

# The EPO Enlarged Board of Appeal decides on dosage regimens (G2/08) and treatment by surgery (G1/07)

Dr. Benjamin Quest and Dr. Franz-Josef. Zimmer

The two recent decisions of the Enlarged Board of Appeal G2/08 and G1/07 differ largely in terms of their clarity and extent of legal certainty conveyed. While the decision on dosage regimens G2/08 is very clear, well reasoned and consistent, despite its exhaustive length the decision G1/07 on treatments by surgery does not give the practitioner much guidance for future cases; legal certainty remains wishful thinking.

## I. Decision G2/08

Decision G2/08 (Dosage regime/ABBOTT RESPIRATORY) of the Enlarged Board of Appeal (EBoA) confirms established case law with regard to second (and further) medical use claims. In the application underlying the decision (EP 94306847.8), claim 1 reads as follows:

The use of nicotinic acid [...], for the manufacture of a sustained release medicament for *use in the treatment by oral administration once per day prior to sleep, of hyperlipidaemia* characterized in that the medicament does not comprise [...].

In this case, the feature “*once per day prior to sleep*” was the only distinguishing feature with respect to the prior art. The first instance saw this as a medical activity excluded from patentability under Article 52(4) EPC 1973<sup>1</sup> (Article 53(c) EPC 2000), and referred to decisions T317/95 and T584/97 in their refusal of the application. The applicant lodged an Appeal against

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<sup>1</sup> Article 52(4) EPC 1973 reads: (4) *Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.* The provision was transferred in essence to Article 53(c) EPC 2000.

the Decision of the Examining Division and the then-competent Appeal Board decided to refer the case to the EBoA.

## THE QUESTIONS REFERRED TO THE ENLARGED BOARD OF APPEAL

The EPO’s Technical Board of Appeal dealing with the case considered the standards by which the patentability of the claim in question should be assessed as an exceedingly important point of law, and referred the following questions to the Enlarged Board of Appeal (EBoA):

1. Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC for use in a different, new and inventive treatment by therapy of the same illness?
2. If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime?
3. Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?

Prior to answering the first question, the EBoA ascertained that the new regulations, Articles 53(c) and 54(5) of the EPC 2000, apply to the instant case and the Board addressed the question of

whether or not these new regulations are to be interpreted differently from the corresponding provisions under Article 52(4) of the EPC 1973. In view of the preparatory documents to the EPC 2000 and in view of the general rules of interpretation of international law (Vienna Convention), the EBoA decided that the new provisions are not to be interpreted any differently than the corresponding provisions of the EPC 1973; the intention of the legislator was to properly enshrine the intentions set by decision G 5/83 (the “birth” of the Swiss-type second medical use type claim) and the case law established since then into the revised EPC. According to the legal practice under the EPC 1973 methods of treatment were not as such literally exempted as non-patentable matter. Instead they were – as a legal fiction – held to be not susceptible of industrial application, the latter requirement – industrial applicability – being one of the requirements for an invention to be patentable. With the revision of the EPC 1973 resulting in the EPC 2000, purpose-limited product claims for second and further medical uses became admissible, just as purpose-limited product claims for first medical uses. The EBoA in G2/08 makes it clear that transferring the regulation of Article 52(a) (1973) to Article 53(c) (2000) is, in practice, an editorial change as stated in the explanatory remarks of the EPC 2000<sup>2</sup>, but not a substantive change.

THE ANSWER TO QUESTION 1 IS “YES”

The EBoA decided that “[w]here it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness.”

<sup>2</sup> Point 6 of the explanatory remarks, Special Ed. of the OJ EPO 2001, 134 and Special Ed. No. 4 OJ EPO 2007, 50

The Board affirmed that Article 54(5)<sup>3</sup> EPC does not define the nature of the further therapeutic use, instead referring expressly to “any specific use”. The Board further concluded that the wording of Article 54(5) EPC should not be interpreted or weighted differently than the wording of Article 54(4) EPC and the term “any specific use” should not be interpreted as limiting in any way. This view is also supported by the preparatory documents of the EPC 2000.<sup>4</sup>

The term “for any specific use in a method referred to in Article 53(c)” is thus not limited to the treatment of a new medical condition. Numerous decisions of the Appeal Boards had previously established that second medical uses directed to the treatment of a novel group of subjects<sup>5</sup>, or relating to new routes or modes of administration,<sup>6</sup> or relating to a different technical effect leading to a truly new application of the medicament<sup>7</sup> are considered new in the sense of Art. 54 EPC. The novelty of such medical use claims resides in the intended new therapeutic application. This case law continues to be valid under G 2/08.

THE ANSWER TO QUESTION 2 IS “YES”

The EBoA decided that “[s]uch patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art.”

In view of the answer to the first question, the EBoA restated that the “specific use” of Article 54(5) may reside in something else than the treatment of a different illness and that there is no reason to approach a feature relating to a dosage regime differently than other specific uses

<sup>3</sup> Article 54(5) EPC 2000 states that “Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.”

<sup>4</sup> compare CA/PL 7/99 points 19, 24-26 and CA/110/99 page 1 point 1 No.5 and page 2, point 2 No. 19

<sup>5</sup> T 19/86, T 893/90, T 233/96

<sup>6</sup> T 51/93, T 138/95

<sup>7</sup> T 1020/03 (OJ EPO 2007, 204), T 290/86, T 254/93

acknowledged in the case law (e.g. novel group of subjects treated, new route or mode of administration, new technical effect).

Consequently, a feature directed to a dosage regimen can also confer novelty, provided that the feature reflects a truly new technical teaching.<sup>8</sup> The Board states that this also holds true for features where the existing jurisprudence for selection inventions needs to be applied.

As an aside, the EBoA included a note on the scope of protection of the new purpose-limited product claim format for second and further medical uses as compared with the Swiss-type claim format. While it appears that the Patentee's rights under the new claim category are likely broader and may lead to possible restrictions in the freedom of medical practitioners to prescribe or administer generics (Reasons point 6.5), the EBoA found that the provisions of the EPC are clear and that the EBoA is not empowered to broaden or reduce the scope of the provisions by way of attributing to the term "any specific use" a meaning that is not explicitly specified in the EPC. The freedom of medical practitioners thus needs to be protected on the national level, if necessary.

In practice, these differences on the national level already exist and are referred to by the EBoA, in particular with respect to dosage regimens<sup>9</sup>. Presently, applicants should consider the differences of the jurisdictions on the national level at the latest when bringing an action to court to ensure that the claim format as allowed

by the EPO is not in conflict with national requirements.

### THE ANSWER TO QUESTION 3: ENDING THE PRACTICE OF THE SWISS-TYPE SECOND MEDICAL USE CLAIM

The EBoA further decided that "[w]here the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such a claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83".

The EBoA took the opportunity of question 3 to end the practice of pursuing Swiss-type claims in the future. A time limit of three months after publication of the decision in the Official Journal of the EPO was set to allow future applicants to comply with the new situation. The new practice will apply to applications having a filing date, or, if priority has been claimed, a priority date which is after the above-mentioned three-month period. The publication of the decision in the Official Journal of the EPO has yet to occur (as of May 20, 2010).

This change in the legal practice may not come as a surprise. The legal constraints that made the Swiss-type second medical use type claims a necessary workaround no longer exist in the revised EPC. Therefore, the decision to lay this practice to rest is a consequent step. Presently, however, no national case law with respect to the scope of protection of the new claim format has been established. One may therefore find it premature to end the Swiss-type claim format without good cause. The transition to the new practice is a very "soft" one (without retroactive effect). Due to the lack of national case law regarding the scope of protection rendered by the new purpose-limited product claims, applicants should seriously consider retaining both claim formats for second and further medical use claims on file as long as such practice is allowed under G2/08. One "loose end" of G2/08 from the practitioners point of view is thus

<sup>8</sup> T 290/86 (OJ EPO 1992, 414), T 1020/03, T 836/01 and T 1074/06

<sup>9</sup> - UK Court of Appeal Decision of May 21 2008 in re Actavis UK Limited v. Merck & Co. Inc. (2008) EWCA Civ. 444) which ruled in the same way as the present decision of the EBoA;

- Switzerland Tribunal of the Canton of Zurich, Decision of 14 April 2009, AA 090075 and AA 090077 rules in the opposite direction;

- Germany, Federal Court of Justice, Decision of 19 December 2006, X ZR 236/01 „Carvedilol II“ requires a special claim format for claims including dosage regimes.

the departure from the well-established Swiss type claim format, in particular since this claim format is presently the only acceptable claim format for second and further medical uses in Switzerland.

Still, G2/08 gratifyingly clarifies that basically any further improvement in therapeutic treatments can form the basis for a patent in Europe. The decision G2/08 gives an incentive to further explore inventive medical uses for known substances in order to improve treatment efficiency in the interest of public health. Even “minor” improvements, such as optimizing the timing of the administration of a drug, can be protected by a patent in Europe.

## II. Decision G1/07

As outlined in the introduction of this report, the decision G1/07 (Treatment by surgery/MEDI-PHYSICS) rather illustrates than resolves the existing dilemma on how to handle claims directed to methods involving a surgical step. The key question remaining - one which it would have been desirable to clarify - is which actions fall under the term “surgery” and hence may represent a bar to patenting. In G1/07 the Board refrained from providing a definition in this case and the entire decision suffers from the lack of a clear definition of this term.

In the application underlying the decision (EP 99918429.4), claim 1 read as follows:

A method for MRI imaging the pulmonary and/or cardiac vasculature using dissolved-phase polarized  $^{129}\text{Xe}$ , comprising the steps of; positioning a patient in an MRI apparatus [...]; *delivering polarized  $^{129}\text{Xe}$  gas to a predetermined region of the patient's body, [...];* exciting a predetermined region of the patient's body, having a portion of the dissolved phase polarized gas therein with [...]; and acquiring at least one MR image

associated with the dissolved phase polarized gas after said exciting step.

The feature “*delivering polarized  $^{129}\text{Xe}$  gas to a predetermined region of the patient's body*” was described in the application to comprise inter alia injection into the heart.

The Examining Division refused the application on the grounds that the method was a diagnostic method practiced on the human or animal body and that, as far as it pertained to injection of polarized  $^{129}\text{Xe}$  into the heart, it furthermore comprised a surgical step. The claimed method was therefore deemed to fall under the exclusion provision of Article 52(4) EPC which inter alia excludes surgical methods from patenting. The Applicant lodged an appeal against this decision, which was dealt by a Technical Board of Appeal (TBA) in T 992/03.

## THE QUESTIONS REFERRED TO THE EBoA

Firstly, with regard to the aspect of diagnosis on the human body, the TBA decided that the claimed method was restricted to the examination phase in the sense of G1/04 and that it therefore did not constitute a diagnostic method practiced on the human or animal body. For addressing the objection of the Examining Division in relation to the surgical step, the TBA tried several approaches in order to come to a conclusion on this point. One approach was to review the existing case law with respect to existing attempts to define the term “surgery”<sup>10</sup>. The TBA found that the existing jurisprudence is inconsistent because two different criteria are

<sup>10</sup> T182/90 and T35/99 both found that treatment by surgery is today not limited to therapeutic treatments and took the view that the nature of the treatment is the decisive aspect;

T383/03 ruled that a surgical method needs to be at least suitable for maintaining or restoring the health of a patient (i.e. needs to be of a therapeutic nature) in order to fall under the exclusion of Article 52(4) EPC 1973; the view of T383/03 was confirmed by T1102/02 and T9/04;

In an obiter dictum, G1/04 took the view that surgery includes any physical intervention in which maintaining the life or health of in a subject was of paramount importance.

employed for defining surgery. One aspect is the nature of the physical intervention. The other is the purpose of the intervention (i.e. whether or not it is for therapy). Another approach to define surgery as encompassing those treatments that require professional medical expertise was previously found impracticable in G1/04. As a further possible way to define surgery, it was suggested to evaluate the degree of invasiveness required.

Other considerations of the TBA pertained to the possible form of allowable claims and particularly whether a disclaimer may be formulated in this respect or whether the nature of the claimed technique and its ability to enable a surgeon to decide on the course of action taken need be considered. The TBA refrained from taking a decision in these matters and considered them to represent an important point of law requiring a decision from the EBoA (Article 112 EPC). In its referral to the EBoA under T 992/03, the TBA hence referred the following questions to the EBoA:

1. Is a claimed imaging method for a diagnostic purpose (examination phase within the meaning given in G 1/04), which comprises or encompasses a step consisting in a physical intervention practised on the human or animal body (in the present case, an injection of a contrast agent into the heart), to be excluded from patent protection as a "method for treatment of the human or animal body by surgery" pursuant to Article 52(4) EPC if such step does not per se aim at maintaining life and health?
2. If the answer to question 1 is in the affirmative, could the exclusion from patent protection be avoided by amending the wording of the claim so as to omit the step at issue, or disclaim it, or let the claim encompass it without being limited to it?

3. Is a claimed imaging method for a diagnostic purpose (examination phase within the meaning given in G 1/04) to be considered as being a constitutive step of a "treatment of the human or animal body by surgery" pursuant to Article 52(4) EPC if the data obtained by the method immediately allow a surgeon to decide on the course of action to be taken during a surgical intervention?

Prior to addressing the referred questions, the EBoA clarified that the substantive law to be applied to this case is the EPC 2000 (Article 53(c) EPC).

#### THE ANSWER TO THE FIRST QUESTION

The EBoA decided that "[a] claimed imaging method, in which, when carried out, maintaining the life and health of the subject is important and which comprises or encompasses an *invasive step* representing a *substantial physical intervention on the body* which requires *professional medical expertise* to be carried out and which entails a *substantial health risk* even when carried out with the required professional care and expertise, is excluded from patentability as a method for treatment of the human or animal body by surgery pursuant to Article 53(c) EPC." (emphasis added)

Firstly, the EBoA did not adopt the position that the exclusion clause should be interpreted narrowly to exclude only "surgery for therapy," because it would then be redundant with the exclusion of methods by therapy also mentioned in Article 53(c) EPC. Rather, the purpose of the exclusion clause (the ratio legis) was deemed decisive, this purpose being to protect the freedom of the medical practitioner from patent rights. The three alternative exclusions in Article 53(c) EPC (i.e. methods for treatment of the human or animal body by (i) surgery, (ii) therapy and (iii) diagnostic methods practised on the human or animal body), are thus per se independent exemptions.

The Board also ruled that for a multi-step method to be inadmissible, it suffices that the method comprises one step that constitutes one of the exemptions of Article 53(c) EPC.

With respect to the scope of the term “surgery”, the EBoA adopted the view that the decisive criterion should not be the *purpose* but rather the *nature* of the surgical treatment. The answer to the first question is – at first sight – more elaborate and contains more details than required to answer the original question that referred by the TBA. The EBoA did not feel itself in the position to provide a definition of the term “surgery,” and reformulated the question in order to finally regard “an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise” as falling under the definition of a treatment by surgery. The EBoA further stated that the determination of whether a given treatment may be surgical must be decided on a case-by-case basis.

This part of the decision is critical, as it avoids naming or clearly defining the actions that fall under the term “surgery”. While the EBoA may have had good reasons not to define the term via a level of invasiveness or the definition of a skilled practitioner, the answer they give to the first question is intimidatingly unclear. The EBoA defines neither a “substantial physical intervention”, nor the level of “professional medical expertise” needed, nor what one should understand as representing an action “entailing a substantial health risk”. Even the term “invasive” may not have a clear-cut meaning. For example, must a penetration of a bodily epithelium take place, or does an intubation or an esophago-gastro-duodeno-scopy suffice as an invasive step? Almost any physical intervention on the body may entail a health risk, even a simple intramuscular injection can lead to severe complications.

All these undefined and vague terms render the answer of the EBoA rather useless in the attempt to assess whether or not a given method comprising an invasive step may be in conflict with Article 53(c) EPC. A simple intravenous injection (that requires the professional medical expertise of a nurse) may thus well be within the above definition of the EBoA.

The EBoA explicitly stated that the holding of T383/03, which regarded the therapeutic purpose of the method as essential to fall under the exemption of Article 52(4) EPC 1973, was in error on this point<sup>11</sup>. The Examining Divisions of the EPO may thus continue to object to any method which involves the penetration of a bodily epithelium (since it is invasive and may bear a substantial health risk) although the President of the EPO apparently indicated in her comments that it may be desirable to restrict the exemptions to “non-insignificant” interventions (point VIII-5 of the G1/07). The EBoA further adopted the view that the findings of G1/04 in respect of diagnostic methods shall equally apply to surgical methods. As in G1/04, the EBoA does not want to base the assessment on whether a method is to be excluded from patentability on the basis of a definition of the skilled practitioner (inter alia because the level of skill is not uniform within the contracting states, and because the progress in the field may render the presence of a skilled practitioner dispensable).

In their attempt to interpret the term “surgery”, however, the Board found that applying the definition given in G1/04 (i.e. that “any physical intervention on the human or animal body ...”) to a method of surgery would be too broad, thus agreeing with the President's suggestions not to exclude methods involving “insignificant” invasive techniques from patentability. However, the Board did not come up with

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<sup>11</sup> The EBoA reviewed the preparatory documents to the EPC, and noted the absence of any indications for limiting surgery to therapeutic surgery.

a more precise definition of this term; all attempts of a definition of the terms “invasiveness”, “medical expertise needed”, and “health risk” were dismissed as being either difficult to define themselves or “moving targets”, the definition of which changes over time. Finally, the EBoA found itself unable to give a general definition of the term “surgery” and confined the present decision to the very case referred to it. Thus, the definition given above is to be understood in the context of the application EP 99918429.4, i.e. that the injection into the heart is considered a surgical intervention. The assessment of any other kind of invasive technique as a surgical or non-surgical step remains to be decided on a case-by-case basis.

#### THE ANSWERS TO THE SECOND QUESTION

##### One step in a multi-step method is sufficient for the method to be in conflict with Article 53(c) EPC

The EBoA ruled that “[a] claim which comprises a step encompassing an embodiment which is a “method for treatment of the human or animal body by surgery” within the meaning of Article 53(c) EPC cannot be left to encompass that embodiment.”

The above also holds true where the claim comprises a surgical step on a higher level of abstraction (“delivering”) without explicitly claiming the surgical step (“injection into the heart”) as such.

This aspect of the present decision may also have a critical impact in practice as it may affect applications that were drafted to encompass a vast variety of techniques to deliver a substance needed for e.g. diagnostic purposes into the body, and/or those cases in which it is required to take a blood or tissue sample. The most critical point is that such techniques per se need not even be recited in the claim. Rather, it may suffice that they are comprised inherently (i.e. on a higher level of

abstraction). Due to the EBoA's failure to define which actions are insignificant, the Examination Divisions of the EPO might potentially consider every injection or taking of a blood sample as being “surgical”. Many objections of the EPO Examiners can be foreseen for applications where the claimed technology involves at least some kind of an invasive step.

##### Disclaimers are allowed, but not easy to draft

The Board also held that “[t]he exclusion from patentability under Article 53(c) EPC can be avoided by disclaiming the critical embodiment, it being understood that in order to be patentable the claim including the disclaimer must fulfil all the requirements of the EPC and, where applicable, the requirements for a disclaimer to be allowable as defined in decisions G 1/03 and G 2/03 of the Enlarged Board of Appeal [must be met].”

The EBoA did not comment on potentially allowable disclaimers. The admissibility of a disclaimer was left to be decided on a case-by-case basis. Clearly, in order to allow a concise (and practical) disclaimer like “non-surgical”, a clear cut definition of the term “surgery” would have been helpful. Decisions G1/03 and G2/03 set high standards for formulating allowable disclaimers. In view of these standards, and considering the Board's failure to come to a conclusion on the definition of “surgery” in G1/07, a workable and concise disclaimer will now be difficult to achieve. Moreover, it must be kept in mind that a disclaimer would also have to fulfil the clarity requirements of Article 84 EPC. Consequently, merely defining a claimed method as a non-surgical method may raise a clarity objection in view of the unclear term “surgery”.

While terms like “pre-delivered” or “pre-implanted” may be used to omit the invasive step from the claim wording, these terms might be not allowable disclaimers in the sense of G1/03 and

G2/03, because an Examiner might require literal basis for such terms in order to comply with Article 123(2) EPC, not allowing the introduction of such terms into a claim by way of amendment after filing.

For drafting applications it may thus be a sensible approach to pre-emptively adopt respective language that may provide a basis for a claim amendment in order to overcome a objections caused by an overly narrow interpretation of the term "surgery" by the competent Examining Division or TBA.

#### Omission of the surgical step

The EBoA decided that *"[w]hether or not the wording of the claim can be amended so as to omit the surgical step without offending against the EPC must be assessed on the basis of the overall circumstances of the individual case under consideration."*

Importantly, the method omitting the surgical step needs to meet the requirements of Article 84 EPC and Article 123(2) EPC, particularly in the sense that it constitutes an invention that is fully and completely defined by the remaining features of the claim<sup>12</sup> and finds sufficient support in the application as originally filed. The Board also confirmed established case law that a method which is only concerned with the operation of a device without any functional link between the claimed method and the effects produced on the body is not excluded from patentability<sup>13</sup>. The assessment as to whether or not the method excluding the surgical step still meets all requirements of the EPC was held to be decided on a case-by-case basis.

#### THE ANSWER TO THE THIRD QUESTION IS "NO"

<sup>12</sup> G 1/04, Reasons point 6.2

<sup>13</sup> T 245/87, OJ EPO 1989, 171, Reasons point 3.2.3; T 789/96 OJ EPO 2002, 364 Reasons points 2.2.2.1 et seq.; T 329/94 OJ EPO 1998, 241 Reasons points 4 et seq.;

T 1102/02, T 9/04, T542/06 and T 810/06; a view also reflected by the Guidelines of Examination C-IV,12

According to the present decision "[a] claimed imaging method is not to be considered as being a "treatment of the human or animal body by surgery" within the meaning of Article 53(c) EPC merely because during a surgical intervention the data obtained by the use of the method immediately allow a surgeon to decide on the course of action to be taken during a surgical intervention."

Hence, the per se patentable imaging method is not exempted from patentability merely due the fact that the imaging method allows a surgeon to decide on the course of a given surgical intervention.

#### PRACTICAL IMPLICATIONS OF G1/07

For the time being, the situation in respect of surgical methods or methods encompassing a surgical step remains essentially unclear. The only guidance G1/07 provides is that surgery is not to be construed to be limited to surgery for therapy. The other points on which a clarification would have been desirable remain pretty obscure. As in the stem cell case (G2/06), the EBoA limited its comments to the very specific case on file without giving any more general guidance. It therefore remains to be seen whether the instant decision will have a major practical impact on the prosecution of similar cases before the EPO. In any case, it appears all the more advisable to draft applications in a way so as to provide a basis for the omission of any potentially critically viewed steps.

#### CONCLUDING REMARKS / RESUMEE

It appears that the recent decisions of the Enlarged Board of Appeal in the field of life science have in part lost their character of setting guiding principles. This holds especially true for those cases in which a decision does not come easy (e.g. G2/06 on stem cells). In 2010, the EBoA continues to walk on eggshells in G1/07. While in the stem cell case one could at

least understand the political sensitivity of the underlying subject matter, and therefore accept that the EBoA limited their argument to the very specific case in question, the matter to be decided in G1/07 does not appear to be influenced by such major political or ethical concerns.

By ruling that a method is surgical if one step may encompass a surgical step even on a higher order of abstraction, G1/07 does certainly not make the life of applicants easier. Applicants that are now in the state of drafting applications directed to methods useful in the diagnostic field should therefore pay careful attention to those parts of the specification that deal with any kind of invasive step and include language that allows disclaiming or obviating those techniques or steps which may be interpreted as surgery by the Examining Divisions of the EPO.

However, the shortcomings of G1/07 do not apply to G2/08, as this latter decision is clear and provides applicants with a sound legal certainty. This decision is to the relief of those who may have had concerns that the amendments implemented with the EPC 2000 may actually lead to a different practice under the EPC, in particular to a renunciation of the very liberal practice under T1020/03, which was the first case allowing a dosage regime as a technical feature that can establish novelty and inventive step over the prior art. Fortunately, G2/08 confirmed the applicant-friendly practice of the Appeal Boards established over the years.