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Datasheet for the decision of 7 May 2021

Case Number: T 1590/17 - 3.3.01

Application Number: 11172812.7

Publication Number: 2402754

IPC: G01N33/53, G01N33/567, C12N15/06

Language of the proceedings: EN

Title of invention:
Unstructured recombinant polymers and uses thereof

Patent Proprietor:
Amunix Operating Inc.

Opponents:
Novo Nordisk A/S
XL-protein GmbH

Headword:
Unstructured recombinant polymers/AMUNIX

Relevant legal provisions:
EPC Art. 123(2), 83, 111(1)
RPBA Art. 12(4), 13(1), 15(3)
EPC R. 115(2)

Keyword:

Amendments - allowable (yes)
Sufficiency of disclosure - (yes)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1590/17 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 7 May 2021

Appellant: (Patent Proprietor)	Amunix Operating Inc. 500 Ellis Street Suite B Mountain View, CA 94043 (US)
Representative:	Mewburn Ellis LLP City Tower 40 Basinghall Street London EC2V 5DE (GB)
Respondent: (Opponent 1)	Novo Nordisk A/S Novo Allé DK-2880 Bagsvaerd (DK)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Respondent: (Opponent 2)	XL-protein GmbH opposition withdrawn
Representative:	

Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 May 2017 revoking European patent No. 2402754 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	A. Lindner
Members:	T. Sommerfeld
	R. Romandini

Summary of Facts and Submissions

I. European patent 2402754 is based on application 11172812.7, which was filed as divisional application of the earlier European patent application 07752636.6, filed as international application and published as WO 2007/103515. The patent is entitled "Unstructured recombinant polymers and uses thereof" and was granted with 15 claims.

II. Two oppositions were filed against the granted patent, both opponents requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC), lack of sufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

III. During the proceedings before the opposition division, opponent 2 withdrew its opposition (letter of 30 September 2015).

IV. By its decision announced at the oral proceedings, the opposition division revoked the patent under Article 101(2) and (3)(b) EPC.

The opposition division decided that the claim set according to the main request did not comply with Article 123(2) EPC and that the claim sets according to auxiliary requests 1 to 4 did not comply with Article 83 EPC.

V. The patent proprietor (appellant) lodged an appeal against that decision. With the statement of grounds of appeal, the appellant requested that the decision of

the opposition division be set aside and that the patent be maintained on the basis of the main request or, alternatively, according to one of auxiliary requests 1 to 4, all identical to the claim requests pursuant to the appealed decision but refiled with the grounds of appeal. The appellant moreover requested that documents D52 to D72 not be admitted into the proceedings or, in the event that they are admitted, that documents D73, D74, D76 and D77 be likewise admitted.

Claim 1 of the **main request** reads as follows:

"1. A fusion protein incorporating:

(I) an unstructured recombinant polymer (URP) comprising a contiguous sequence of at least 200 amino acids, wherein said URP is characterized in that:

(a) it contains only 3, 4, 5, or 6 different types of amino acids;

(b) the sum of glycine (G), aspartate (D), alanine (A), serine (S), threonine (T), glutamate (E) and proline (P) residues constitutes more than about 80% of the total amino acids;

(c) at least 50% of the amino acids are not present in secondary structure as determined by Chou-Fasman algorithm; and

(d) it has a Tepitope score of less than -4;

the fusion protein further comprising:

(II) a heterologous protein,

wherein said fusion protein exhibits a serum half-life at least two time longer as compared to the corresponding heterologous protein that is deficient in said URP,

wherein said heterologous protein is a pharmaceutically active protein selected from the group consisting of cytokines, growth factors, hormones, erythropoetin, adenosine deiminase, asparaginase, arginase, interferon, growth hormone, growth hormone releasing hormone, G-CSF, GM-CSM, insulin, hirudin, TNF-receptor, uricase, rasburicase, axokine, RNAse, DNAse, phosphatase, pseudomonas exotoxin, ricin, gelonin, desmoteplase, laronidase, thrombin, blood clotting enzyme, VEGF, protropin, somatropin, alteplase, interleukin, factor VII, factor VIII, factor X, factor IX, dornase, glucocerebrosidase, follitropin, glucagon, thyrotropin, nesiritide, alteplase, teriparatide, agalsidase, laronidase, methioninase."

VI. With its reply to the statement of grounds of appeal, opponent 1 (respondent) requested that the appeal be dismissed and the patent revoked in its entirety. It moreover requested that "all documents we filed be admitted" and submitted a new document, D78.

VII. A summons to oral proceedings before the board was issued, followed by a communication pursuant to Article 15(1) RPBA providing the board's preliminary opinion on some issues.

VIII. By letters dated 23 March 2021 and 16 April 2021 the respondent informed that it would not attend the oral proceedings.

IX. Oral proceedings before the board took place on 7 May 2021 by videoconference, as requested by the only participating party. At the end of the oral proceedings, the chairman announced the decision.

X. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

D1 Chou and Fasman (1974) Biochemistry 13:222-245
D25 Sturniolo T et al (1999), Nature Biotech 17:555-561
D56 IUPAC Extract
D58 Atkins and de Paula, Atkins' Physical Chemistry (8th Ed., 2006) WH Freeman and Company (NY, USA)
D65 Declaration of Professor Sternberg
D70 CF scores for 50 sequences listed in D51
D76 Reply to enquiry to IEDB Solutions Center
D78 Patentee's response to the examining division on EP07752636.6, dated 1 March 2010

XI. The appellant's submissions may be summarised as follows.

Article 123(2) EPC

Feature (a) of claim 1 of the main request had a basis in paragraph [0121] of the application as filed, while feature (b) was part of the claims as filed. While the opposition division apparently considered that features (a) and (b) made a "specific combination", feature (a) was not more specifically combined with feature (b) than it was with feature (c) or (d). Feature (a) did not impose any limitation to feature (b), as it was not a limitation on the number of GADSTEP amino acids but merely a general limitation to the URPs of the invention, entirely consistent with the teaching of the application.

Article 83 EPC

The opposition division concluded wrongly that two particular features of the claim were unclear and that this ambiguity was a matter of Article 83 EPC rather than Article 84 EPC. There was ample teaching in the specification to explain and provide URPs as claimed. The invention was based on the use of a class of URPs which were prepared from a mixture of several types of amino acids primarily selected from a particular subset of amino acids, i.e. the GADSTEP group. Such URPs could be prepared, according to the teaching of the specification, to be hydrophilic and adopt a highly unstructured conformation with little or no identifiable secondary structure. This could be confirmed using the CF algorithm. The specification defined in paragraph [0073] unstructured protein sequences as peptides that behaved like denatured peptide sequences under physiological conditions. Furthermore, URPs prepared using (or avoiding) certain amino acids according to the teaching of the specification could be made to have a low immunogenicity, e.g. by choosing sequences that resisted antigen processing in antigen presenting cells, and choosing sequences that did not bind MHC by eliminating T cell epitopes ([0101]). This could be confirmed by using the prediction algorithm Tepitope (paragraph [0121]). Moreover, all these features were related, for example using primarily hydrophilic amino acids allowed for the lack of secondary structure and avoidance of T cell epitopes (e.g. paragraphs [0119] and [0121]). URPs prepared in this way could enhance the serum half-life of a protein compared to the protein without the URP, and this was a feature that could be confirmed using standard methods. There was no evidence on file that a person skilled in the art would be unable to carry out the invention based on the patent specification.

The skilled person would have no difficulty in performing the tests for the CF and the Tepitope scores. The opposed patent taught using the CF algorithm to determine secondary structure. Computer programs implementing the CF algorithm being available and generally accepted for determining secondary structure, the person skilled in the art would not need more information than the reference to the algorithm in order to find an appropriate computer program and to use it. Contrary to the conclusions of the opposition division, it was clear that the definition of (absence of) secondary structure given in the claim was that according to CF in D1. The algorithm derived directly from D1 was available on the web, and all that was needed to implement it was to paste in an amino acid sequence.

Similarly, the Tepitope algorithm was referred to throughout the specification, its purpose being, as taught in the specification, to confirm an absence of likely T cell epitopes (paragraph [0121], explicitly cross-referencing D25). It was available on the web, and all that would be required was the pasting-in of an amino acid sequence; other user variables were clearly taught in D25. The output of the algorithm was a set of scores for each 9mer in the protein, and the skilled person would then be able to assess the feature of the claim by merely confirming that no score was -4 or higher.

XII. The respondent's arguments may be summarised as follows.

Article 123(2) EPC

The combination of paragraphs [0113] and [0121] would not be envisaged by the person skilled in the art, because paragraph [0121] was silent on which group of amino acids, if any, the repeated amino acids should be selected from. Moreover, the disclosure as a whole was highly inconsistent with respect to the amino acids which should be "preferred" or "enriched" in URPs, so that it was not apparent that amino acids other than GADSTEP should be excluded.

Article 83 EPC

The features (c) and (d) of claim 1 of the main request referred to algorithms, namely Chou-Fasman (CF) and Tepitope, which were not sufficiently disclosed in the patent, even upon review of the description. The "one way" requirement had not been met, as correctly highlighted in the appealed decision. In fact, the invention as claimed was significantly broader than the examples, which simply detailed specific sequences alleged to be URPs. Only two of such sequences, J288 and H288, actually fit the "structural" requirements, and they were both repetitive sequences based upon three specific amino acids. Furthermore, the examples never even contemplated measuring CF or Tepitope for the disclosed sequences. Moreover, what the claims required from the CF and Tepitope algorithms was not the standard outputs: D1 and D25 did not describe "% secondary structure of a protein" or "a protein Tepitope score" respectively. Thus, the skilled person required further information in order to map the outputs of the referenced algorithms to the technical features as required by the claimed invention.

D1 did not define what secondary structure was, and, according to common general knowledge, secondary structure as a term referred to the dihedral angles for any given peptide (D56, D58), i.e. there was a secondary structure for every single amino acid residue. This was supported by the patent's description itself, teaching that "random coils" and "unstructured loops" fall under the definition of secondary structure (paragraphs [0077] and [0100]). Moreover, D1 did not teach a computer program but rather a pen-and-paper algorithm with several subjective decisions, which were described on pages 223 to 224 of D1 (in particular the steps shown on page 224), as explained by an eminent professor in the area of bioinformatics in the declaration D65. As evidenced for example by D70, there was clearly a discrepancy between the web-based implementation of CF compared to D1, and it was also of relevance whether beta turns or coils were unambiguously secondary structures.

As to the Tepitope score, it was not established in the patent what this should be; the only passage in the patent which described Tepitope in detail (paragraph [0149] of the patent) provided a definition that was not possible. This was evidenced by D76, which showed that one could arbitrarily set limits of their own will and not in line with anything disclosed in D25. As to the meaning of "a Tepitope score equal to or less than -4", even the appellant conceded that Tepitope yields numerous scores for a given peptide; it was not made clear in the patent how this was converted to a single score.

The opposition division was wrong when deciding that the skilled person would "have been able to use a known standard method" in order to assess serum half-life.

The description of the patent disclosed two quite different tests (in vivo and in vitro), and it was highly unlikely that these tests would give the same result. The choice of whether to use one or the other being completely arbitrary, this again represented a burden on the skilled person to determine which was intended to be used.

XIII. The appellant requests that the appealed decision be set aside and that the patent be maintained on the basis of the main request or, alternatively, according to one of auxiliary requests 1 to 4, all filed with the grounds of appeal. The appellant moreover requests that documents D52 to D72 not be admitted into the proceedings or, in the event that they are admitted, that documents D73, D74, D76 and D77 be also admitted.

The respondent requested that the appeal be dismissed and the patent revoked in its entirety. It moreover requested that "all documents we filed be admitted" and that new document D78 be also admitted.

Reasons for the Decision

1. The appeal is admissible.

2. As announced by letters dated 23 March 2021 and 16 April 2021, the respondent was not represented at the oral proceedings. According to Rule 115(2) EPC, if a party duly summoned to oral proceedings does not appear as summoned, the proceedings may continue without that party. As stipulated by 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 on its written case.

Main request

3. Articles 100(c)/123(2) EPC

3.1 According to Article 123(2) EPC, the European patent application or the European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. The "gold standard" for assessing compliance with Article 123(2) EPC is that any amendment to the parts of a European patent application or European patent relating to the disclosure can only be made within the limits of what a skilled person would derive directly and unambiguously, using the common general knowledge available at the date of filing, from the whole of these documents as filed.

3.2 According to the decision under appeal, claim 1 of the main request did not fulfil Article 123(2) EPC because the combination of feature (a) "it [the URP] contains only 3, 4, 5, or 6 different types of amino acids" with feature (b) further defining the amino acids as being more than 80% GADSTEP had no basis in the application as filed.

3.3 The board agrees with the appellant that the disputed amendment of claim 1 has a basis in the application as filed. Feature (a) has a basis in paragraph [0121] that reads: "URPs or the repeats inside URPs often contain only 1, 2, 3, 4, 5 or 6 different types of amino acids". The passage does not refer to any group of amino acids from which to select the different types of amino acids. Hence, it is interpreted as referring to

any possible amino acid. This reading applies to the feature in the claim too. Feature (b), on the other hand, has a basis in the claims as filed (e.g. claim 2 of the parent application, identical to claim 2 as filed). Because the passage in paragraph [0121] is a general disclosure, applying generally to the URPs of the invention, the feature disclosed there can be combined with the features of the claims as filed.

3.4 According to the respondent, the combination of paragraphs [0113] and [0121] would not be envisaged by the person skilled in the art, because paragraph [0121] was silent on which group of amino acids, if any, the repeated amino acids should be selected from. The board agrees that the disclosures of the two paragraphs cannot be combined; however, as explained above, there is no need to rely on paragraph [0113] as basis for any of the claimed features.

3.5 As regards the further claims of the main request, the respondent stated that it maintained its objections of added subject-matter in relation to all claims (letter of reply to the grounds of appeal, top of page 5). The board notes that it is not apparent from the appealed decision nor from the minutes of the oral proceedings before the opposition division that the respondent had raised objections to claims other than claim 1 of the main request. As regards claim 1 of the main request, the respondent had objected to a number of features under Article 123(2) EPC, but, apart from the objection dealt with above, the opposition division came to the conclusion that they were not valid. Hence, if the respondent still wanted to rely on these objections in appeal, it should have submitted its arguments as to why the opposition division was wrong in this respect. In the absence of any such arguments, the board sees no

reason to deviate from the conclusions of the opposition division. Hence, in the board's view, claim 1 of the main request fulfils the requirements of Article 123(2) EPC.

4. Article 83 EPC

4.1 Claim 1 of the main request is directed to a fusion protein incorporating an unstructured recombinant polymer (URP) and a heterologous protein. The URP is further defined by a number of structural and functional features as follows (for the exact wording of the claim, see section I): it comprises a contiguous sequence of at least 200 amino acids; it contains only 3, 4, 5 or 6 different types of amino acids; the sum of glycine (G), aspartate (D), alanine (A), serine (S), threonine (T), glutamate (E) and proline (P) residues constitutes more than about 80% of the total amino acids; at least 50% of the amino acids of the URP are not present in secondary structure as determined by Chou-Fasman algorithm; it has a Tepitope score equal to or less than -4. The fusion protein is further characterised in that it exhibits a serum half-life at least two time longer as compared to the corresponding heterologous protein lacking said URP, and the heterologous protein is a pharmaceutically active protein selected from a list given in the claim.

4.2 The requirement that the fusion protein exhibit a serum half-life at least two time longer as compared to the corresponding heterologous protein lacking said URP is a limiting feature of the claim. Hence, only those embodiments that achieve this effect fall within the scope of that claim. For the purposes of sufficiency of disclosure, the application must thus provide an enabling disclosure of the URPs as claimed and must

also show, or at least render it plausible, that use of those URPs in a fusion protein as claimed achieves the effect of increasing the serum half-life of the heterologous protein.

4.3 In the board's view the patent fulfils both conditions in the present case. Indeed, the patent discloses how to produce URPs with the features as claimed, and it describes the technical basis for the half-life extension of a protein when using a URP as claimed, thereby rendering it plausible that such a URP can be successfully used for increasing serum protein half-life as claimed.

4.4 The respondent argued that preparing a URP according to the definition in the claims was not enabled by the disclosure in the patent, because the "one way" requirement had not been met; the invention as claimed was significantly broader than the examples. In particular, the features of items (c) and (d), namely "at least 50% of the amino acids of the URP are not present in secondary structure as determined by Chou-Fasman algorithm" and "URP has a Tepitope score equal to or less than -4" were considered to be not sufficiently disclosed in the patent.

4.5 The board notes that the URPs as claimed are already structurally defined as having at least 200 amino acids, which belong only to 3, 4, 5 or 6 different types, of which more than 80% should be of the GADSTEP group. Accordingly, the skilled person already knows that, for a URP of 200 amino acids, at least 80% of the amino acids (i.e. at least 160 amino acids) should be selected from G, A, D, S, T, E or P, while the remaining 40 at the most are to be selected from a limited number (in any case not more than 5) of

different amino acid types. It then only remains to be decided what the order of the amino acids in the sequence is. With the teaching of the patent, the skilled person can make the necessary decisions to produce the URPs according to the invention without undue burden.

4.6 The skilled person knows from the patent application (e.g. paragraph [0075]) that the term "unstructured recombinant polymer" (URP) refers to amino acid sequences that share commonality with denatured peptide sequences, i.e peptide sequences in "denatured conformation" or "unfolded conformation"; this conformation is defined in the preceding paragraph as referring to a state of a peptide in solution that is characterised by a large conformational freedom of the peptide backbone. Paragraph [0075] further teaches that URP sequences lack a defined tertiary structure and have limited or no secondary structure as detected by, for example, the Chou-Fasman (CF) algorithm. Paragraph [0102], which again defines URPs as comprising "amino acid sequences that typically share commonality with denatured peptide sequences under physiological conditions", goes on to teach that "[a] variety of methods have been established in the art to ascertain the second and tertiary structures of a given polypeptide", those methods including CD spectroscopy and "computer programs or algorithms such as the Chou-Fasman algorithm (Chou, P. Y., et al. (1974) Biochemistry, 13: 222-45)", the cited reference being document D1 in the proceedings. The algorithm is able to predict, for a given URP sequence, "whether there exists some or no secondary structure at all".

4.7 The following paragraph (paragraph [0103]) then teaches that "[t]he subject URPs can be sequences with low

immunogenicity" and that "[l]ow immunogenicity can be a direct result of the conformational flexibility of URP sequences", preferred URPs being "designed to avoid formation of conformational epitopes". Possible sequences with low immunogenicity can be "sequences having a low tendency to adapt [sic] compactly folded conformations in aqueous solution", and "low immunogenicity can be achieved by choosing sequences that resist antigen processing in antigen presenting cells, choosing sequences that do not bind MHC well and/or by choosing sequences that are derived from human sequences". Paragraph [0125] further teaches how to design URP sequences that are "substantially free of epitopes recognized by human T cells" by synthesising "a series of semi-random sequences with amino acid compositions that favor denatured, unstructured conformations and evaluate these sequences for the presence of human T cell epitopes and whether they are human sequences" by using known assays. One possible approach is "to design URP sequences that result in low scores using epitope prediction algorithms like TEPITOPE (Sturniolo, T., et al. (1999) *Nat Biotechnol*, 17: 555-61 [document D25 in the proceedings])".

4.8 Paragraph [0108] provides a specific teaching concerning the preferred amino acids to be used in the construction of URPs. It refers to the predominance of hydrophilic amino acids, such as glycine, serine, aspartate, glutamate, lysine, arginine and threonine (GADSTEP). Paragraph [0109] then teaches that "As a result of their amino acid composition, URP sequences have a low tendency to form aggregates in aqueous formulations and the fusion of URP sequences to other proteins or peptides tends to enhance their solubility and reduce their tendency to form aggregates, which is a separate mechanism to reduce immunogenicity."

4.9 Hence, the patent application provides a detailed teaching on how to obtain URPs suitable for use in the method as claimed. It also makes clear that the functional properties of the claimed URPs derive from their structural features. Hence, while these functional features may not be very clearly defined in the claims, this does not hinder the skilled person from carrying out the invention without undue burden.

4.10 The board agrees with the respondent that the feature "at least 50% of the amino acids of the URP are not present in secondary structure as determined by Chou-Fasman (CF) algorithm" is unclear. In fact, it is common general knowledge, evidenced by D56 and D58 for example, that all amino acids in a protein are part of a secondary structure, since they all contribute to the protein backbone chain and thus to the spatial arrangement, independently of them being part of a highly ordered secondary structure such as helices or sheets, or of non-ordered secondary structures such as random coils or unstructured loops. This definition is also in agreement with the patent's disclosure in paragraphs [0077] and [0100], referring to "unstructured loops" and "random coil structures", respectively. The implementation of the CF algorithm, described in D1, also does not exclude coils as secondary structure, as extensively argued by the respondent. In accordance with this definition of secondary structure, all amino acids of a URP will be found to be present in "secondary structure", and the percentage of amino acids not in secondary structure according to the CF algorithm would always be 0. It is also true, as argued by the respondent, that the CF scores can change drastically depending on whether some

secondary structure types (e.g. beta turns) are taken into account or not (D65, D70).

4.11 While the above is true, the board considers that the skilled person would still be in a position to decide what the URPs are according to the claim or not. It follows from the definition of URPs itself (given in the patent, e.g. in paragraphs [0073] and [0100]) that these should have a "denatured conformation" or "unfolded conformation" and that this is what is meant by having little or no secondary structure. It would therefore be immediately obvious to the skilled person reading the patent that the URPs according to the invention should have few to no highly ordered structures such as helices and sheets and rather have more unordered structures such as random coil. The skilled person would thus know how to apply the CF algorithm accordingly, i.e. which secondary structures should be taken into account in order to end up with a URP with "unstructured conformation".

4.12 The respondent moreover argued that it was not clear how the Tepitope score was to be calculated and that the skilled person could arbitrarily set limits not in line with anything disclosed in D25, as evidenced in D76. Moreover, it was not apparent how the score should be evaluated for a whole peptide of 200 amino acids, since the algorithm would yield numerous scores for such a peptide, and it was not clear how this should be converted into one single score. The board agrees that there might be a lack of clarity as to how the Tepitope score is to be calculated but again considers that the disclosure of the patent application would put the skilled person in a position of being able to determine which URPs are part of the invention or not. As mentioned above, the patent application (paragraph

[0125], corresponding to paragraph [0121] of the patent) teaches how to design URP sequences that are "substantially free of epitopes recognized by human T cells" and that these sequences can be evaluated for the presence of human T cell epitopes by using known assays such as the Tepitope disclosed in D25. It would also be clear for the skilled person that, when calculating the Tepitope score for larger peptides, it would be important that none of the values obtained had a score over -4; anything else would not make sense in the context of the patent.

4.13 Finally, the respondent's objection concerning the feature "serum half-life" is not convincing. It is true that different methods to assess serum half-life can be used, which may lead to different results. However, since the claim requires only that there is an increase in serum half-life for the fusion protein in comparison to the heterologous protein alone, it is not relevant what the absolute values are and whether they differ according to the method used.

4.14 The board thus comes to the conclusion that claim 1 of the auxiliary request fulfils the requirements of Article 83 EPC.

5. Admission of documents

Documents D52 to D77

5.1 All these documents were submitted during the proceedings before the opposition division. In the appealed decision (Reasons, section 2), the opposition division stated that "[d]uring the discussion on Art. 83 EPC, D55, D59 as well as D70 to D72 were admitted into the proceedings", that "concerning the remaining

documents" (D52 to D54, D56 to D58, D60 to D69, D73 to D77), these were late-filed and did not appear to add anything new to the proceedings, and that therefore the admissibility of these further documents was not discussed. In the appeal proceedings the respondent requested that all the documents it had filed be admitted into the proceedings, while the appellant requested that documents D52 to D72 not be admitted into the proceedings or, in the event that they are admitted, that documents D73, D74, D76 and D77 be also admitted.

5.2 In the communication pursuant to Article 15(1) RPBA, the board gave its preliminary opinion that, apart from documents D71 and D72 which, having been mentioned as part of the reasoning in the appealed decision, were *de facto* in the proceedings, the admission of all other documents was still open to discussion.

5.3 The parties have not provided any further arguments concerning the admission of these documents. The board sees no reason not to admit documents D56 and D58, which are merely extracts of textbooks, and document D65, which is a declaration from a technical expert. Likewise, document D76, a document submitted by the appellant but also relied upon by the respondent, is also admitted.

5.3.1 As to the remaining documents (D52 to D55, D57, D59 to D64, D66 to D70 and D73 to D75, D77), the board did not find them relevant for the present decision. Since they may however be relevant for other issues still to be examined, such as novelty and inventive step (see below: Remittal for further prosecution), the board found it appropriate not to decide on the admission of

these documents and rather leave it to the discretion of the opposition division.

Document D78

5.4 Document D78 was submitted by the respondent with the letter of reply to the grounds of appeal. In the communication pursuant to Article 15(1) RPBA, the board gave its preliminary opinion that, in the absence of any objections to its admission, it saw, *a priori*, no reason not to admit it. There have been no further arguments from the parties in this respect, and hence the board makes use of its discretion pursuant to Article 12(4) RPBA to admit D78 into the proceedings.

6. Remittal for further prosecution

6.1 Under Article 111(1) EPC, the boards, following the examination as to the allowability of the appeal, are to decide on the appeal and may either exercise any power within the competence of the department which was responsible for the appealed decision or remit the case to that department for further prosecution. The boards may remit the case for further prosecution if essential questions regarding the patentability of the claimed subject-matter have not yet been examined by the department responsible for the appealed decision and their analysis in appeal proceedings would imply a significant burden.

6.2 In the present case the opposition division reached a decision on Articles 123(2) and 83 EPC but did not discuss, let alone decide, any other of the remaining objections of the opponents, namely Articles 54 and 56 EPC. Both parties were of the opinion that the case should be remitted to the department of first instance

for discussion on these issues. The board considers that examining these two requirements from scratch and deciding (possibly) on the several requests would imply a significant burden. For this reason it considered it appropriate to remit the case to the department of first instance for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated