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Datasheet for the decision
of 7 May 2014

Case Number: T 0135/10 - 3.4.01
Application Number: 02785651.7
Publication Number: 1493162
IPC: G21G4/08, A61J1/00, G21F5/015
Language of the proceedings: EN

Title of invention:
RADIOISOTOPE GENERATOR

Applicant:
GE Healthcare Limited

Headword:

Relevant legal provisions:
EPC 1973 Art. 56, 113(1), 116(1), 84
EPC Art. 123(2)
EPC R. 103(1)(a)
RPBA Art. 13(1)
Guidelines for examination E-II.4, edition September 2013

Keyword:
Substantial procedural violation -
violation of the right to be heard - main request (no)
Inventive step - revised first auxiliary request (no)
Remittal to the department of the first instance -
revised second auxiliary request (yes)
Decisions cited:
T 0734/91, T 0033/93, T 0311/94, T 0153/89, T 0763/04,
T 0246/08, T 1170/07, J 0007/82, T 0079/82, T 0295/94,
T 0478/91

Catchword:
DECISION
of Technical Board of Appeal 3.4.01
of 7 May 2014

Appellant: GE Healthcare Limited
(Applicant)
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Decision under appeal: Decision of the Examining Division of the European Patent Office posted on 7 July 2009 refusing European patent application No. 02785651.7 pursuant to Article 97(2) EPC.

Composition of the Board:
Chairman G. Assi
Members: T. Zinke
C. Schmidt
Summary of Facts and Submissions

I. The appeal filed on 31 July 2009 lies from the decision of the examining division, posted on 7 July 2009, refusing European patent application No. 02 785 651.7 published with publication No. 1 493 162 (WO-A-03/088270). The appeal fee was paid on the same date. The statement setting out the grounds of appeal was filed on 6 November 2009.

II. In the decision under appeal, the examining division held that the subject-matter of independent claim 1 of a pending main request did not fulfil the requirements of Article 56 EPC 1973 having regard to document D1 (US-A-3 774 035) in combination with document D2 (US-A-4 211 588). Further, the examining division held that the subject-matter of independent claim 1 of a pending auxiliary request did not fulfil the requirements of Article 56 EPC 1973 taking into account the disclosure of documents D1 and D2 and considering that the selection of a PTFE filter was merely one of several straightforward possibilities from which the skilled person would select in accordance with the circumstances.

III. In the notice of appeal the appellant (applicant) requested that the decision under appeal be cancelled in its entirety.

IV. With the statement setting out the grounds of appeal the appellant requested, as a main request, that the case be remitted to the examining division for further prosecution on the basis of claims 1 to 4 as originally filed. In support of this request, the appellant argued that the act of summoning to oral proceedings after only a first written communication was inappropriate,
since the appellant had made a "bona fide attempt" in his response to overcome the objections raised by the examining division in the first written communication. In this regard the appellant cited decision T 0734/91.

Further, the appellant argued that the right to be heard (Article 113(1) EPC 1973) had not been respected and cited decisions T 0153/89, T 0033/93, and T 0311/94 in order to support its view. The appellant held that the examining division did not provide sufficient reasoning for its decision to refuse the application on all the issues that had been raised during the examination proceedings.

Since the right to be heard had not been respected a substantial procedural violation occurred. The appellant thus requested reimbursement of the appeal fee (Rule 103(1)(a) EPC).

As a first auxiliary request the appellant again requested that the case be remitted to the examining division for further prosecution based on claims 1 to 4 as originally filed and provided arguments as to why the subject-matter of independent claim 1 was based on an inventive step when considering documents D1 and D2.

The appellant further requested as a second auxiliary request that the case be remitted to the examining division for further prosecution based on new claims 1 to 3 as filed together with the statement setting out the grounds of appeal and provided arguments with regard to disclosure of the amendments and to inventive step of the subject-matter of these claims.

As a third auxiliary request the appellant requested that the case be remitted to the examining division for
further prosecution based on a single claim 1 as filed with the statement setting out the grounds of appeal. Arguments were provided with regard to disclosure of the amendments and with regard to inventive step.

Moreover, the appellant provisionally requested oral proceedings.

V. On 02 January 2014 the Board issued a summons to oral proceedings scheduled to take place on 7 May 2014. A communication under Article 15(1) RPBA was issued on 6 March 2014 drawing attention to issues to be discussed.

With the communication, the Board introduced document D3 (EP-A-0 385 424) disclosing a filter made of polytetrafluoroethylene for preventing bacteria in the air from being introduced into the interior of a container.

VI. With a letter dated 11 April 2014 the appellant filed an amended claim 1 of a revised third auxiliary request and a revised Figure 1. Moreover, further arguments in order to support its position with regard to all requests were provided. In particular, the appellant further referred to decisions T 0763/04, T 0246/08, J 0007/82, T 1170/07 with regard to the question in which detail a decision should deal with arguments provided by a party. With regard to the question whether documents of a certain age could be combined or not, the appellant cited T 0079/82, T 0295/94 and T 0478/91.

VII. On 5 May 2014 the Board forwarded by fax a copy of document D4 (US-A-3 783 291) and introduced it into the proceedings.

During the oral proceedings the appellant finally requested:

as a main request, that the decision under appeal be set aside and the case be remitted to the examining division for further prosecution on the basis of claims 1-4 as originally filed and, moreover, that the appeal fee be reimbursed,

as a revised first auxiliary request, that the decision under appeal be set aside and the case be remitted to the examining division for further prosecution on the basis of claims 1-3 as filed during the oral proceedings, and

as a revised second auxiliary request, that the decision under appeal be set aside and the case be remitted to the examining division for further prosecution on the basis of a single claim 1 as filed during oral proceedings.

IX. Claim 1 of the appellant's main request reads as follows:

"A device for producing a fluid containing a radioactive constituent, the device comprising: a shielded chamber within which is located an isotope container housing a radioactive isotope, the shielded
chamber including first and second fluid connections to opposing ends of the isotope container and a fluid conduit extending from each of the first and second fluid connections to a fluid inlet and a fluid outlet respectively characterised in that the fluid inlet comprises a single spike having a substantially circular cross-section, the spike being adapted to penetrate the rubber seal of a vial and the spike having two bores, the first bore extending from a first aperture adjacent the tip of the spike to a fluid connection with the fluid conduit and the second bore extending from a second, separate aperture in the spike to a filtering air inlet."

X. Claim 1 of the appellant's revised first auxiliary request reads as follows:

"A device for producing a fluid containing a radioactive constituent, the device comprising: a shielded chamber within which is located an isotope container housing a radioactive isotope, the shielded chamber including first and second fluid connections to opposing ends of the isotope container and a fluid conduit extending from each of the first and second fluid connections to a fluid inlet and a fluid outlet respectively characterised in that the fluid inlet comprises a single spike having a substantially circular cross-section, the spike being adapted to penetrate the rubber seal of a vial and the spike having two bores, the first bore extending from a first aperture adjacent the tip of the spike to a fluid connection with the fluid conduit and the second bore extending from a second, separate aperture in the spike to a filtering air inlet, wherein the filtering air inlet contains a filter disk of polytetrafluoroethylene."
XI. Single claim 1 of the appellant's revised second auxiliary request reads as follows:

"A radioisotope generator (1) comprising:

an outer container (2) in which is located a shielded container (5), said shielded container (5) comprising an upper opening (19) which is closed by a container plug (18), wherein said shielded container (5) surrounds a tube (6) containing an ion exchange column (7), and wherein said tube (6) has frangible rubber seals (8) and (9) at opposing ends (10) and (11) which, when in use, are pierced by respective hollow needles (12) and (13) that are in fluid communication with a respective fluid conduits (14) and (15) that are in turn in fluid communication with an eluent inlet (16) and an eluate outlet (17) respectively, and wherein conduit (14), extending from hollow needle (12), passes through a channel in container plug (18), and then extends from the container plug (18) to the eluent inlet (16) and wherein conduit (15), extending from hollow needle (13) passes through a channel in the shielded container (5) to the eluate outlet (17) wherein the inner shielded container (5) is smaller than the outer container (2) so there is free space (20) within the outer container (2) above the shielded container (5) wherein said free space (20) accommodates part of the tubing (14, 15) as the lengths of the tubing (14, 15) are both much greater than the minimum length required to connect the hollow needles (12, 13) with the respective eluate [read "eluent"] inlet (16) and eluate outlet (17);

a top plate (3) which is sealingly secured to said outer container (2), wherein said top plate (3) has a pair of apertures (21) through which respective eluent inlet and eluate outlet components project, wherein
each of said eluent inlet and eluate outlet components is a hollow spike (22) consisting of an elongate, generally cylindrical, spike body (23) and an annular retaining plate (24) attached to or moulded as a single part with one end of the spike body (23), wherein the opposing end of said spike body (23) is shaped to a point and has an aperture communicating with the interior of the spike body adjacent the point, and wherein said annular retaining plate (24) forms a skirt projecting outwardly from the spike body (23); wherein for said eluant [read "eluent"] inlet component the hollow spike (22) is a single body (28) which is substantially circular in cross-section and has two bores (29, 30) leading to opposed apertures in the sharpened point of the spike, the first of the bores (29) being an eluate [read "eluent"] bore communicating directly with the outlet fluid connection of the spike which is, in turn, connected to tubing 14, and the second of the bores (30) being an air bore leading to a filter chamber (31) and an air hole (32) wherein the filter chamber (31) contains a filter disk (33) of polytetrafluoroethylene (PTFE) or polyvinylidenefluoride (PVDF); and wherein each hollow spike (22) is arranged to be held and supported by its annular retaining plate (24) by component supports (26) provided on the inside of said top plate (3); and, a separate top cover (4) which is secured to said outer container (2) over said top plate (3), wherein said top cover (4) also includes a pair of apertures (25) arranged so as to align with the apertures (21) in said top plate (3) and shaped to allow through passage of each spike body (23), wherein each of the apertures (25) is located at the bottom of a well (27) that is shaped to receive and support either an isotope collection vial or a saline supply vial."
Reasons for the Decision

1. The appeal is admissible.

2. Main request

2.1 The main request to remit the case to the first instance for further prosecution is based on the allegation that the right to be heard (Article 113(1) EPC 1973) had been disregarded by the examining division because of two reasons. First, the appellant stated that a second written communication should have been issued. Second, the appellant put forward that a substantial procedural violation occurred, since the decision under appeal provided insufficient reasoning.

2.2 Second written communication

2.2.1 According to Article 94(3) EPC "the Examining Division shall invite the applicant, as often as necessary, to file his observations" (emphasis added). Hence, the number of communications sent out by the examining division lies in its discretion, as long as Article 113(1) EPC is respected, i.e. "The decisions of the European Patent Office may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments."

2.2.2 In the present case, the appellant was summoned to oral proceedings by the examining division. As the examining division pointed out in its decision (see Reasons, point 1), "The examining division found the arguments provided by the applicant in his letter of 20.07.2005 not convincing and had to maintain this objection. At this stage, the issue of a further communication merely repeating a previous objection
would have unnecessarily delayed the procedure." Thus, it is obvious that the examining division had no reason to issue a further communication because it maintained its objections already submitted. The Board, therefore, is unable to identify any substantial procedural violation in the way the examining division exercised its discretionary power.

2.2.3 The appellant cited decision T 0734/91 in order to support its view that a further written communication would have been appropriate and/or a telephone conference could have been arranged instead of summoning to oral proceedings. This decision, however, deals with the case where the examining division refused the application within written proceedings directly after having received a response to a sole written communication. The present case is different in that oral proceedings were scheduled on demand of the appellant, which thus had an opportunity to comment in writing on the objections raised by the examining division and a further opportunity during oral proceedings. Due to its absence, the appellant, however, waived this further opportunity.

2.2.4 In the letter of 11 April 2014 the applicant argued that the present case was to some extent similar to the situation in T 0734/91, because - if oral proceedings had not been requested - the present application could have been refused without a second communication. This argumentation, however, misses the point, because in the present case the oral proceedings were scheduled and in the response of 21 May 2009 to the summons and in the oral proceedings on 22 June 2009 the applicant indeed had the opportunity to present its comments. Hence, Article 113(1) EPC 1973 is fulfilled.
2.2.5 The appellant also provided a timeline of the events of the present application in order to show that the applicant was not responsible for any delay during the prosecution of this application. The timeline was used to rebut the argumentation of the examining division that oral proceedings were scheduled to avoid that the procedure would have been "unnecessarily delayed." The Board notes that the corresponding statement of the examining division "the issue of a further communication merely repeating a previous objection would have unnecessarily delayed the procedure" (see point 1 of the Reasons for the decision under appeal) does not reflect any intent to make the applicant responsible for the delay, but is simply addressing the opinion of the examining division that oral proceedings would have been a more appropriate way of ending the proceedings. In the light of this understanding the further statement of the examining division "Since the examining division could not agree with the applicant's written arguments, the examining division considered it appropriate to give the applicant the possibility to discuss the case orally." should be read. Hence, the Board has no reason to see any undue way of exercising the examining division's discretionary power to summon to oral proceedings after a single communication and the corresponding reply of the appellant.

2.2.6 The appellant also referred to the additional costs resulting from oral proceedings as mentioned in the Guidelines E-II.4 (edition September 2013):

"Oral proceedings will normally only be expedient if after an attempt at written clarification there are still questions or doubts which have a crucial bearing on the decision to be reached and which may be more efficiently or surely settled by oral discussion with
the party or parties .... The competent department should also bear in mind the need for economy in such procedures, since oral proceedings give rise to costs for both the EPO and the party or parties."

This passage from the Guidelines, however, is only a recommendation and does not confer any right to the appellant to avoid oral proceedings. Article 116(1) EPC 1973 states clearly that oral proceedings shall take place at the instance of the EPO if it considers this to be expedient or at the request of any party to the proceedings. In the present case, the applicant itself requested oral proceedings and the examining division considered the summons after a single communication and the appellant's reply to be expedient.

2.2.7 With regard to the requirement of Article 113(1) EPC 1973 it is noted that the summons to attend oral proceedings and the oral proceedings themselves provided an opportunity to present comments. The appellant alone bore responsibility not to waive this opportunity.

2.2.8 Hence, in the present case the Board can not identify any obligation for the examining division to send out a further written communication instead of summoning to oral proceedings.

2.3 Insufficient reasoning

2.3.1 In the statement setting out the grounds of appeal the appellant argued that Article 113(1) EPC 1973 was infringed, since the decision to refuse the application did not deal in substance with all its arguments provided in the first letter dated 20 July 2005 and the response to the summons dated 21 May 2009. The decision
was based on the ground of lack of inventive step taking into consideration documents D1 and D2.

2.3.2 The Board identifies the following major inventive step arguments provided by the appellant in the above-mentioned letters:

(a) The problem to be solved by the alleged invention, i.e. to avoid the tearing of a vial stopper by rotation of the eluent container, was not known at the time the invention was made (see e.g. letter of 20 July 2005, page 2, paragraphs 1 to 5 and letter of 21 May 2009, page 4, paragraph 2).

(b) The devices of D1 and D2 were handled by different groups of people. Devices for producing radioactive fluids were operated by specialist pharmacists whereas intravenous drips were used by doctors or nurses. Therefore, the devices of D1 and D2 were in different fields of art which meant that one of skill in the art of devices for producing radioactive fluids would not necessarily also be skilled in the art of intravenous drips (see letter of 20 July 2005, page 2, paragraph 6 and letter of 21 May 2009, page 3, paragraph 3).

(c) Document D1 dated from 1973 and document D2 from 1980, whereas the priority date of the present application was 11 April 2002. Both documents were therefore available in the art for a long time before the present invention was made and this surely had to be an indication that the problem and its solution were not obvious to one of skill in the art at the priority date of the invention (see letter of 20 July 2005, page 2, last

2.3.3 The appealed decision deals with all these arguments. Points (a) and (b) are discussed in sections 2.1 to 2.4 of the Reasons of the decision. The arguments in section 2.2, second paragraph, and 2.4 are mentioned for the first time in the decision and discuss the arguments provided in the response to the summons.

Point (c) has been discussed in section 2.5 of the Reasons of the decision under appeal, the second paragraph of which deals with additional arguments brought forward by the applicant with its response to the summons.

2.3.4 Hence, the decision addresses the applicant's arguments. It is clear from the additional arguments as compared to the first communication of 17 March 2005 and to the summons of 3 March 2009 that the examining division considered all the essential submissions of the appellant. Consequently, the Board can not identify any substantial procedural violation resulting from an inadequate reasoning of the decision to refuse.

2.3.5 The appellant cited decisions T 0153/89, T 0033/93 and T 0311/94 in order to support its view that the decision of the examining division was not provided with adequate reasoning. These decisions simply underline the fact that a decision of an examining division should contain a reasoned statement in respect of all requirements of the EPC which the examining division considers not to have been met. In the present case, only an inventive step objection was raised in the examination proceedings and thus discussed in the decision under appeal.
2.3.6 Decisions T 1170/07, J 0007/82, T 0246/08 and T 0763/04 were also cited by the appellant with regard to the question, whether arguments of a party are sufficiently reflected in the corresponding first instance decisions.

In decision T 1170/07 the decision under appeal did not contain any reasoning in connection with insufficiency of disclosure although this ground for opposition had been submitted by the opponent and discussed during the oral proceedings. Hence, this decision came to the conclusion that a substantial procedural violation had occurred (point 7 of the Reasons). In the present case, however, the sole raised objection of lack of inventive step was considered in the decision under appeal.

In decision J 0007/82 (point 6 of the Reasons) none of the arguments submitted by the appellant were taken into account and the final decision was based on a ground on which the appellant had had no opportunity to present his comments. This was considered a substantial procedural violation (see Headnote II.). As mentioned above, in the present decision under appeal the sole ground of refusal was lack of inventive step.

Decision T 0246/08 states that "a decision must show that all potentially refutative arguments adduced by a party are actually refutable" (see point 2.2 of the Reasons).

Decision T 0763/04 dealt with a case, where the "reasons of the decision, apart from minor editorial changes, are identical to those given in the final communication. There is no mention or consideration of the arguments submitted by the Appellant." (see point
4.1.3 of the Reasons). In this decision the respective board concluded: "In summary, Article 113(1) requires not merely that a party be given an opportunity to voice comments, but more importantly it requires that the deciding instance demonstrably hears and considers these comments." (see point 4.4 of the Reasons).

However, as shown above, in the decision under appeal the examining division discussed on the merits of all the arguments brought forward by the appellant. Hence, no infringement of the right to be heard (Article 113(1) EPC 1973) could be identified and, consequently, no substantial procedural violation was present.

2.3.7 A negative assessment (in the view of the applicant) of the applicant's arguments by the examining division is not "per se" a substantial procedural violation. Such a negative assessment can be overruled or confirmed by the second instance.

2.3.8 Since a substantial procedural violation did not occur, the request for reimbursement of the appeal fee is refused (Rule 103(1)(a) EPC).

3. Revised first auxiliary request

3.1 The revised first auxiliary request was submitted during the oral proceedings and corresponds to the second auxiliary request as filed together with the statement of grounds. Hence, this request was admitted (Article 13(1) RPBA).

3.2 Document D4 discloses a device for producing a fluid containing a radioactive constituent (column 1, lines 19 to 23), the device comprising a shielded chamber (housing 10, column 1, lines 48 to 52) within which is
located an isotope container housing a radioactive isotope (sterile generator 12, column 1, lines 48 to 52, and claim 1), the shielded chamber including first and second fluid connections to opposing ends of the isotope container (hypodermic needle 42 and hypodermic needle 66) and a fluid conduit extending from each of the first and second fluid connections to a fluid inlet (composite hypodermic needle 68, column 2, lines 26 to 30) and a fluid outlet (conduit means 48, column 2, lines 5 to 8) respectively. The fluid inlet comprises a single spike (composite hypodermic needle 68) having a substantially circular cross-section (Figure 4), the spike being adapted to penetrate the rubber seal of a vial (column 2, lines 57 to 59) and the spike having two bores (delivery conduit 71, passageway 72, column 2, lines 30 to 34), the first bore extending from a first aperture adjacent the tip of the spike to a fluid connection with the fluid conduit (see Figure 4, delivery conduit 71) and the second bore extending from a second, separate aperture in the spike to an air inlet (see Figure 4, passageway 72, inlet tube 77, column 2, lines 30 to 34).

3.3 The distinguishing feature of claim 1 as compared to the disclosure of document D4 is the provision of a filter disk of polytetrafluoroethylene in the air inlet.

3.4 The technical effect of the distinguishing feature consists in that bacteria in indrawn air are precluded from reaching the radioisotope solution. The technical problem related to this effect can thus be formulated as providing a device for the production of radioactive fluids with better sterility.
3.5 Document D1 discloses the use of an antibacterial plug 37 having a sterile barrier 38 (e.g. cotton) at the top thereof in a vent system for the preparation of radionuclide eluates (column 2, lines 65 to 68). Hence, for a person skilled in the art starting from the disclosure of document D4 and having to solve the above-mentioned problem it would be obvious to improve the device as disclosed in document D4 with a filter as disclosed in document D1. Whereas D1 discloses cotton as a filter, the person skilled in the art is aware of other suitable filter materials from his common general knowledge as is evidenced by the textbook D5, wherein the suitability of disks made of Teflon (which is the trade name for polytetrafluoroethylene or PTFE, see page 377) as a filter for sterile air venting is discussed (see page 333, third paragraph). Replacing cotton by PTFE does not, in the Board's view, involve an inventive step.

3.6 The appellant pointed to the particular construction of the device of document D4, wherein the inlet tube 77 as part of the vent system is arranged on top of the device. With this construction there would be no motivation for the person skilled in the art to replace hydrophilic cotton with hydrophobic polytetrafluoroethylene, since there would be no danger that the filter material becomes wet due to leaking solution from the eluent vial. The Board considers this argumentation not convincing, since the claim wording of claim 1 is silent with regard to the position of the air inlet. Hence, the position of the air inlet can not be taken into account, when evaluating inventive step.

3.7 During the proceedings a point of discussion was whether the age of a prior art document could represent a criterion for assessing inventive step. The Board
notes that the decisions cited by the appellant in this respect (T 0079/82, T 0295/94 and T 0478/91) make it clear that the age of documents known long before the filing date of an invention might only be an indication of inventive step if a need for the solution of an unsolved problem had existed for the whole time between the date of the documents and that of the invention and the skilled persons were not able to find a solution to the problem (T 0079/82, point 4 of the Reasons; T 0295/94, point 4.3 of the Reasons; T 0478/91, point 4.6 of the Reasons).

The documents which are available to the Board in the present case, however, do not show that the sterility problem could not be solved in the time between the publication of the cited prior art documents and the filing date of the present application.

3.8 Consequently, the subject-matter of claim 1 of the revised first auxiliary request lacks an inventive step (Article 56 EPC 1973) in view of the combination of documents D4 and D1 in the light of the skilled person's general knowledge as resulting from document D5.

4. Revised second auxiliary request

4.1 The revised second auxiliary request was filed during the oral proceedings in reaction to the fact that document D4 had been introduced into the proceedings shortly before the oral proceedings. The revised second auxiliary request was thus admitted (Article 13(1) RPBA).
4.2 Article 123(2) EPC

As a basis for the amendments made in the revised second auxiliary request, the appellant referred in particular to Figure 1 of the application and the corresponding description on page 5, line 10 to page 8, line 10. Single claim 1 closely claims the embodiment depicted in Figure 1.

The Board is satisfied that Article 123(2) EPC is fulfilled.

4.3 Article 84 EPC 1973

The Board has no objections with regard to clarity (Article 84 EPC 1973) of the single claim 1.

4.4 In claim 1 of the revised second auxiliary request the following obvious corrections should be made (Rule 139 EPC):

- page 10, line 22: eluate inlet (16) --> eluent inlet (16),
- page 11, line 10: eluant inlet --> eluent inlet,
- Page 11, line 13: eluate bore --> eluent bore (see also page 8, line 14 of the application as published).

4.5 Amended Figure 1 as filed with the letter of 11 April 2014 overcomes the deficiency of missing reference sign 4.

4.6 Since the wording of claim 1 of the revised second auxiliary request includes several features disclosed in the description with regard to the embodiment of Figure 1, the Board considers it appropriate to remit the case to the first instance for further prosecution.
In this respect, the Board does not exclude that an additional search may be appropriate.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of the following application documents:
   - claim 1 of the revised second auxiliary request submitted during the oral proceedings before the Board on 7 May 2014,
   - description pages 1-9 as originally filed,
   - Figure 1 as filed with letter of 11 April 2014 and
   - Figure 2 as originally filed.

The Registrar: 

The Chairman:

R. Schumacher 

G. Assi 

Decision electronically authenticated