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Datasheet for the decision of 20 July 2016

Case Number: T 2374/13 - 3.3.01

Application Number: 06734512.4

Publication Number: 1848749

IPC: C07D487/04, A61K31/5025, A61P3/04

Language of the proceedings: EN

Title of invention:
Contact drug delivery system

Applicant:
Auburn University

Headword:
Molecular imprinted contact lenses/AUBURN

Relevant legal provisions:
EPC Art. 83, 111(1)
RPBA Art. 15(3)

Keyword:
Oral proceedings - held in absence of appellant
Main request, auxiliary requests 1 and 2: sufficiency of disclosure - undue burden (yes)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:
T 0014/83, T 0292/85, T 0409/91, T 0435/91, T 0019/90, T 0931/91, T 0694/92, T 0636/97, T 0731/00

Catchword:

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Case Number: T 2374/13 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 20 July 2016

Appellant: (Applicant)	Auburn University 215 East Thach Avenue Auburn, AL 36830 (US)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 10 June 2013 refusing European patent application No. 06734512.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	G. Seufert
	M. Blasi

Summary of Facts and Submissions

I. The applicant lodged an appeal against the decision of the examining division refusing European patent application No. 06734512.4

II. The present decision refers to the following documents:

(2) H. Hiratani, C. Alvarez-Lorenzo, Journal of Controlled Release, Vol. 83, 2002, pages 223 to 230

(5) Methods in Molecular Biology, vol. 275: Chemoinformatics: Concepts, Methods and Tools for Drug Discovery, Ed. J. Bajorath, Humana Press Inc., New Jersey (US), 2004, pages 131 to 213

(6) S. Dey *et al.*, Expert Opinion on Biological Therapy, Vol. 3, No. 1, 2003, pages 23 to 44

(7) F. Fanelli *et al.*, Bioorganic and Medicinal Chemistry, Vol. 2, No. 3, 1994, pages 195 to 211

(8) F. Stoll *et al.*, Molecular Pharmacology, Vol. 62, No. 5, 2002, pages 1103 to 1111

(9) A. Tieppo *et al.*, Journal of Controlled Release, Vol. 157, 2012, pages 391 to 397

(10) C. J. White, M. E. Byrne, Expert Opinion on Drug Delivery, Vol. 7, No. 6, 2010, pages 765 to 780

(11) C. J. White *et al.*, Journal of Drug Delivery Science and Technology, Vol. 21, No. 5, 2011, pages 369 to 384

(12) H. Hiratani *et. al.*, Biomaterials, Vol. 26, 2005, pages 1293 to 1298

(13) J. Xu *et al.*, Drug Delivery, Vol. 18, No. 2, 2011, pages 150 to 158

(14) C. C. S. Karlgard *et al.*, International Journal of Pharmaceutics, Vol. 257, 2003, pages 141 to 151

III. The decision under appeal is based on the set of claims submitted with letter of 12 February 2013.

The examining division held that the claimed subject-matter contravened Article 83 EPC. In particular, it took the view that the application provided no guidance as to how step a) of claims 1 and 8 was to be put into practice.

IV. With the statement of grounds of appeal, the appellant resubmitted the set of claims underlying the decision under appeal as main request and filed an auxiliary request and documents (9) to (14).

V. In a communication accompanying the summons to oral proceedings, the board expressed its preliminary opinion. In particular, it indicated that it agreed with the examining division's findings concerning insufficiency of disclosure.

VI. In response to the board's communication, the appellant filed a new main request and auxiliary requests 1 to 4, with letter dated 16 June 2016.

The main request consists of seven claims with independent claims 1 and 5 reading as follows:

"1. A method for making a drug delivery system, the method comprising:

a) synthesizing or selecting a functionalized monomer(s) by identifying receptor sites or molecules associated with a target biological tissue to be treated with a drug, wherein functionalized portions of the functionalized monomer(s) are synthesized to

chemically and/or structurally resemble the receptor sites or molecules that are associated with the biological mechanism of action of the drug;
b) forming a recognitive polymeric hydrogel, wherein forming the polymeric hydrogel comprises forming a solution comprising amounts of the drug, the functionalized monomer and a cross-linking monomer and initiating copolymerization of the functionalized monomer and the cross-linking monomer;
c) forming the polymeric hydrogel into contact lenses."

"5. A contact lens formed from a recognitive polymeric hydrogel matrix said polymeric hydrogel matrix being formed from;

a) a functionalized monomer(s) synthesized or selected by identifying receptor sites or molecules associated with a target biological tissue to be treated with a drug, wherein functionalized portions of the functionalized monomer(s) are synthesized to chemically and/or structurally resemble or mimic the receptor sites or molecules that are associated with the biological mechanism of action of the drug;
b) a bio-template; and
c) a cross-linking monomer;

for use in dispensing a drug to a biological tissue."

Claim 1 of auxiliary request 1 is identical to claim 1 of the main request. The claims directed to the contact lens have been deleted.

Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that step a) has been deleted, the remaining steps b) and c) have been renamed steps a) and b), the drug has been defined as an anti-histamine

and the functionalised monomers have been chosen to mimic aspartic acid, asparagine and tyrosine.
Claim 4, directed to the contact lens, has been adapted accordingly and reads as follows:

"4. A contact lens formed from a recognitive polymeric hydrogel matrix said polymeric hydrogel matrix being formed from;

a) a functionalized monomer(s) which mimics aspartic acid, asparagine and tyrosine;
b) a drug; and
c) a cross-linking monomer;

for use in dispensing the drug to a biological tissue; wherein the drug is an anti-histamine."

In claim 1 of auxiliary request 3 the functionalised monomers are further characterised as comprising acrylic acid, acrylamide and N-vinyl pyrrolidinone.
Claim 3, directed to a contact lens, has been adapted accordingly.

Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 3 in that the anti-histamine has been further defined as being "ketotifen fumarate".
Claim 2, directed to a contact lens, has been adapted accordingly.

VII. With letter of 15 July 2016, the appellant informed the board that it would not be attending the oral proceedings scheduled for 20 July 2016.

VIII. The appellant's arguments, as far as they are relevant to the present decision, can be summarised as follows:

The claimed subject-matter properly reflected the technical contribution made by the invention, namely the use of a biomimetic molecular imprinting technique in the production of contact lenses for the delivery of a drug to a subject. This was achieved by incorporating functionalised monomers into a polymeric hydrogel, whereby the functionalised portions in the polymeric hydrogel that was formed resembled or mimicked the receptor site of the drug. Documents (9) to (14) provided further evidence in support of this technical contribution. The major advance in the field of ocular drug delivery provided by the invention justified the breadth of the claims (see EPO Guidelines for Examination, Part F-IV, 6.2 dealing with the extent of generalisation; decision T 409/91, point 3.5 of the Reasons). Moreover, the breadth of a claim was not in itself a ground for insufficiency of disclosure, as was apparent from numerous decisions of the boards of appeal, including T 19/90 (OJ EPO 1990, 476), T 636/97 or T 694/92. Rather a proper balance needed to be found between the technical contribution to the art and the terms in which the invention was claimed, to provide the appellant with the fair and adequate protection to which it was entitled (see T 694/92, OJ EPO 1997, 408, Headnote I).

The inventive concept was illustrated in the application through the preparation of a biomimetic polymeric hydrogel capable of binding the anti-histamine ketotifen. It was known that the amino acids aspartic acid, asparagine and tyrosine were involved in the binding of anti-histamines at the histamine receptor site. These amino acids were mimicked by acrylic acid, acrylamide and N-vinyl-pyrrolidinone (see page 11, lines 22 to 31, Figure 4). It was further taught in the application that the functionalised

monomers to be incorporated into the hydrogel were synthesised with functional groups that mimicked or resembled molecules or functional groups that were associated with the action of a drug at the target tissue (page 11, lines 7 to 21). Based on this information and the fact that the details of interaction between drug and receptor site were known in the art or could be routinely established, as was apparent from documents (5) to (8), the skilled person would have no difficulties in carrying out the invention.

Furthermore, since the invention did not relate to methods for identification and synthesis of functionalised monomers as such, the fact that step a) could be performed in many different ways did not negate the appellant's technical contribution. According to the jurisprudence of the boards of appeal, it was not relevant for sufficiency of disclosure that some variants of a functionally defined component feature were unavailable, as long as suitable variants were known to the skilled person through the disclosure or common general knowledge (see T 292/85, OJ EPO 1989, 275, point 3.1.5 of the Reasons; T 435/91, OJ EPO 1995, 188, point 2.2.2 of the Reasons). Furthermore, there was no basis to find a claim unallowable under Article 83 EPC, if a skilled person was able to distinguish between workable and unworkable embodiments with the help of simple, routine experiments addressed in the description (see T 731/00, point 3 of the Reasons). Even occasional failure was acceptable if only a few attempts were required to transform failure into success (see T 931/91, point 3.2 of the Reasons; T 14/83, OJ EPO 1984, 105, point 6, paragraph 1 of the Reasons).

Moreover, sufficiency of disclosure had to be assessed in the light of the particular drug that the skilled person wished to deliver, rather than the hypothetical mass of potentially non-working examples. Hence, sufficiency had to be looked at on a compound-by-compound basis. Where the target site/mechanism of action was known, there was no undue burden; where the target site/mechanism of action was not known, as would be the case for some drugs, a structure-activity-relationship study needed to be performed. Such studies were routine in the art and did not amount to undue burden. Once the biological mechanism of action was known and the receptor site identified, the skilled person could readily select the functionalised monomers.

With regard to figure 4 and the list of potentially useful functionalised monomers on page 6, the skilled person was provided with sufficient information to make an appropriate selection. Suitable functionalised monomers had the same or equivalent functional groups as those compounds which were involved in the interaction of the drug in the ligand binding pocket of the receptor. It was well within the common general knowledge of the person skilled in the art to recognise monomers which would match an amino acid residue present in the receptor site for a particular drug. Furthermore, improvements in the delivery of the drug, which was a measurable and verifiable parameter, could be used in the selection of appropriate functionalised monomers.

In addition, identification and replication of the exact receptor site of the drug to be delivered were not required. Nor did the recognitive polymeric hydrogel have to exhibit the same degree of interaction

with the drug to be delivered as the biological target site. It was sufficient if it displayed a higher degree of chemical bonding with the drug to be delivered than the polymer without the functionalised portions.

IX. The appellant requested that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution on the basis of the set of claims of a new main request, alternatively of one of auxiliary requests 1 to 4, all filed together with the letter dated 16 June 2016.

X. At the oral proceedings, which took place as scheduled, the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. Procedural matters

2.1 The board considered the submission of the main request and auxiliary requests 1 to 4 to be an attempt to address objections concerning certain terms and amendments raised in the board's communication accompanying the summons to oral proceedings. It therefore admitted them into the proceedings (Article 114(2) EPC and Article 13(1) RPBA).

2.2 According to Article 15(3) RPBA, the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned, who may then be treated as relying only on its written case. The explanatory note to this Article (see CA/133/02 dated

12 November 2002) states that "This provision does not contradict the principle of the right to be heard pursuant to Article 113(1) EPC since that Article only affords the opportunity to be heard and, by absenting itself from the oral proceedings, a party gives up that opportunity."

The appellant had been informed in the board's communication accompanying the summons to oral proceedings that sufficiency of disclosure was an issue which the board would consider and decide on during the oral proceedings. It therefore had an opportunity to present its observations and comments on the grounds and evidence on which the board's decision is based. Hence, the board was in a position to take a decision at the oral proceedings, despite the absence of the duly summoned appellant, without violating the appellant's right to be heard (Article 113(1) EPC).

Main request and auxiliary request 1

3. Sufficiency of disclosure (Article 83 EPC)

3.1 Claim 1 of the main request is directed to a method for making a drug delivery system (i.e contact lenses) comprising the formation of a recognitive polymeric hydrogel from the drug, a functionalised monomer and a cross-linking monomer, and the formation of the hydrogel into contact lenses (steps b) and c), see point VI above). The functionalised monomer(s) is(are) selected or synthesised in such a way that the functional portions chemically and/or structurally resemble the receptor site or molecules that are associated with the biological mechanism of action of the drug (step a), see point VI above). Claim 1 of

auxiliary request 1 is identical to claim 1 of the main request.

3.2 In order to assess whether the requirement of sufficiency of disclosure is fulfilled it has to be examined whether the application as a whole makes available to the person skilled in the art, in the light of his common general knowledge, all the information necessary to carry out the claimed method and, in the present case, to prepare the recognitive hydrogels designed to mimic biological recognition or exploit biological mechanisms (see page 4, lines 13 to 21, page 11, lines 7 to 21 and Figure 3 of the application) without undue burden over the whole scope of the claims.

3.3 A prerequisite for the preparation of the recognitive hydrogels, in particular the synthesis or selection of appropriate functionalised monomers in step a), is knowledge or identification of the receptor site of the drug, in particular the structure of the binding pocket and the determination of the molecules involved in, or essential for, the binding of the drug, or knowledge or identification of "molecules associated with a target biological tissue to be treated by the drug". The application contains no information at all about these issues. In the experimental part of the application, step a) is not described. Instead, the examples deal exclusively with steps b) and c). With respect to step a) they rely on the fact that the receptor site and the amino acids involved in the binding of anti-histamines, such as ketotifen fumarate - the only drug that has been used in the examples - are known in the art (see page 11, lines 26 to 31 of the application). This information, in particular regarding the amino acids, is specific to the recognition domain or binding

pocket of the histamine/anti-histamine receptor and cannot be extended to other drugs, such as antibiotics, antiviral agents, immunosuppressants, etc. (see page 7, line 15, to page 8, line 22, claim 4), which bind to different receptors. No evidence has been provided that for the majority of the broadly defined classes of drugs on pages 7 and 8 of the application the receptor site, in particular the structure of the binding pocket and the molecules involved in the binding of the drug, are common general knowledge.

3.4 The board agrees with the appellant that if the binding site and the relevant molecules involved in the binding of the drug or the mechanism of action are unknown, a study of the structure-activity relationship (SAR) or of the biological mechanism and the molecules associated therewith has to be carried out. However, such a study, even for a specific drug, constitutes in essence an entire research programme and exceeds the reasonable amount of experimentation which, according to established jurisprudence of the boards of appeal, is permissible when it comes to sufficiency of disclosure. It places undue burden on the average skilled person trying to put the invention into practice, irrespective of the fact that tools are known which can assist him in carrying out such a programme (for example SAR methods as disclosed in document (5)). As is apparent from documents (7) and (8), such SAR studies require extensive experimental data, including sequence and mutagenesis studies for the receptor, binding assays, pharmacophore definition, conformational analysis, the building of a suitable model, and detailed and extensive correlation analysis (see documents (7) and (8), abstracts). In view of the high complexity of such studies, success is not a certainty and the appellant's argument that they are

mere routine for an average skilled person is not accepted.

3.5 Furthermore, even if the board agreed with the appellant that for the majority of drugs the receptor sites and the binding pockets with the relevant molecules involved in the binding of the drugs, or the molecules associated with the biological mechanism of action, are known, the person skilled in the art and trying to carry out the invention, would still have to select suitable functionalised monomers for the preparation of a recognitive hydrogel which resembles or mimics the receptor site. No information or guidance for a proper selection of such monomers is provided in the application as filed, which merely postulates that the functionalised monomers acrylic acid, acrylamide and N-vinyl pyrrolidinone mimic the amino acids aspartic acid, asparagine and tyrosine, which are relevant for the binding of anti-histamines to the receptor (see page 11, lines 22 to 31 and Figures 4A to 4C). The vague and extremely general "definition" that the functional portions must chemically and/or structurally "resemble" the receptor site or molecules associated with the biological mechanism of action is not sufficient in this respect, particularly in the complete absence of any criteria as to how "resemblance" is to be determined or verified. The board is not aware of any common general knowledge that would help the person skilled in the art in deciding this question, and none has been provided by the appellant.

3.6 Nor is it possible to deduce clear selection criteria from Figures 4A to 4C, as argued by the appellant. A comparison between aspartic acid and acrylic acid in Figure 4A and asparagine and acrylamide in Figure 4B

reveals certain similarities and may initially lead the skilled person to assume that identity of the functional group in the functionalised monomer and the amino acid side chain is sufficient as a selection criterion. However, this assumption is immediately called into question when considering Figure 4C. The functionalised monomer N-vinyl pyrrolidinone does not share a common functional group with the amino acid tyrosine, nor does any chemical or structural similarity or equivalence strike the eye. Hence, Figures 4A to 4C, contrary to the appellant's view, offer no guidance at all on how to select suitable functionalised monomers. Page 6 of the application, to which the appellant also referred in this context, merely provides a list of functionalised monomers (see lines 23 to 37) without any information as to which amino acids they are supposed to match or mimic. No selection criteria can therefore be deduced from this passage.

3.7 The release studies or release profiles or the loading capacity described in the application are not helpful in this respect. They demonstrate the performance of hydrogels prepared with a particular functionalised monomer or combination of monomers and can be used to compare various hydrogels with each other. However, they are not suitable for establishing whether the aim of resembling receptor sites or molecules associated with a target biological tissue is indeed achieved. In this context the board notes that improvements in the release profile (i.e. sustained release) or loading capacity of polymeric hydrogels prepared in the presence of a drug, compared to polymeric hydrogels prepared in the absence of a drug, as allegedly shown in the application, are not an indication of "resemblance to a receptor site". The same effect is

achieved in document (2) (see for example page 228, figure 3; page 229, right-hand column, lines 10 to 12 and point 4 "Conclusion"), which according to the appellant (see letter of 12 July 2010, page 3, last line to page 4, line 12) does not disclose a biomimetic approach. The appellant's contention that "resemblance" simply means "improvement in binding and release" is therefore not persuasive.

Moreover, release studies or release profiles, although they may be useful to determine whether hydrogels formed with a specific functionalised monomer or group of monomers achieve the same effect as the hydrogels made with acrylic acid, acrylamide and N-vinyl pyrrolidinone, and therefore mimic aspartic acid, asparagine and tyrosine, do not provide any guidance as to how to initially select suitable functionalised monomers. In view of the fact that the person skilled in the art has no criteria at his disposal enabling him to identify suitable functionalised monomers (see point 3.5 above) he can establish only by trial-and-error experimentation on arbitrarily selected functionalised monomers whether they provide the claimed effect. In the board's judgement, that amounts to undue burden.

3.8 With regard to the appellant's arguments concerning the technical contribution and the breadth of the claims the board notes the following:

The board, in accordance with established jurisprudence of the boards of appeal, does not dispute that the breadth of a claim is not in itself a sufficient reason for an objection of insufficiency. However, the principle of "just reward" or "fair and adequate protection" for the technical contribution, on which

the appellant relied, requires that an applicant provides sufficient instructions for the person skilled in the art to enable him to readily perform the invention without undue burden over the whole scope of the claims. In the present case, the technical contribution lies in advancing the known technology of molecular imprinting contact lenses, as illustrated for example in document (2), to a biomimetic molecular imprinting technique characterised in that it mimics the binding pocket of a drug's receptor. In the board's judgement, to fulfil the requirement of sufficiency of disclosure the application must provide the skilled person with sufficient guidance for him to be able to achieve this result over the whole breadth of the claims. As explained in points 3.3 to 3.7 above, such guidance is missing from the application, even if, as argued by the appellant, sufficiency is looked at on a compound-by-compound basis.

Documents (9) to (11) and (13), relied on by the appellant, are post-published and not pertinent. They cannot overcome an existing issue of disclosure, which must be sufficient as from the date of filing. Document (12) is concerned with the same type of imprinted contact lenses as document (2) and confirms that molecular imprinting techniques, although allegedly not based on a biomimetic approach, provide contact lenses with improved drug-loading and sustained release properties (cf. document (2), page 229, right-hand column, "conclusion" and document (12), page 1297, right-hand column, conclusion). Document (14) refers to non-imprinted, soaked contact lenses and is therefore even less pertinent than documents (2) or (12).

Decisions T 292/85, T 435/91, T 731/00 and T 931/91 cannot support the appellant's case. Contrary to the

statements in T 292/85 (see point 3.1.5 of the Reasons) and T 435/91 (see point 2.2.2 of the Reasons), no suitable variants are known to the skilled person through the disclosure of the application or common general knowledge. Moreover, in the absence of any criteria on how to determine resemblance to a receptor site or how to select appropriate functionalised monomers, the skilled person is unable to distinguish between workable and non-workable embodiments (see T 731/00, point 3 of the Reasons) or to transform occasional failure into success within reasonable bounds (T 931/91, point 3.2 of the Reasons and T 14/83, point 6 of the Reasons).

3.9 For the aforementioned reasons, the board concludes that the application does not provide sufficient information for the skilled person to be able to carry out the invention according to claim 1 of the main request without undue burden over the whole breadth of the claim. The requirement of Article 83 EPC is therefore not met, with the consequence that the main request and, in view of the identical wording of its claim 1, auxiliary request 1 must be refused.

Auxiliary request 2

4. Sufficiency of disclosure

4.1 Claim 1 of auxiliary request 2 is directed to a drug delivery method comprising steps a) and b), which are identical to steps b) and c) of the main request. Furthermore, the drug to be delivered is defined as anti-histamine. Step a) of the main request is no longer present. Instead, the functionalised monomers are chosen to mimic aspartic acid, asparagine and tyrosine (see point VI above).

4.2 As set out in point 3.3 above, the only functionalised monomers satisfying this requirement which are disclosed in the application are acrylic acid, acrylamide and N-vinyl pyrrolidinone (see page 11, lines 22 to 31 and Figure 4A to 4C). The application does not however provide any explanation or reasons as to why these compounds qualify as compounds mimicking the amino acids specified in claim 1. Nor can a person skilled in the art deduce any selection criteria from Figures 4A to 4C or page 6 of the application (see point 3.6 above). Release studies or release profiles as disclosed in the application cannot remedy the lack of selection criteria, as set out in point 3.7 above.

4.3 Hence, the same conclusion as for the main request and auxiliary request 1 applies to auxiliary request 2, with the consequence that it too must be refused for non-compliance with Article 83 EPC.

Auxiliary request 3

5. Sufficiency of disclosure

5.1 Claim 1 of auxiliary request 3 is directed to a drug delivery method comprising steps a) and b), which are identical to steps b) and c) of the main request. In addition, the drug to be delivered is defined as anti-histamine, and the functionalised monomers chosen to mimic aspartic acid, asparagine and tyrosine comprise acrylic acid, acrylamide and N-vinyl pyrrolidinone.

5.2 The functionalised monomers to be used for the formation of a recognitive polymeric hydrogel are now limited in such a way that they include the specific monomers, which mimic aspartic acid, asparagine, and

tyrosine. Further technical information concerning the formation of the hydrogel can be found in the application on page 11, last paragraph to page 12, line 37. The formation of contact lenses is known in the art (see page 10, lines 1 to 5 and last paragraph, lines 1 to 3).

5.3 Hence, in the board's judgement, the skilled person can reproduce the invention as defined in claims 1 and 3 of auxiliary request 3 without undue burden over the whole scope of the claims. The requirement of Article 83 EPC is therefore met.

6. Remittal

6.1 It follows from the above that the sole reason for the refusal has been removed and the decision under appeal is to be set aside. In these circumstances, and in view of the appellant's request (see point IX above), the board exercises its discretion under Article 111(1) EPC and remits the case to the examining division for further prosecution on the basis of auxiliary request 3 filed with letter of 16 June 2016.

However, the board would like to point out that in claims 1 and 8 the expression "a functionalised monomer" appears to be inconsistent with the expression "the functionalised monomers" in the same claims and the required presence of acrylic acid, acrylamide and N-vinyl pyrrolidinone.

6.2 Having come to the conclusion that auxiliary request 3 complies with the requirements of Article 83 EPC and having decided to remit the case, there is no need for the board to decide on auxiliary request 4.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution on the basis of the set of claims of auxiliary request 3 as filed together with the letter of 16 June 2016.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated