in said region as compared with a normal control value indicates that said mammal is suffering from or is at risk of developing an amyloidogenic disorder."

Claims 2 to 14 are dependent claims. The claims corresponding to claims 17 and 18 of the main request were deleted.

2nd auxiliary request:

Independent claim 1 reads as follows (changes over the main request highlighted in bold):

"A non-invasive method of diagnosing an amyloidogenic disorder, or a predisposition thereto, in a mammal, said method being characterised by:

illuminating a mammalian ocular lens with an excitation light beam;
detecting light signals emitted from the supranuclear or cortical region of said lens;
analysing said detected light signals by quasi-elastic light scattering (QLS), Raman spectroscopy or fluorimetry **with a digital autocorrelator to yield a time autocorrelation function and analysing said autocorrelation function to determine the diffusivity of the aggregates in said region** to detect protein aggregates in said supranuclear or cortical region;
comparing the amount of aggregates in said supranucleur or cortical region with the amount of aggregates in a normal control subject;
wherein the presence or an increase in the amount of aggregates in said region as compared with a normal control value indicates that said mammal is suffering from or is at risk of developing an amyloidogenic disorder."

Claims 2-14 are dependent claims. The claims corresponding to claims 17 and 18 of the main request were deleted.

3rd auxiliary request:

Independent claim 1 reads as follows (changes over the main request highlighted in bold):

"A non-invasive method of diagnosing an amyloidogenic disorder, or a predisposition thereto, in a mammal, said method being characterised by:
illuminating a mammalian ocular lens with an excitation light beam;
detecting light signals emitted from the supranuclear or cortical region of said lens; **by delivering light**

collected by a probe to a photomultiplier tube and delivering signals to an autocorrelator linked to a computer;
analysing said detected light signals by quasi-elastic light scattering (QLS), Raman spectroscopy or fluorimetry to detect protein aggregates in said supranuclear or cortical region;
comparing the amount of aggregates in said supranuclear or cortical region with a normal control subject;
wherein the presence or an increase in the amount of aggregates in said region as compared with a normal control value indicates that said mammal is suffering from or is at risk of developing an amyloidogenic disorder"

Claims 2 to 15 are dependent claims. The claims corresponding to claims 17 and 18 of the main request were deleted.

4th auxiliary request:

Independent claim 1 reads as follows (changes over the main request highlighted in bold and strike-through):

"1. A non-invasive method of diagnosing an amyloidogenic disorder, or a predisposition thereto, in a mammal, said method being characterised by:
illuminating a mammalian ocular lens with an excitation light beam;
detecting light signals emitted from the supranuclear or cortical region of said lens; and
analyzing ~~said~~ detected **scattered** light signals **from the supranuclear or conical region of said lens** ~~by quasi-elastic light scattering (QLS), Raman spectroscopy or fluorimetry to detect protein aggregates in said supranuclear or cortical region~~ **with a digital**

autocorrelator to yield a time autocorrelation function and analyzing said autocorrelation function to determine the diffusivity of the aggregates in said region
wherein the presence or an increase in the amount of aggregates in said region as compared with a normal control value indicates that said mammal is suffering from or is at risk of developing an amyloidogenic disorder."

Independent claim 10 is not the subject of this decision. Claims 2 to 9 and 11 to 14 are dependent claims. The claims corresponding to claims 17 and 18 of the main request were deleted.

5th auxiliary request:

Independent claim 1 reads as follows (changes over the main request highlighted in bold and strike-through):

"A ~~non-invasive~~ method ~~of~~ **useful in** diagnosing an amyloidogenic disorder, or a predisposition thereto ~~in a mammal~~, said method being characterized by:
~~illuminating a mammalian ocular lens with an excitation light beam;~~
~~detecting light signals emitted from the supranuclear or cortical region of said lens; and~~
~~analysing said detected light signals by quasi-elastic light scattering (QLS), Raman spectroscopy or fluorimetry to detect protein aggregates in said supranuclear or cortical region;~~
analysing light signals which correspond to protein aggregation or accumulation or a disposition of amyloidogenic proteins or peptides in a supranuclear or cortical region of an ocular lens detected by quasi-

elastic light scattering (QLS), Raman spectroscopy or fluorometry
wherein the presence or an increase in the amount of **light signals corresponding to** aggregates **or amyloidogenic proteins or peptides from** ~~in~~ said region as compared with a normal control value indicates ~~that said mammal is suffering from or is at~~ **the presence of, or the** risk of developing, an amyloidogenic disorder."

Claims 2 to 14 are dependent claims. The claims corresponding to claims 17 and 18 of the main request were deleted.

VI. The appellants' arguments are summarised as follows:

Paragraph 6 of G 1/04 made it clear that the exclusion of Article 53(c) EPC had to be interpreted narrowly. The considerations in G 1/07 regarding a narrow or a broad interpretation of exclusion from patentability (cf. item 3.1 together with preceding Question 1 in G 1/07) were not pertinent to the present case since they referred to methods of **treatment by surgery**. The principle of a narrow interpretation of exclusion from patentability had to be applied whenever diagnostic methods were under scrutiny. As a consequence, a multi-step (diagnostic) method would have to be excluded from patentability provided that **all** of the preceeding steps, which were constitutive for making a diagnosis as an intellectual exercise, were performed on a living human or animal body (cf. G 1/04, items 6, 6.1 and 6.4.4). This was the logical and common sense approach. In direct contradiction with the rational and the logic principles set forth by G 1/04, the Boards in T 1197/02 and T 143/04 had, without any reason, re-interpreted G 1/04. The Boards who issued these decisions - without an appropriate basis — had been misguided by

erroneously applying conclusions outlined by G 1/07. They had invented a requirement for multi-step methods, which went beyond and was even in stark contrast to G 1/04. Therefore, these decisions violated the principles as set forth by G 1/04.

In view of the fact that a narrow interpretation of the exclusion from patentability had to be applied to multi-step methods in line with G 1/04, the character and the significance of the data processing step in the context of the present invention had to be considered. In the impugned decision, data processing was allegedly not classified as being a step of the "examination phase". The Examining Division had erroneously (in line with decisions T 1197/02 and T 143/04, but violating G 1/04) interpreted the list of steps (i) to (iv) in item 5 of G 1/04 as exhaustive and therefore limiting. According to that interpretation, **only** steps (i) to (iv) were alleged to become relevant when applying the criterion "practised on the human or animal body", whereas any additional or intermediate steps were alleged to become dismissible. However, from item 5 of G 1/04 it became clear that the issue underlying G 1/04 was **not** the definition of steps (i) to (iv) but whether, for a method to be excluded from patentability under Article 53(c) EPC, only the diagnosis stricto sensu was considered when interpreting the criterion "practised on a human or animal body" or, rather, whether **further technical steps** involved in the method had to be considered in this regard as well. Item 6 of G 1/04 generally referred to "several method steps" and "**preceding steps** which are constitutive for making a diagnosis as an intellectual exercise" **without any limitation** to particular steps (item 6.1, first sentence). The limiting interpretation of those "preceding steps" in T l197/02 did not have any basis

in G 1/04. T 1197/02 could not refer to G 1/04 at all, but rather directly contradicted the basic idea underlying G 1/04. There was no doubt that data processing in the present case represented a step which was constitutive for making a diagnosis since raw signals derived from scattered light did neither allow any comparison with normalised data nor any conclusion with respect to a clinically relevant condition of a subject. The Examining Division's interpretation was based on a misunderstanding of the rationale behind G 1/04. Point 6.4.3 of G 1/04 explicitly referred to method steps which actually coincided with the data processing step according to claim 1. The step of "analysing said detected light signals by quasi-elastic light scattering (QLS), Raman spectroscopy or fluorimetry" related to highly sophisticated optical methods, which necessarily involved the processing of a large raw signal data output detected thereby. As also evident from pages 27 and 28 of the description, the data processing was certainly not merely an operation that could be carried out "mentally", but required a complex arithmetical conversion of the raw data to an analysable data set based on advanced computer and software tools. It went far beyond the human being's capabilities to convert and analyse such raw data "mentally". The complexity of the mathematics behind the conversion of the raw data into data which could then subsequently be compared with the data set used for normalisation necessarily implied the use of a computer with a specific software program (item 6.4.3 of G 1/04). The data processing step involved in the analysis of the light signals according to claim 1 represented a **preceding** step of **technical** nature, which was not practised on the human or animal body and which was **constitutive** for making a diagnosis. All of the criteria established by G 1/04 were thus fulfilled by

the subject-matter of claim 1. Moreover, even if the approach in T 1197/02 were followed, the data processing step would form part of step a) as defined in item 2.1 of T 1197/02 and was a step of a technical nature that was **not** practised on the human or animal body. Therefore, even if the logic of T 1197/02 were erroneously applied, the claim would not be excluded from patentability under Article 53(c) EPC.

Furthermore G 1/07 (point IV.2) and the underlying referring decision T 992/03 of 20 October 2006 considered the question of what constituted a diagnostic method in the context of G 1/04 and concluded that there was no need to ignore certain steps which were required in the method. From paragraph 3 of referring decision T 992/03 it became clear that all the steps being part of the claimed method were considered and none of them were ignored. The steps were, as a whole, considered to be the examination phase of a medical diagnosis.

An "amyloidogenic disorder" as mentioned in claim 1 merely represented an "intermediate finding", which, according to point 6.2.3 of G 1/04, was not to be confounded with the diagnosis for **curative** purposes stricto sensu. Such an intermediate finding did not permit to immediately determine the nature of a disease and to decide on a particular course of medical treatment (point 3.4.1 of T 385/86, the approach of which was confirmed in G 1/04), i.e. a therapeutic strategy. An amyloidogenic disorder could be caused by a wide range of different diseases as indicated in the description, requiring entirely different types of therapeutic treatment. Even if the amyloidogenic disorder was indicative of, for instance, Alzheimer's disease, this was not yet a final diagnosis since

further examinations such as cognitive tests were necessary to arrive at the final diagnosis. Since step (iv) was thus missing, claim 1 could not fall under the exclusion clause, as also held in item 3.3 of T 1255/06. This was in line with "Schulte, Patentgesetz mit EPÜ, Kommentar, 9. Auflage, Rdnr. 78" and "Benkard, EPÜ, 2. Auflage, Rdnr. 129".

The term "useful in diagnosis" in claim 1 of the 1st auxiliary request further emphasised that the final diagnosis with the attribution of a full clinical picture was not obtained, but that the claimed method only served to support the actual finding of the diagnosis.

The amendment in claim 1 of the 2nd auxiliary request that the step of analysing was performed "with a digital autocorrelator to yield a time autocorrelation function and analysing said autocorrelation function to determine the diffusivity of the aggregates in said region" further clarified that this step involved extensive data processing and thus was of a technical nature and not performed on the human or animal body.

Claim 1 of the 2nd and the 3rd auxiliary requests explicitly included the step of "comparing the amount of aggregates in said supranuclear or cortical region with a normal control subject", which was clearly of a technical nature. By denoting the comparison step (ii) as "principally of a non-technical nature" in item 2.2 of T 1197/02, the board had severely misinterpreted the term "predominantly of a non-technical nature" in item 6.4.1 of G 1/04.

The wording "analysing light signals ... detected by quasi-elastic light scattering (QLS), Raman

spectroscopy or fluorometry" in claim 1 of the 5th auxiliary request implied the presence of a measurement step, thus being in line with the requirements of Article 123(2) EPC and overcoming the respective objection in item 3.6.3 of the impugned decision.

The appellants requested the Board to refer the following questions to the Enlarged Board of Appeal:

"1. May a claim directed to a method, which addresses the detection of a phenomenon (in the present case: aggregation of an amyloid protein in the eye lense) be classified as a diagnostic method allowing diagnosis for curative purposes *stricto sensu* being excluded from patentability under Art. 53(c) EPC, even even [sic] if such a method is not suitable to provide a clinical picture, which allows to be addressed by an appropriate treatment, but the results of which rather constitute intermediate findings, which do not make immediately clear the underlying clinical picture (here: large diversity of distinct amyloidogenic disorders, all of which are characterized by amyloid protein aggregation in the eye lens)?

2. If for such a method as exemplified above (here: *a method of diagnosing an amyloidogenic disorder or a method useful in diagnosing an amyloidogenic disorder*) patentability were denied due to its character as a diagnostic method according to Art. 53(c) EPC, does denial of patentability of such a method under Art. 53(c) EPC violate the principles set forth in G 1/04 (following T 385/86), which states that

"*intermediate findings of diagnostic relevance must not be confounded with diagnosis for curative purposes stricto sensu as referred to under point 5 above, which*

consists in attributing the detected deviation to a particular clinical picture. It follows that a method for obtaining such results or findings does not constitute sufficient basis for denying patentability by virtue of Art. 52(4) EPC (now: Art. 53(c) EPC)"?

3. If methods according to question 1 above were excluded from patentability due to their nature as providing a particular clinical picture, would Board-of-Appeal decisions T 1197/02 and T 143/04 apply G 1/04 appropriately, if one or more technical steps (here: the step of analyzing detected light signals), which are not practiced on the human or animal body, were disregarded as "*preceding steps, which are constitutive for making that diagnosis*" (see Conclusion of G 1/04 under point 1(ii)) - due to their nature as "*intermediate steps*" (see T 1197/02 and T 143/04) as allegedly not falling within the scope of steps (i), (ii) and (iii) under point 5 of the Reasons of G 1/04 - for the assessment of whether such a method is a diagnostic method under Art. 53(c) EPC or not?

Or, must all preceding steps prior to the "*diagnosis for curative purposes stricto sensu representing the deductive medical or veterinary decision phase as a purely intellectual exercise*" (G 1/04, Conclusion, point 1(i)) be considered for the above assessment, irrespective of whether such steps are "intermediate steps" or not?"

The appellants argued that these questions related to points of law of fundamental importance. In particular, question 1 addressed an issue which was of general significance well beyond the present case, as it referred to a frequently occurring problem in many cases potentially affected by the exclusion clause with

regard to diagnostic methods. Question 3 was also important for ensuring uniform application of the law, since an entirely new approach had been taken in T 1197/02 and T 143/02 which went far beyond G 1/04. Under Article 112 EPC, the Board's decision to refer questions to the Enlarged Board of Appeal was generally not a discretionary one, but one which merely involved a certain freedom of evaluation ("Beurteilungsspielraum").

Reasons for the Decision

1. The appeal is admissible.

2. Main request

2.1 In the Conclusion of its Opinion G 1/04 (referred to as "G 1/04" in the following) the Enlarged Board of Appeal stated inter alia that:

"*1. In order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body falls under the prohibition of Article 52(4) EPC* [EPC 1973, now Article 53(c) EPC], *the claim is to include the features relating to:*

(i) the diagnosis for curative purposes stricto sensu representing the deductive medical or veterinary decision phase as a purely intellectual exercise,

(ii) the preceding steps which are constitutive for making that diagnosis, and

(iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.

2. [...]

3. In a diagnostic method under Article 52(4) EPC [1973]*, the method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes stricto sensu must satisfy the criterion "practised on the human or animal body".*

4. Article 52(4) EPC [1973] *does not require a specific type and intensity of interaction with the human or animal body; a preceding step of a technical nature thus satisfies the criterion "practised on the human or animal body" if its performance implies any interaction with the human or animal body, necessitating the presence of the latter.*"

2.2 In point 5 of G 1/04 it is further stated that the method steps to be carried out when making a diagnosis as part of the medical treatment of humans or the veterinary treatment of animals for curative purposes include:

(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, and

(iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase.

The final phase (iv) is also referred to as "*the diagnosis for curative purposes stricto sensu*", whereas the prior steps (i) to (iii) are termed as "*preceding steps related to examination, data gathering and comparison*".

The expression "*preceding steps*" is also used subsequently in point 5.3 (referring back to point 5) and point 6 (referring back to point 5.3). Further on in this section, terms such as "*preceding steps which are constitutive for making such a diagnosis*" are also used (points 6.2.2, 6.2.3, 6.2.4, 6.4.1, all of which directly or indirectly refer back to point 5). In the overall context of G 1/04, it is thus clear that steps (i) to (iii) are meant when the terms "preceding steps" or "preceding steps which are constitutive for making a diagnosis" and the like are used.

2.3 In claim 1, steps (i) to (iv) are identified as follows:

step (i), the examination phase involving the collection of data:

"illuminating a mammalian ocular lens with an excitation light beam;
detecting light signals emitted from the supranuclear or cortical region of said lens;"

step (ii), the comparison of these data with standard values:

"wherein the presence or an increase in the amount of aggregates in said region as **compared with a normal control value** ..." [emphasis added]

step (iii), the finding of any significant deviation, i.e. a symptom, during the comparison:

"wherein **the presence or an increase in the amount of aggregates in said region** as compared with a normal control value **indicates that** said mammal is suffering from or is at risk of developing an amyloidogenic disorder." [emphasis added]. The wording "the presence or an increase ... indicates that" goes beyond the mere comparison in step (ii) and implies that a further evaluation of the comparison is performed, i.e. ascertaining that there is a deviation from the normal control value and that it is "significant", thus being indicative of a "symptom".

step (iv), the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase:

"wherein the presence or an increase in the amount of aggregates in said region as compared with a normal control value indicates that said mammal is suffering from or is at risk of developing **an amyloidogenic disorder**" [emphasis added].

Accordingly, claim 1 includes steps (i) to (iv), and the first condition for a method to qualify as diagnostic, falling under the exception clause of Article 53(c) EPC, as required in point 1.(i) and (ii) of the Conclusion of G 1/04 is fulfilled.

2.4 The appellants argued that the assignment of step (i) in the impugned decision (which corresponds to the analysis presented above) was incorrect and should, in addition to the steps of "illuminating ..." and

"detecting ..." further include the step of "analysing said detected light signals by quasi-elastic light scattering (QLS), Raman spectroscopy or fluorimetry to detect protein aggregates in said supranuclear or cortical region" in claim 1. There was no appropriate basis in G 1/04 for leaving out such a step. On the contrary, it was explicitly required in points 6, 6.1 and 6.4.4 that **all** preceding steps which were constitutive for making the diagnosis had to be taken into account. The step of "analysing ..." was undoubtedly constitutive for making the diagnosis. Ignoring additional steps which were not part of the above-mentioned steps (i) to (iii) when assessing diagnostic character, as ruled in T 1197/02 and T 143/04, went beyond and was in contrast to G 1/04. The Board does not share the appellants' view, for the following reasons.

Firstly, step (i) as defined in G 1/04 concerns the examination phase involving the **collection** of data. The step of "analysing said detected light signals ..." is an additional ensuing step relating to further processing of the collected data.

Secondly, the above-mentioned passages in G 1/04 referred to by the appellants are taken out of context. As mentioned above in point 2.2, steps (i) to (iii) are clearly defined in point 5 of G 1/04, and the subsequent use of the term "preceding steps [...]" in G 1/04 is to be understood as referring to these definitions. In the context of the "preceding steps", point 6 explicitly refers back to point 5.3 which itself refers back to the definition in point 5. Accordingly, the reference to "all of the preceding steps which are constitutive for making a diagnosis as an intellectual exercise" in point 6 is to be

understood as relating to all of the (three) preceding steps in point 5, viz. steps (i) to (iii). The use of the wording "preceding steps ..." is also consistent in the passages that follow. Point 6.4.1 explicitly refers back to the definition in point 5. Points 6.4.2, 6.4.3 and 6.4.4 refer back to point 6.4.1. Accordingly, the additional criteria discussed in these passages (which will be dealt with below) are to be understood as relating to the preceding steps (i) to (iii). Point 6.4.4 gives a justification for the requirement that "all method steps of a technical nature" should satisfy the "on the body" criterion (see point 2.7 below), in contrast to the "broad interpretation" whereby it would suffice that only a single step fulfils this criterion. Read in isolation, this might suggest that the criterion is not limited to the "preceding steps" (i)-(iii), as suggested by the appellants, but from the (repeated) reference to point 6.4.1 at the beginning of this paragraph it becomes clear that the (potentially) technical method steps mentioned in point 6.4.1, i.e. (i) to (iii), must be meant. Points 8 (which explicitly refers back to 6, 6.2.3 and 6.4.4) and 9 (which explicitly refers back to 6.4.3) of the "Recapitulation" must be read in that context and cannot be construed to suggest a different meaning, as attempted by the appellants. The sentence in point 6.1 cited by the appellants is also taken out of context. It reads "*... the text of the provision* [i.e. present Article 53(c) EPC] *itself already gives an indication towards a narrow interpretation in the sense that, in order to be excluded from patentability, the method is to include all steps relating to it*". It is presented to explain that the broader interpretation as previously discussed in G 1/04 has no basis in the EPC, and does not at all refer to the "**preceding** steps". Finally, the use of the term "include" in the statement

in point 5 of G 1/04 (cited above in point 2.2) that "the method steps to be carried out when making a diagnosis ... include [steps (i) to (iv)]" does not mean that any further steps need to be considered in the assessment of the diagnostic character, which is to be carried out according to the criteria detailed in the subsequent passages of G 1/04. These will be discussed below, but in the present context it is worth noting that point 1.(iii) of the Conclusion refers to "*the specific interactions with the human or animal body which occur when carrying those out among* ***these*** *preceding steps which are of a technical nature*"[emphasis added], emphasising that only these preceding steps (i) to (iii) are to be considered. This also becomes evident from the fact that the term "include" is used at the beginning of point 1 of the Conclusions ("*...the claim is to include the features relating to: ...*"), implying that these and only these features are to be assessed.

Finally, the Board is unable to discern from point 3 of the Interlocutory Decision T 992/03 that all the steps of the underlying method claim were considered and assigned to the examination phase of a medical diagnosis. It was simply held that the claimed method led to the acquisition of data in the form of an image or a spectroscopic signal, which thus related only to the examination phase. Since steps (ii) to (iv) were lacking, the claims were considered not to relate to diagnostic methods falling under the exception clause. Accordingly, this decision does not provide support for the appellants' view that any further steps in addition to steps (i) to (iv) need to be included when assessing the diagnostic character of a method either.

2.5 Referring to section 6 of G 1/04, the appellants pointed out that the exception clause of Article 53(c) EPC had to be interpreted narrowly with regard to diagnostic methods. The Board considers, however, that the term "narrow interpretation" is used in the specific context of this section to denote the approach taken in T 385/86, to be distinguished from the "broad interpretation" according to T 964/99. In G 1/04 it was concluded that the "broad interpretation" was not justified in case of diagnostic methods. With reference to G 1/04, it is stated in the penultimate paragraph of point 3.1 of G 1/07 that "*the Enlarged Board came to its conclusion that the said exclusion was indeed to be interpreted narrowly only after a thorough investigation of the wording and the purpose of the exclusion clause concerned*". This is reflected by point 6.2.4 of G 1/04, where the Enlarged Board explicitly addresses the problem that, in the event of a "narrow interpretation", the exclusion could be circumvented by missing out one of the essential features of the method. Also in point 3.1 of G 1/07, it was concluded that "*no general principle of narrow interpretation of exclusions from patentability*" could be derived from the Vienna Convention on the Law of Treaties, and that the provision is to be "*interpreted in such a manner that it takes its effect fully and achieves the purpose for which it was designed*". Point 6.2.4 of G 1/04 addresses the concern that in the event of a narrow interpretation, the exclusion could perhaps be circumvented by missing out at least one of the essential features of a diagnostic method, i.e. steps (i) to (iv) as mentioned in point 6.2.3. Likewise it should not be acceptable that the exclusion could easily be circumvented by including any further technical steps not performed "on the body" (see point 2.7 below) in addition to the preceding steps (i) to

(iii), such as the step of "analysing ..." in the present case. Article 53(c) would then no longer achieve the purpose for which it was designed. This concern was also raised in point 3.1.7 of the impugned decision and is shared by the Board.

2.6 The appellants further argued that an "amyloidogenic disorder", identified as step (iv) in claim 1 as indicated above, merely represented an "intermediate finding". Consequently, and according to "Schulte, Patentgesetz mit EPÜ, Kommentar, 9. Auflage, Rdnr. 78", the claimed subject-matter did not constitute a diagnostic method falling under the exception clause. According to point 6.2.3 of G 1/04, such "intermediate findings" were not to be confounded with diagnosis for **curative** purposes stricto sensu. Such an intermediate finding did not make it possible to immediately determine the nature of a disease and to decide on a particular course of medical treatment (points 3.4.1 and 3.2 of T 385/86), i.e. a therapeutic strategy, since an amyloidogenic disorder could be caused by a wide range of different diseases as indicated in the description, requiring entirely different types of therapeutic treatment. Since step (iv) was thus missing, claim 1 could not fall under the exception clause, in analogy to T 1255/06. The Board does not share this view, for the following reasons.

As indicated above (point 2.1), step (iv) is defined in point 5 of G 1/04 as "the attribution of the deviation to a particular clinical picture", and this is also referred to as "the diagnosis for curative purposes stricto sensu". G 1/04 provides a detailed analysis and discussion of T 385/86, but the Enlarged Board did not include in its definition of step (iv) the above-mentioned restrictions of identifying the nature of a

disease or permitting a decision on a particular course of medical treatment, as postulated in T 385/86. Instead, the much broader expression "a particular clinical picture" is used (also in points 6.2.3 and 6.2.4). The term "disease" is not at all used in G 1/04 in the context of diagnosis (it only occurs in point 6.2.1 dealing with surgery). Consequently, what is decisive when determining whether or not step (iv) is present in a claim according to G 1/04 is to ascertain if "a particular clinical picture" is attributed to the deviation determined in step (iii). The fact that step (iv) is also termed "diagnosis for curative purposes stricto sensu" in G 1/04 cannot be interpreted to the effect that something going beyond the primary definition "attribution of the deviation to a particular clinical picture" is meant. This primary definition in G 1/04 thus supersedes the previous definition developed in T 385/86. The passage in "Benkard, EPÜ, 2. Auflage, Rdnr. 129" cited by the appellants merely refers to this previous definition.

In the present case, the Board considers that an "amyloidogenic disorder", detected on the basis of the amount of [amyloid] protein aggregates present in a particular region (supranuclear or cortical) of the ocular lens, is not merely an "intermediate finding" but does indeed represent a "particular clinical picture". Moreover, as stated in paragraph [0004] of the present application, amyloidogenic disorders **include** a wide range of different diseases such as Alzheimer's or Parkinson's disease. These diseases are also specified in claims 17 and 18. Accordingly, an "amyloidogenic disorder" undoubtedly represents a "particular clinical picture". It follows that step (iv) is clearly present in claim 1.

2.7 According to the Conclusion of G 1/04 reproduced above under point 2.1, further criteria are to be fulfilled by the "preceding steps" in order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body falls under the exception clause:

- the claim must include the **specific interactions with the human or animal body** which occur when carrying those out among these **preceding steps** which are of a **technical nature** (point 1.(iii));

- the method steps of a **technical nature** belonging to the **preceding steps** which are constitutive for making the diagnosis for curative purposes stricto sensu must satisfy the criterion **"practised on the human or animal body"** (point 3).

- a **preceding step** of a **technical nature** thus satisfies the criterion **"practised on the human or animal body"** if its performance implies any interaction with the human or animal body, necessitating the presence of the latter (point 4).

Accordingly, the additional criteria to be fulfilled for the preceding steps (i) to (iii) are that, if they are of a technical nature (referred to hereinafter as the "technicality criterion"), then they must also be practised on the human or animal body, in specific interaction therewith ("on the body criterion"). In point 6.4.1 it is clarified that the "on the body criterion" is to be considered only in respect of method steps of a technical nature, and that it thus does not apply to the diagnosis for curative purposes stricto sensu, i.e. the deductive decision phase, which as a purely intellectual exercise cannot be practised

on the human or animal body. It follows that the criteria need not be assessed with regard to step (iv). Their evaluation with regard to steps (i) to (iii) of the present case, as further elaborated and specified in section 6.4 of G 1/04, will be discussed in the following.

2.7.1 Step (i)

Step (i), the examination phase involving the collection of data, consists in "illuminating a mammalian ocular lens with an excitation light beam" and "detecting light signals emitted from the supranuclear or cortical region of said lens" in claim 1. It is clearly of a technical nature and performed on the human or animal body, necessitating the presence of the latter and implying an interaction therewith (point 6.4.2 of G 1/04). The criteria are thus fulfilled (which was not disputed by the appellants).

2.7.2 Steps (ii) and (iii)

Steps (ii) and (iii) were identified in claim 1 (see point 2.3 above) as contained in the definition "wherein the presence or an increase in the amount of aggregates in said region as compared with a normal control value indicates that ...". This definition does not comprise anything going beyond what is stated in point 6.4.1 of G 1/04, namely "*in a diagnostic method, the preceding steps which are constitutive for making a diagnosis for curative purposes may, in addition to method steps of a technical nature, include method steps such as comparing data collected in the examination phase (cf. point 5 above) with standard values belonging to the common general knowledge of the person skilled in the art. These activities are*

predominantly of a non-technical nature and, in any event, are not normally practised on the human or animal body". From this it may be concluded that the comparison step (ii) does not fulfil the "technicality" criterion, and that the "on the body" criterion is hence of no further relevance. The use of the term "*method steps* ***such as*** *comparing data ...*" [emphasis added] "indicates that this statement may in fact also be extended to step (iii), which is defined as "*the finding of any significant deviation, i.e. a symptom,* ***during the comparison***" [emphasis added] and thus anyhow interlinked with step (ii). Accordingly, steps (ii) and (iii) as assigned to claim 1 are "predominantly of a non-technical nature" and "in any event, not normally practised on the human or animal body" within the meaning of G 1/04.

Referring to point 6.4.3 of G 1/04, the appellants argued that if a preceding step is carried out by a device without involving any interaction with the human or animal body, for instance by using a specific software program, it may not be considered to satisfy the "on the body criterion". This was the case for the comparison step as defined in the last paragraph of claim 1 which involved complex data processing by a computer going far beyond common general knowledge. The Board considers, however, that complex data processing may be involved in the analysing step (which is left out of consideration in the assignment of steps as detailed above in point 2.4). With regard to step (ii), however, the Board does not accept this argument since what is defined in the last paragraph of claim 1 amounts to just a simple comparison which does not necessitate any complex computation using data-processing devices.

2.7.3 Accordingly, all the method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes stricto sensu (which in the present case are only the steps of "illuminating ..." and "detecting ... " assigned to the examination step (i)), do satisfy the criterion "practised on the human or animal body", as required in point 6.4.4 of G 1/04.

2.8 Since the subject-matter of claim 1 of the main request fulfils all the criteria of a diagnostic method practised on the human or animal body as defined in G 1/04, it falls under the exception clause of Article 53(c) EPC.

3. 1st auxiliary request

Claim 1 differs from claim 1 of the main request in that it is directed to a method **useful in** diagnosing an amyloidogenic disorder, instead of a method **of** diagnosing ... . However, the passages of the claim to which steps (i) to (iv) were assigned are identical. The content of the claim relevant for the assessment of the applicability of the exception clause has not been changed by denoting the claimed method in a slightly different way in the introductory part of the claim. Accordingly, the above-mentioned objection with respect to the main request also applies to claim 1 of this request. The appellants' argument that the term "useful in" is to indicate that only intermediate results are obtained and that a final diagnosis is not performed is not convincing in view of the fact that step (iv) still forms part of the claim. Its subject-matter also therefore falls under the exception clause of Article 53(c) EPC.

4. 2nd auxiliary request

Claim 1 differs from claim 1 of the main request in that it specifies that a digital autocorrelator is used in the step of "analysing ..." and that a further explicit step of "comparing the amount of aggregates in said supranucleur or cortical region with the amount of aggregates in a normal control subject" is added (shown in bold in point V above). Since the step of "analysing ..." does not form part of the preceding steps (i) to (iii), the amendment therein is of no relevance for the assessment of the applicability of the exception clause. The added step of "comparing ..." amounts to a mere comparison with normal control values. It does not comprise anything going beyond what is stated with respect to step (ii) in point 6.4.1 of G 1/04, i.e. it is "predominantly of a non-technical nature and ... not normally practised on the human or animal body" as explained above in point 2.7.2.
The subject-matter of claim 1 of the 2nd auxiliary request therefore also falls under the exception clause of Article 53(c) EPC.

5. 3rd auxiliary request

Claim 1 differs from claim 1 of the main request in that after the step of "detecting ..." the expression "by delivering light collected by a probe to a photomultiplier tube and delivering signals to an autocorrelator linked to a computer;" is added, and in that the step of "comparing ..." as discussed above in point 4 is inserted (highlighted in bold in point V above). The added expression does not change the assessment regarding step (i): the step is still

present in the claim and fulfils the criteria of "technicality" and "on the body". With regard to the step of "comparing ...", the same consideration applies as indicated above under point 4. The subject-matter of claim 1 of the 3rd auxiliary request therefore also falls under the exception clause of Article 53(c) EPC.

6. 4th auxiliary request

Claim 1 differs from claim 1 of the main request in that the step of "analysing ..." is further modified, which is of no relevance since this step is not taken into consideration, as already stated above in point 4. Again, the passages of the claim to which steps (i) to (iv) were assigned are identical to those of the main request. The subject-matter of claim 1 of the 4th auxiliary request therefore also falls under the exception clause of Article 53(c) EPC.

7. 5th auxiliary request

Claim 1 corresponds to that of the 5th auxiliary request underlying the impugned decision. It differs from claim 1 of the main request in that

a) it is directed to a method **useful in** diagnosing an amyloidogenic disorder

b) the steps of "illuminating ..." and "detecting ..." are omitted

c) the step of "analysing ..." is modified into "analysing light signals which correspond to protein aggregation or accumulation or a disposition of amyloidogenic proteins or peptides in a supranuclear or cortical region of an ocular lens detected by quasi-

elastic light scattering (QLS), Raman spectroscopy or fluorometry"

d) the phrase "that said mammal is suffering from" is replaced by "the presence of" in the last paragraph of the claim.

Amendment a) does not change the assessment as explained in point 3. With respect to amendment b), the appellants stated that the step of collecting data is still implicitly comprised in the step of "analysing ..." (amendment c)), in line with "Interpretation I" in point 3.6.2 of the impugned decision (thus avoiding the objection under Article 123(2) EPC raised with regard to "Interpretation II"). Accordingly, taking the appellants' statement at face value, step (i) is implicitly still present in claim 1. It fulfils the criteria of "technicality" and "on the body" (even though the term "mammal" is no longer present in the claim, it is implicit from the expression "ocular lens" that the measurement is performed "on the body"). Amendment d) does not change the finding that step (iv) is identified in "the presence of, or the risk of developing, an **amyloidogenic disorder**" [emphasis added], as explained supra in points 2.3 and 2.6. The subject-matter of claim 1 of the 5th auxiliary request thus falls under the exception clause of Article 53(c) EPC as well.

8. Request for referral of questions to the Enlarged Board

Under Article 112(1)(a) EPC it is for the Boards of Appeal to refer a question to the Enlarged Board of Appeal if this appears necessary for ensuring uniform application of the law or if a point of law of fundamental importance arises. According to the

established jurisprudence ("Case Law of the Boards of Appeal of the EPO", 7th ed. 2013, point IV.E.9.1), such a referral is within the discretion of the board of appeal concerned.

It is also established jurisprudence of the Boards of Appeal (loc. cit., point IV.E.9.1.2.a)) that, for a referral to be admissible, an answer to the question must be necessary in order for the referring board to be able to decide on the appeal. As is clear from its reasoning above, the Board considers that none of the three questions raised by the appellants requires an answer from the Enlarged Board of Appeal for deciding the case at issue.

Issues relevant for the present decision raised by questions 1 and 2 have been dealt with in point 2.6. As detailed in this section, a requirement that it must be possible for the "particular clinical picture" to be addressed by an appropriate treatment cannot be derived from G 1/04. It was also clarified that G 1/04 did not follow T 385/86 with regard to the definition of step (iv).

Issues relevant for the present decision raised by question 3 have been dealt with in point 2.4. It was found that G 1/04 does not require that further steps other than the "preceding steps" (i), (ii) and (iii) need to be considered in the assessment of whether or not a method is diagnostic. In the present case, the Board came to conclusions similar to those in decisions T 1197/02 and T 143/04 and saw no reason to depart therefrom in applying G 1/04. There is no lack of uniformity in the application of the law that would justify a referral on this matter.

Accordingly, the Board was able to reach the present decision based on the EPC and on what was held in G 1/04, and there is no room or need for further interpretation of G 1/04 as suggested by the appellants. A referral is not necessary in order to decide the case at issue.

Therefore, the request of the appellants for referral of the three questions to the Enlarged Board of Appeal is rejected under Article 112(1)(a) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

I. Aperribay E. Dufrasne

Decision electronically authenticated