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Datasheet for the decision of 17 March 2011

Case Number: T 0663/02 - 3.4.01

Application Number: 96944505.5

Publication Number: 0812151

IPC: G01R 33/563

Language of the proceedings: EN

Title of invention:
Method for magnetic resonance imaging of arteries using a magnetic resonance contrast agent

Patentee:
Prince, Martin, R.

Opponent:
Koninklijke Philips Electronics N.V.

Headword:
-

Relevant legal provisions:
EPC Art. 53(c)

Relevant legal provisions (EPC 1973):
-

Keyword:
-

Decisions cited:
T 0182/90, G 0001/04, G 0001/07

Headnote:

I. The fact that an intravenous injection of a magnetic resonance contrast agent can be delegated by a physician to a qualified paramedical professional indicates that such an injection may be considered as representing a minor routine intervention which does not imply a substantial health risk when carried out with the required care and skill. Such acts would be ruled out from the scope of the application of the exclusion clause pursuant to Article 53(c) EPC following the narrow understanding advocated by the EBA (G 0001/04 and 0001/07) (Reasons, 3.2.4).

II. A possible way of assessing health risks is to use a risk matrix permitting to combine the levels of likelihood and health impact of a complication of a medical act with regard to a large number of patients, so as to obtain statistical health risk scores which may be used to decide what action should be taken. Such a risk assessment supports the view that an intravenous injection of a magnetic resonance contrast agent represents a minor routine intervention involving no substantial health risks when carried out with the required care and skill (Reasons, 3.2.5).

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0663/02 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 17 March 2011

Appellant I: (Patent Proprietor)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 11 June 2002 revoking European patent No. 0812151 pursuant to Article 102(1) EPC 1973.**

Composition of the Board:

Chairman: B. Schachenmann
Members: G. Assi
H. Wolfrum

Summary of Facts and Submissions

I. A notice of opposition was filed on 19 December 2000 against the European patent No. 0 812 151 (application number 96944505.5) as a whole. The opposition was based on the grounds pursuant to Article 100(a) EPC 1973 that the subject-matter of the patent was not patentable within the terms of Articles 52(4), 52(1), 54 and 56 EPC 1973.

In its decision revoking the patent, dispatched on 11 June 2002, the opposition division held that the subject-matter of claims 1-11 of the granted patent was novel and involved an inventive step having regard to the prior art documents cited by the opponent. However, the subject-matter of claims 1-11 was excluded from patentability under Article 52(4) EPC 1973 because it constituted a diagnostic method practised on the human or animal body and, moreover, included a step of treatment of the human or animal body by surgery.

II. On 27 June 2002 the proprietor of the patent (appellant I) lodged a notice of appeal against the decision of the opposition division and paid the appeal fee. A statement setting out the grounds of appeal was filed on 2 October 2002.

III. On 2 August 2002 the opponent (appellant II) lodged a notice of appeal against the decision of the opposition division and paid the appeal fee. No statement setting out the grounds of appeal was filed.

IV. With a communication of 6 December 2002 the Board noted that the appellant II had not filed the statement

setting out the grounds of appeal. It was therefore to be expected that the appeal would be rejected as inadmissible pursuant to Article 108 EPC 1973 in conjunction with Rule 65(1) EPC 1973. Any observations had to be filed within two months from notification of the communication.

V. On 29 December 2003, the President of the EPO, making use of his power under Article 112(1)(b) EPC 1973, referred a point of law to the Enlarged Board of Appeal (hereinafter referred to as "*EBA*") concerning diagnostic methods practised on the human or animal body within the meaning of Article 52(4) EPC 1973.

In view of this pending referral bearing the number G 1/04, the Board informed the parties with a communication of 6 May 2004 that it intended to await the opinion of the EBA before dealing with the substance of the present case.

VI. Opinion G 1/04 (OJ 2006, 334) was issued on 16 December 2005.

VII. With a communication of 24 March 2006 the Board invited the parties to submit their comments on the present case in the light of said opinion.
The Board also noted that the opponent was not adversely affected by the decision revoking the patent in suit. Therefore, the appeal filed by the opponent was not admissible. Pursuant to Article 107 EPC 1973, however, the opponent was party to the appeal proceedings as of right.

VIII. The appellant I filed its comments with a letter of 20 June 2006.

IX. With an interlocutory decision T 992/03 of 20 October 2006 (OJ 2007, 557) a point of law was referred to the EBA concerning methods for treatment of the human or animal body by surgery within the meaning of Article 52(4) EPC 1973.

In view of this pending referral bearing the number G 1/07, the Board informed the parties with a communication of 23 August 2007 that it intended to await the opinion of the EBA before dealing with the substantive merits of the present case.

X. Decision G 1/07 (to be published) was issued on 15 February 2010.

XI. On 23 June 2010 the parties were summoned to oral proceedings scheduled to take place on 20 October 2010. On 2 July 2010 a communication of the Board was sent.

XII. With a letter of 9 July 2010 the appellant II informed the Board that it would not appear at the oral proceedings scheduled for 20 October 2010 and, moreover, that it did not intend to make any written submissions.

XIII. On 9 July 2010 the oral proceedings were postponed until 22 October 2010.

XIV. With a letter of 22 September 2010 the appellant I filed a set of new claims 1-11 as a first auxiliary request.

XV. Oral proceedings before the Board were held on 22 October 2010. Nobody was present on behalf of the appellant II as announced by letter of 9 July 2010.

At the oral proceedings, the appellant I requested, as a main request, that the decision under appeal be set aside and that the patent be maintained as granted.

As a first auxiliary request, the appellant I requested that the patent be maintained in amended form on the basis of claims 1-11 filed with letter of 22 September 2010.

As a second auxiliary request, the appellant I requested that the Board refer a point of law to the EBA pursuant to Article 112(1)(a) EPC concerning the interpretation of "*methods for treatment of the human or animal body by surgery*" within the meaning of Article 53(c) EPC. The appellant I, however, did not submit any specific questions to be referred.

After deliberation by the Board, it was announced that the proceedings were continued in writing. A time limit of four months from the notification of the minutes was set for the parties to provide observations concerning the interpretation of the concept of "*substantial health risk*" within the meaning of G 1/07 and evidence for the medical risk involved with the claimed step of injecting a magnetic resonance contrast agent into a vein.

XVI. With a letter of 19 January 2011 the appellant I made further submissions.

XVII. The appellant II requested in the notice of appeal that the patent be revoked in its entirety on the grounds of lack of novelty and inventive step.

XVIII. The wording of claim 1 of the granted patent reads as follows:

"*A method of imaging an artery in a region of interest in a patient using magnetic resonance imaging and a magnetic resonance contrast agent, the method containing the steps of:*
injecting the magnetic resonance contrast agent into a vein remote from the artery;
monitoring the region of interest by using a series of magnetic resonance radio frequency pulses and measuring the response of the region of interest to the series of magnetic resonance radio frequency pulses;
detecting the arrival of the contrast agent in the region of interest by comparing the response of the region of interest to the series of magnetic resonance radio frequency pulses before injecting the contrast agent to the patient to the response of the region of interest to the series of magnetic resonance radio frequency pulses during or after injecting the contrast agent to the patient;
generating an imaging initiation signal after detecting the arrival of the contrast agent in the region of interest;
collecting magnetic resonance image data in a magnetic resonance imaging sequence in response to the imaging initiation signal, wherein the magnetic resonance image data which is representative of the central portion of k-space is collected at the beginning of the imaging

sequence and the data which is representative of the periphery of k-space is collected thereafter; and constructing an image of said artery, using the magnetic resonance image data, wherein the artery appears distinct from the adjacent veins and background tissue."

XIX. Claim 1 of the first auxiliary request of the appellant I corresponds to claim 1 of the main request with the following underlined amendments:

"*A method of imaging an artery in a region of interest in a patient using magnetic resonance imaging and a magnetic resonance contrast agent, wherein a catheter has been inserted into a vein remote from the artery of interest, the method containing the steps of: injecting the magnetic resonance contrast agent into the vein remote from the artery via the catheter; ...*".

XX. The remaining claims 2-11 according to both requests of the appellant I are dependent claims.

XXI. In the present decision, reference is made to "*EPC 1973*" or "*EPC*" for EPC 2000 (EPC, 13th edition, July 2007, Citation practice, pages 4-6) depending on the version to be applied according to Article 7(1) of the Revision Act dated 29 November 2000 (Special Edition No. 1 OJ EPO 2007, 196) and the decisions of the Administrative Council dated 28 June 2001 (Special Edition No. 1 OJ EPO 2007, 197) and 7 December 2006 (Special Edition No. 1 OJ EPO 2007, 89).

Reasons for the Decision

1. Admissibility of the appeal of the appellant I

The appeal of the appellant I complies with the requirements of Articles 106 to 108 EPC and Rule 99 EPC.

Therefore, it is admissible.

2. Admissibility of the appeal of the appellant II

2.1 Pursuant to Article 107 EPC "*any party to proceedings adversely affected by a decision may appeal*".
In the present case, the appellant II (as former opponent) is not adversely affected by the decision of the opposition division which revoked the patent.

2.2 According to Article 108 EPC a statement setting out the grounds of appeal shall be filed within four months of notification of the appealed decision.
In the present case, no statement of the grounds of appeal was filed.

2.3 Therefore, the appeal of the appellant II does not comply with the requirements of Articles 107 and 108 EPC.

Consequently, it is rejected as inadmissible (Rule 101(1) EPC).

2.4 The opponent, however, is party to the appeal proceedings as of right (Article 107 EPC).

3. Main request of the appellant I

3.1 Diagnostic methods practised on the human or animal body (Article 53(c) EPC)

3.1.1 Opinion G 1/04 of the EBA

In its opinion G 1/04 the EBA stated that there was no reason to deviate from the established jurisprudence of the boards of appeal, according to which "*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*" (Reasons, 5).

In this context, the EBA considered the question "*whether the diagnostic methods referred to in Article 52(4) EPC [1973] comprise only the deductive medical or veterinary decision phase consisting in attributing the detected deviation to a particular clinical picture, i.e. the diagnosis for curative purposes stricto sensu, or whether they are also meant to include one or more of the preceding steps related to examination, data gathering and comparison*" (Reasons, 5).

The conclusion drawn by the EBA was that "*The diagnostic methods referred to in Article 52(4) EPC*

[1973] include the method step related to the deductive medical or veterinary decision phase, i.e. the diagnosis stricto sensu, representing a purely intellectual exercise" (Reasons, 7). Moreover, "*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 [1973], the claim is to include (in view of Article 84 EPC [1973]) the feature pertaining to the diagnosis for curative purposes as a purely intellectual exercise representing the deductive medical or veterinary decision phase ..., as well as the features relating to ... the preceding steps which are constitutive for making the diagnosis ..., and ... the specific interactions with the human or animal body which occur when carrying those out among said preceding steps which are of a technical nature ...*" (Reasons, 8; Headnote, 1).

3.1.2 Present case

In the present case, the method of claim 1 of the granted patent does not include the deductive medical or veterinary decision phase, i.e. the diagnosis stricto sensu. Rather, it only includes the preceding steps of gathering information which are constitutive for making the diagnosis ("*monitoring ..., detecting ..., generating ..., collecting ..., constructing ...*"), and the specific interactions with the human or animal body ("*injecting ...*") which occur when carrying out said preceding steps.

3.1.3 Therefore, the subject-matter of claim 1 of the granted patent does not constitute a diagnostic method

practised on the human or animal body within the meaning of Article 53(c) EPC.

3.2 Methods for treatment of the human or animal body by surgery (Article 53(c) EPC)

3.2.1 Opinion G 1/04 of the EBA

In its opinion G 1/04 the EBA stated that "*Methods of surgery within the meaning of Article 52(4) EPC [1973] include any physical interventions on the human or animal body in which maintaining the life and health of the subject is of paramount importance*" (Reasons, 6.2.1).

Moreover, the EBA confirmed the established jurisprudence of the boards of appeal, according to which "*a method claim falls under the prohibition of Article 52(4) EPC [1973] if it includes at least one feature defining a physical activity or action that constitutes a method step for treatment of the human or animal body by surgery or therapy*" (Reasons, 6.2.1). Therefore, the surgical or therapeutic nature of a method claim can be established by a single method step.

The EBA also considered the development of medicine with regard to diagnostic methods. In particular, "*technological advances penetrate human and veterinary medicine and the medical and veterinary profession. Today, and more than at any time before, technology is about to fundamentally alter how and by whom health care is administered, with the result that human and veterinary medicine is gradually being reshaped by technology. In a changing medical or veterinary*

environment brought about by technological progress, the need for reconsidering the relationship between medical or veterinary practitioners and non-medicinal support staff will become more pressing than ever before. This will have implications for the non-medicinal support staff in terms of profile and expansion in that a great variety of diagnostic and other information will have to be procured and gathered by these persons" (Reasons, 6.3).
These considerations have a general character and, therefore, should not be limited to diagnostic methods only.

3.2.2 Decision G 1/07 of the EBA

In its decision G 1/07 the EBA held that the introduction of the exclusion of surgical methods from patentability (Article 53(c) EPC) derived from socio-ethical considerations and considerations of public health ("*Medical and veterinary practitioners should be free to use their skills and knowledge of the best available treatments to achieve the utmost benefit for their patients uninhibited by any worry that some treatment might be covered by a patent*"; Reasons, 3.3.6).
This is the ratio legis of the exclusion clause.

In the judgement of the EBA, the broad construction of the kind of interventions being of a surgical nature developed in decision T 182/90 (OJ 1994, 641) *("any non-insignificant intervention performed on the structure of an organism by conservative ("closed, non-invasive") procedures such as repositioning or by operative (invasive) procedures using instruments*

including endoscopy, puncture, injection, excision, opening of the bodily cavities and catheterisation") should be considered "*as being or having become overly broad when considering today's technical reality*" (Reasons, 3.4.2.1 and 3.4.2.2).
It is noted that the explicit referral to the "*today's technical reality*" shows a manifest parallelism with the considerations made in opinion G 1/04 (Reasons, 6.3) pointing to the importance of "*technological advances*".
Moreover, the EBA again referred to the today's technical reality with regard to the application of routine interventions in the medical field. In particular, the EBA held that "*Today, numerous and advanced technologies do exist in the medical field concerning the use of devices which in order to operate must in some way be connected to the patient. Methods for retrieving patient data useful for diagnosis may require administering an agent to the patient, potentially by an invasive step like by injection, in order to yield results or at least they yield better results when using such a step. Considering this technical reality, excluding from patentability also such methods as make use of in principle safe routine techniques, even when of invasive nature, appears to go beyond the purpose of the exclusion of treatments by surgery from patentability in the interest of public health*" (Reasons, 3.4.2.2).

Consistently with the criticism of T 182/90, the EBA held that the definition given in G 1/04 ("*any physical intervention on the human or animal body ...*"; Reasons, 6.2.1) also appeared too broad (Reasons, 3.4.2.2).

Thus, the EBA consistently pleaded for a narrow construction. "*Hence, a narrower understanding of what constitutes by its nature a "treatment by surgery" within the meaning of Article 53(c) EPC is required*" (Reasons, 3.4.2.3).
The wording used by the EBA ("*is required*") clearly underlines the necessity of a new definition consistent with the today's technical reality in the medical field. Such a need was indeed already acknowledged in G 1/04 (Reasons, 6.3), as mentioned above.

In order to find elements of a narrower understanding, the EBA stated that "*any definition of the term "treatment by surgery" must cover the kind of interventions which represent the core of the medical profession's activities, i.e. the kind of interventions for which their members are specifically trained and for which they assume a particular responsibility*" (Reasons, 3.4.2.3).
The used wording ("*any definition ... must ...*") is categorical about the need of concentrating on the "*core of the medical profession's activities*".

The core referred to above concerns "*the physical interventions on the body which require professional medical skills to be carried out and which involve health risks even when carried out with the required medical professional care and expertise. It is in this area that the ratio legis of the provision to free the medical profession from constraints by patents comes into play. Such a narrower understanding rules out from the scope of the application of the exclusion clause uncritical methods involving only a minor intervention and no substantial health risks, when carried out with*

the required care and skill, while still adequately protecting the medical profession" (Reasons, 3.4.2.3). In this statement, the concepts of "*professional medical skills*", "*medical professional care and expertise*", "*health risks*" and "*substantial health risks*" are introduced as criteria which help in differentiating between major physical interventions on the body to be excluded from patentability and uncritical methods for which the exclusion clause should not apply.
Further criteria may be the "*degree of invasiveness*" or the "*complexity of the operation performed*" ("*the required medical expertise and the health risk involved may not be the only criteria which may be used to determine that a claimed method actually is a "treatment by surgery" within the meaning of Article 53(c) EPC. The referring decision and the President have mentioned the degree of invasiveness or the complexity of the operation performed ...*";
Reasons 3.4.2.4)

With regard to health risks, the EBA also considered the potentially negative side effects of the administration of diagnostic contrast agents. In this respect, it was clarified that "*there is an exclusion from patentability as a surgical method only if the health risk is associated with the mode of administration and not solely with the agent as such*" (Reasons, 3.4.2.3).

3.2.3 Present case

The question to be decided in the present case concerns whether, in the context of claim 1 of the granted

patent concerning a method of imaging an artery in a region of interest in a patient using magnetic resonance imaging and a magnetic resonance contrast agent, the step of "*injecting the magnetic resonance contrast agent into a vein remote from the artery*" has a surgical character. According to the granted patent, this step implies the placement of an intravenous catheter through which the contrast agent may then flow into the vascular system. It may here be left open whether the injecting action stricto sensu, i.e. pumping the contrast agent into the vein, immediately follows or not the placement of the catheter.

It is not for the Board to develop a new narrow construction of what should be regarded as surgical activities excluded from patentability. This would indeed exceed the limits of the present case. Rather, the Board has to judge on the applicability of the exclusion clause to the present method claim in the light of G 1/04 and G 1/07 referred to above. If the step mentioned above is considered as surgical, the claimed imaging method including this step would then fall under the prohibition of Article 53(c) EPC as a method for treatment of the human or animal body by surgery (G 1/04).

3.2.4 Core of the medical profession's activities

The EBA explicitly held in G 1/07 that "*any*" narrower definition of treatment by surgery "*must*" cover the interventions which represent the "*core of the medical profession' activities*". Thus, it has to be assessed whether the injection of a magnetic resonance contrast agent into a vein belongs to the said core. This

assessment should be made in the light of the technical development mentioned by the EBA. In particular, technology is today about to fundamentally alter human medicine, in particular how and by whom medical care is administered (G 1/04).

As a matter of fact, the placement of an intravenous catheter is one of the most common invasive procedures performed in hospitals and consulting rooms. Physicians are traditionally responsible for this intervention. But the increasing qualification level of paramedical professionals (the term "*paramedical*" is used as relating to professions which supplement and support medical work but do not require the level of a fully qualified doctor) has led to the adoption in national healthcare systems of regulations allowing physicians to delegate some activities which were in the past of their exclusive pertinence. This trend appears to reflect social changes like the higher life expectancy, the increasing demand for health services and the need to contain health costs.

For instance, in a current home healthcare system a nurse provides individualized care for patients in their own home following a hospital stay or for long-term care patients. The nurse is thus responsible for carrying out a therapy at home if necessary, which may include the administration of drugs prescribed by a physician through a peripheral venous access. This requires from the nurse adequate levels of training, expertise and experience.

Moreover, the increasing qualification level of paramedical professionals has led to the development of

new professions like, for example, that of radiographers meanwhile officially acknowledged in the United Kingdom. A radiographer is a radiologic technologist who assists a radiologist, i.e. a physician specialised in radiology, in the practice of the medical profession. For example, a diagnostic radiographer interacts with patients and supervises the appropriate radiographic techniques to be used for obtaining the images required by the delegating radiologist. As a matter of fact, a duly trained and qualified radiographer may be delegated to make intravenous injections of a contrast agent when carrying out a magnetic resonance imaging procedure. This happens under the supervision of the delegating radiologist.

Therefore, it appears that in current healthcare systems a physician may delegate medical acts, for example intravenous injections, to paramedical professionals duly trained and qualified for carrying out the delegated act. The delegation is governed by regulations which may differ depending on the national healthcare systems. These regulations define all the acts which may be delegated. Alternatively, they establish the criteria which have to be met for the delegation to be possible and the limits which have to be respected. The delegating physician usually evaluates the risks to the patient, delegates only those acts for which a paramedical professional has been specifically trained, and supervises the work of the delegated professional. De facto, qualified hospital nurses are today entrusted with taking venous blood probes, giving infusions and making intravenous injections.

In view of this development, delegated acts can hardly be considered as belonging to the core of medical activities. As already stated, current regulations, in the interest of an efficient service to the patients, allow a physician to delegate minor interventions which do not imply substantial health risks, when carried out by a qualified paramedical professional with due care and skill. Delegation does not apply to the core of the medical activities which, within the meaning of G 1/07, cover the physical interventions which involve substantial health risks even when carried out with the required medical professional care and expertise and for which the physician assumes particular responsibility.

In summary, an intravenous injection can today be delegated by a physician to a qualified paramedical professional. This gives an indirect hint at the fact that such an injection may be considered as representing a minor routine intervention which does not imply substantial health risks when carried out with the required care and skill. It thus follows that the step of intravenously injecting a contrast agent would be ruled out from the scope of the application of the exclusion clause (Article 53(c) EPC) following the narrow understanding advocated by the EBA (G 1/07).

3.2.5 Substantial health risks

In the following, it is worth to try assessing the health risks of intravenous injections with the aim of verifying whether the indirect hint mentioned above can also be derived in a direct way.

Known complications of intravenous injections are infection, phlebitis, extravasation, bleeding and haematoma.

An effective way of assessing risks is to use a so-called risk matrix. The likelihood that a complication of an intravenous injection may happen is represented on a first scale (x-axis). The health impact of that complication is represented on a second scale (y-axis). According to a simple model, the likelihood is subdivided in three levels, i.e. "*unlikely*", "*likely*" and "*very likely*". The health impact is also subdivided in three levels, i.e. "*minor*", "*moderate*" and "*major*", wherein "*minor*" would cover negligible effects which do not need any treatment, "*moderate*" reversible effects which can be easily treated, and "*major*" serious irreversible effects or even death. The risk matrix thus permits to combine the levels of likelihood and health impact of a complication with regard to a large number of patients so as to obtain statistical health risk scores which may be used to decide what action should be taken, for instance whether or not the intravenous injection may be delegated to a paramedical professional.

Due to its definition, the risk matrix is subdivided in various sectors. A first sector is defined by the levels "*unlikely*" and "*minor*", a second sector by the levels "*likely*" and "*minor*", and so on up to the last sector corresponding to the levels "*very likely*" and "*major*". The heath risk score assigned to each sector increases when moving from the first to the last one.

In the Board's view, such an assessment based on the risk matrix would be in agreement with the understanding of the EBA (G 1/07) in that the sectors with low health risk scores, at least that with the levels "*unlikely*" and "*minor*", would correspond to the uncritical methods involving only a minor intervention and no substantial health risks and the sectors with high health risk scores, at least that with the levels "*very likely*" and "*major*", would correspond to the physical interventions on the body which require professional medical skills to be carried out, which involve substantial health risks even when carried out with the required medical professional care and expertise, and for which the physicians assume a particular responsibility.

In the present case, there should be no doubt that all the complications of intravenous injections mentioned above are reversible and can be solved with standard treatments, if necessary. Thus, the above risk assessment gives a further direct hint at the fact that intravenous injections may be considered as minor routine interventions involving no substantial health risks.

During the appeal proceedings, a serious complication of intravenous injections of a specific magnetic resonance contrast agent was mentioned. Patients with acute or chronic renal insufficiency who receive a gadolinium-based contrast agent appear to be at an increased risk for developing a Nephrogenic Systemic Fibrosis (NSF). This complication, however, only depends on the injected substance.

As a further complication, allergic reactions may be mentioned which also depend on the injected substance. In this respect, the EBA clarified in G 1/07 that there was an exclusion from patentability as a surgical method only if the health risk was associated with the mode of administration and not solely with the agent as such. Therefore, the complications concerning NSF and allergies are irrelevant for the issue of assessing whether the claimed method should be excluded from patentability under Article 53(c) EPC.

3.2.6 Degree of invasiveness and complexity of the operation performed

The Board holds that an intravenous injection is an invasive intervention. However, the degree of invasiveness and the complexity may be considered as being low, at least with regard to injections into superficial arm or leg veins, as it is envisaged in the patent in suit.

Therefore, even considering these criteria, the same conclusions mentioned above could be drawn.

3.2.7 Therefore, it results from the foregoing that the method according to claims 1-11 of the granted patent does not relate to a method for treatment of the human or animal body by surgery falling under the prohibition of Article 53(c) EPC. This conclusion is consistent with G 1/07.

3.3 Novelty (Article 54(1),(2) EPC) and inventive step (Article 56 EPC)

3.3.1 In the decision under appeal (Reasons, 2 and 3), the opposition division held that the subject-matter of claims 1-11 of the granted patent was novel and involved an inventive step with regard to the prior art documents cited by the opponent.

3.3.2 In appeal proceedings the opponent has not made any submissions in this respect.

3.3.3 Under these circumstances, the Board has no reason to depart from the opinion of the opposition division with regard to the issues of novelty and inventive step.

3.4 For these reasons, the main request of the appellant I is allowable.

4. First and second auxiliary requests of the appellant I

Since the main request is allowable, the first and second auxiliary requests of the appellant I need not to be considered.

5. Request of the appellant II

5.1 As stated above, the appeal of the appellant II is inadmissible. However, the request made in the notice of appeal may be considered as a request of the opponent in its status of a party to the appeal proceedings as of right (Article 107 EPC).

5.2 Such a request is rejected because the opponent has not submitted any arguments against the finding of the opposition division in the decision under appeal concerning novelty and inventive step (Reasons, 2 and 3).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar: The Chairman:

R. Schumacher B. Schachenmann