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Datasheet for the decision of 5 June 2019

Case Number: T 2106/15 - 3.3.01

Application Number: 04817923.8

Publication Number: 1697750

IPC: G01N33/543

Language of the proceedings: EN

Title of invention:
METHODS AND COMPOSITIONS FOR IMMUNO-HISTOCHEMICAL DETECTION

Patent Proprietor:
Dako Denmark A/S

Opponent:
Appelt, Christian W.

Headword:
Polymer conjugate/DAKO

Relevant legal provisions:
RPBA Art. 12(4), 13(1)
EPC Art. 54

Keyword:
Novelty - main request, auxiliary requests 1 and 2 (no)
Late-filed auxiliary requests - admitted (no)

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Case Number: T 2106/15 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 5 June 2019

Appellant: (Patent Proprietor)	Dako Denmark A/S Produktionsvej 42 2600 Glostrup (DK)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Respondent: (Opponent)	Appelt, Christian W. Boehmert & Boehmert Pettenkoferstrasse 20-22 80336 München (DE)
Representative:	Engelhard, Markus Boehmert & Boehmert Anwaltspartnerschaft mbB Pettenkoferstrasse 22 80336 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 September 2015 revoking European patent No. 1697750 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	M. Pregetter
	P. de Heij

Summary of Facts and Submissions

I. European patent No. 1 697 750 is based on European patent application No. 04817923.8, filed as an international application published as WO2005/054860.

II. The following documents, cited during the opposition and appeal proceedings, are referred to below:

(1) Rullier et al., Modern Pathol., 2001, 14, 496-505

(2) Savinainen et al., Am.J.Pathol., 2002, 160, 339-345

(3) Wiedorn et al., J.Histochem.Cytochem., 2001, 49(9), 1067-1071

(6) Mokry, Acta Medica, 1996, 39, 129-140

(8) WO 2003/031974

(9) EP 1 437 594 A1

III. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division revoking the patent. In the decision under appeal the opposition division had found that the subject-matter of the main request contravened the requirements of Rule 80 and Article 123(2) EPC, and that the subject-matter of the auxiliary request lacked novelty.

IV. With its statement setting out the grounds of appeal, the appellant re-submitted the main request. Furthermore, auxiliary requests 1 to 5 and amended page 9 of the description were filed.

V. In its reply, the opponent (respondent) requested, inter alia, that auxiliary requests 1 to 5 not be admitted.

VI. In a communication pursuant to Article 15 RPBA, the board summarised some of the issues to be discussed and indicated as its preliminary opinion that auxiliary requests 2 to 5 might not be admitted into the proceedings.

VII. With a letter dated 3 May 2019 the appellant submitted auxiliary requests 3a, 4a, 5a and 6.

VIII. The claim requests on file contain, inter alia, the following independent claims:

Independent claim 1 of the main request reads as follows:

"1. A method of detecting a biological marker in a sample comprising the following steps:

a) contacting the sample with at least one first binding agent, which is first molecule, such that the first binding agent specifically binds to the biological marker in the sample and forms a first complex;

b) contacting the first complex of a) with at least one second binding agent which is a second molecule that specifically binds to the first binding agent such that a second complex is formed, wherein the at least one second binding agent is linked to at least one first polymer;

c) contacting the second complex of b) with at least

one third binding agent, wherein the third binding agent is linked to at least one second polymer, and wherein the at least one third binding agent specifically binds to the second binding agent; wherein at least one detectable agent is linked to at least one of

i. the third binding agent;
ii. the at least one second polymer; or
iii. both the third binding agent and the at least one second polymer;

such that the third binding agent binds to the second complex of b) and forms a third complex;

detecting the third complex of c)."

Claim 1 of auxiliary request 1 and claim 1 of auxiliary request 2 are identical to claim 1 of the main request.

Independent claims 1 and 18 of auxiliary request 3 read as follows:

"1. A method of detecting a biological marker in a sample comprising the following steps:
a) contacting the sample with at least one first binding agent, which is first molecule, such that the first binding agent specifically binds to the biological marker in the sample and forms a first complex;
b) contacting the first complex of a) with at least one second binding agent which is a second molecule that specifically binds to the first binding agent such that a second complex is formed, wherein the at least one second binding agent is linked to at least one first polymer;

c) contacting the second complex of b) with at least one third binding agent, wherein the third binding agent is linked to at least one second polymer, and wherein the at least one third binding agent specifically binds to the second binding agent; wherein at least one detectable agent is linked to at least one of
i. the third binding agent;
ii. the at least one second polymer; or
iii. both the third binding agent and the at least one second polymer;
such that the third binding agent binds to the second complex of b) and forms a third complex;
detecting the third complex of c), wherein the at least one first binding agent is chosen from a primary antibody or a nucleic acid probe,
wherein the at least one second binding agent is a secondary antibody and wherein the at least one third binding agent is a tertiary antibody."

"18. A composition comprising
a) at least one second binding agent that is capable of specifically binding to at least one first binding agent that is a first molecule capable of specifically binding to a biological marker of a sample, wherein the at least one second binding agent is linked to at least one first polymer, or at least one first polymer and a hapten, wherein the hapten is linked to the at least one first polymer or the secondary antibody or both the secondary antibody and the at least one first polymer;
b) at least one third binding agent linked to at least one second polymer, wherein the at least one third binding agent is capable of specifically binding to the at least one second binding agent of (a) or the hapten of (a), wherein the hapten is linked to the secondary antibody or linked to the at least one first polymer

conjugated to the secondary antibody
wherein a detectable substance is linked to at least one of
i. the at least one third binding agent;
ii. the at least one third binding agent and the at least one second binding agent;
iii. the at least one second polymer;
iv. the at least one second polymer and the at least one first polymer;
v. both the at least one third binding agent and the at least one second polymer; or
vi. both the at least one third binding agent and the at least one second polymer and both the at least one second binding agent and the at least one first polymer,
wherein the at least one second binding agent is a secondary antibody and the at least one third binding agent is a tertiary antibody."

Claim 18 of auxiliary request 3a differs from independent claim 18 of auxiliary request 3 by the insertion of the underlined phrases (underlining added for emphasis):

"18. A composition comprising
a) a first conjugate comprising at least one second binding agent that is capable of specifically binding to at least one first binding agent that is a first molecule capable of specifically binding to a biological marker of a sample, wherein the at least one second binding agent is linked to at least one first polymer, or at least one first polymer and a hapten, wherein the hapten is linked to the at least one first polymer or the secondary antibody or both the secondary antibody and the at least one first polymer;
b) a second conjugate comprising at least one third

binding agent linked to at least one second polymer, wherein the at least one third binding agent is capable of specifically binding to the at least one second binding agent of (a) or the hapten of (a), wherein the hapten is linked to the secondary antibody or linked to the at least one first polymer conjugated to the secondary antibody
wherein a detectable substance is linked to at least one of
i. the at least one third binding agent;
ii. the at least one third binding agent and the at least one second binding agent;
iii. the at least one second polymer;
iv. the at least one second polymer and the at least one first polymer;
v. both the at least one third binding agent and the at least one second polymer; or
vi. both the at least one third binding agent and the at least one second polymer and both the at least one second binding agent and the at least one first polymer,
wherein the at least one second binding agent is a secondary antibody and the at least one third binding agent is a tertiary antibody."

Independent claim 1 of auxiliary request 4 differs from independent claim 1 of auxiliary request 3 by the insertion of the phrase:

"wherein the first polymer is conjugated to 2-20 secondary antibodies".

Independent claim 18 of auxiliary request 4 has been amended in the same way.

Claim 18 of auxiliary request 4a is identical to claim

18 of auxiliary request 4 with the exception that it contains amendments analogous to those of claim 18 of auxiliary request 3a.

Independent claim 1 of auxiliary request 5 reads as follows:

"1. A method of detecting a biological marker in a sample comprising the following steps:
a) contacting the sample with at least one first binding agent, which is first molecule, such that the first binding agent specifically binds to the biological marker in the sample and forms a first complex;
b) contacting the first complex of a) with at least one second binding agent which is a second molecule that specifically binds to the first binding agent such that a second complex is formed, wherein the at least one second binding agent is linked to at least one first polymer;
c) contacting the second complex of b) with at least one third binding agent, wherein the third binding agent is linked to at least one second polymer, and wherein the at least one third binding agent specifically binds to the second binding agent; wherein at least one detectable agent is linked to at least one of
i. the third binding agent;
ii. the at least one second polymer; or
iii. both the third binding agent and the at least one second polymer;
such that the third binding agent binds to the second complex of b) and forms a third complex;
detecting the third complex of c), wherein the at least one first binding agent is chosen from a primary antibody or a nucleic acid probe,

wherein the at least one second binding agent is a secondary antibody, wherein the at least one third binding agent is a tertiary antibody, wherein the first polymer is conjugated to 2-20 secondary antibodies and wherein at least one of the first polymer and the second polymer is chosen from:
polysaccharides including dextrans, carboxymethyl dextran, dextran polyaldehyde, carboxymethyl dextran lactone, and cyclodextrins; pullulans, schizophyllan, scleroglucan, xanthan, gellan, O-ethylamino guaran, chitin, chitosans including 6-O-carboxymethylchitin, N-carboxymethyl chitosan; derivatized cellolosics including carboxymethyl cellulose, carboxymethyl hydroxyethyl cellulose, hydroxyethyl cellulose, 6-amino-6-deoxycellulose and O-ethylamine cellulose; hydroxylated starch, hydroxypropyl starch, hydroxyethyl starch, carrageenans, alginates, and agarose; synthetic polysaccharides including ficoll and carboxymethylated ficoll; vinyl polymers including poly(acrylic acid), poly(acryl amides), poly(acrylic esters), poly(2-hydroxy ethyl methacrylate), poly(methyl methacrylate), poly(maleic acid), poly(maleic anhydride), poly(acrylamide), poly(ethyl-co-vinyl acetate), poly(methacrylic acid), poly(vinylalcohol), poly(vinyl alcohol-co-vlnyl chloroacetate), aminated poly(vinyl alcohol), and co block polymers thereof; poly ethylene glycol (PEG) or polypropylene glycol or poly(ethylene oxide-co-propylene oxides) containing polymer backbones including linear, comb-shaped or branched dendrimers; poly amino acids including polylysines, polyglutamic acid, polyurethanes, poly(ethylene imines), pluriol; and polynucleotides, DNA, PNA, LNA, oligonucleotides and oligonucleotide dendrimer constructs."

Independent claim 17 of auxiliary request 5 corresponds to independent claim 18 of auxiliary request 4 with the

addition of the list of polymers for choosing at least one of the first polymer and the second polymer.

Claim 17 of auxiliary request 5a is identical to claim 17 of auxiliary request 5 with the exception that it contains amendments analogous to those of claim 18 of auxiliary request 3a.

Claim 1 of auxiliary request 6 is identical to claim 1 of auxiliary request 5. It is the sole independent claim of auxiliary request 6.

IX. Oral proceedings were held on 5 June 2019.

X. The arguments of the appellant, insofar as they are relevant to the present decision, may be summarised as follows:

Novelty

Claim 1 of the main request shared technical features with documents (1)-(3), (6) and (8)/(9). However, it differed from them in step b). None of these documents disclosed the technical features of step b) of claim 1 of the main request, which defined a second binding agent linked to a first polymer. It was an incorrect approach to take a naturally occurring molecule, in the present case an antibody, and to split it artificially. According to paragraph [0089] of the patent in suit, the polymeric conjugates were formed in conventional ways and the linker was introduced by covalent coupling chemistry. Examples of such chemistry could be found in paragraphs [0089] and [0091]. A conjugation taking place only in the mind of the reader/the skilled person after envisaging a mental split of the naturally occurring molecule was not permissible.

Furthermore, assuming that this incorrect interpretation of the claim were to be adopted, the technical feature defined by the term "polymer" was not anticipated by the polypeptide units of a naturally occurring antibody. The term "polymer" required repeating units (monomers) that were either identical or, if different, arranged in a certain pattern.

The technical reality of the chosen claim wording was represented by a conjugate having two different molecules joined together. The semantic games of the respondent were devoid of any technical meaning.

Thus, an antibody could not anticipate a binding agent linked to a polymer. Consequently, the subject-matter of claim 1 of the main request was novel.

Admission of claim requests

The claim requests filed during the appeal proceedings should be admitted into the proceedings, since they had been filed in response to the decision of the opposition division or the board's communication. There had been no attempt to prevent the opposition division from issuing a decision on certain subject-matter. The claim requests withdrawn at the beginning of the oral proceedings before the opposition division had been withdrawn for reasons relating to issues of added subject-matter. These withdrawn requests were different from the auxiliary requests submitted in appeal proceedings. A claim request had to be seen as the totality of claims and their technical features. It was thus incorrect to state that a decision relating to a single feature (such as the different aspects of the details of step b) of the respective claim 1) had been

avoided. After having issued a positive preliminary opinion on novelty, the opposition division had, surprisingly, switched to a negative assessment. The finding of lack of novelty was a new development for the patent proprietor. Since this change in assessment was communicated only at a late hour during the oral proceedings before the opposition division, it was understandable, from a human perspective, that the then representative could not react immediately. The filing of the present requests 3, 4 and 5 in response to the written reasons presented in the impugned decision was thus justified.

The submission of auxiliary requests 3a, 4a, 5a and 6 was in direct response to the communication pursuant to Article 15(1) RPBA issued by the board, which raised some objections for the first time.

XI. The arguments of the respondent, insofar as they are relevant to the present decision, may be summarised as follows:

Novelty

Documents (1)-(3), (6) and (8)/(9) destroyed the novelty of the subject-matter of claim 1 of the main request. Step b) of claim 1 specified that the "at least one second binding agent is linked to at least one first polymer". The term "linked" referred to a covalent bond. Consequently, the second binding agent and the polymer were present in a single molecule. The molecules linked together might be members of the same class of compounds, e.g. a proteinaceous binding agent linked by a peptide bond to a polypeptide. The claim contained no limitation concerning the type of linkage (type of bond), the origin of the molecules (natural

versus synthetic), and the preparation procedure (e.g. that the binding agent and the polymer had to be prepared separately before the linkage was made). It could be seen from paragraph [0033] of the patent specification that antibody fragments stemming from a naturally occurring antibody were possible binding agents. Paragraph [0047] defined the polymers in broad terms, including various biopolymers and hetero, block, and random polymers. In paragraph [0047] as granted and in various passages of the application as filed, proteins were explicitly included as examples of polymers.

A full length antibody consisting of a F(ab) fragment linked to a Fc fragment, the F(ab) fragment being the binding agent and the Fc fragment the polymer, thus anticipated a binding agent linked to a polymer. This finding was in line with the claim wording and did not lead to a technically illogical interpretation of the claim.

No mental "splitting" of a naturally occurring molecule was performed. The term "linked" in claim 1 did not define an activity, but the presence of a bond.

Documents (1)-(3), (6) and (8)/(9) were thus novelty destroying for the subject-matter of claim 1 of the main request, as set out in the decision of the opposition division.

Admission of claim requests

The purpose of appeal proceedings was to review the findings of the opposition division. Article 12(4) RPBA governed the admission of claim requests that could have already been presented in the opposition

proceedings. The auxiliary requests on file were very similar to claim requests that had been deliberately withdrawn in the opposition proceedings; see item 8 of the opposition decision. An inevitable result of the absence of these requests in opposition proceedings was that the opposition division was prevented from taking a decision on these requests. All the elements that now distinguished the auxiliary requests from the main request, i.e. the second binding agent being an antibody (which was linked to a polymer), the list of polymers and the definition that 2 to 20 secondary antibodies were linked to the first polymer, had already been defined in the withdrawn auxiliary requests. The auxiliary requests submitted in the appeal proceedings could and should have been filed before the opposition division. It was not true that the line of argument underlying the impugned decision came as a surprise to the patent proprietor. In the letters dated 1 October 2014 and 8 April 2015, the arguments that led to a finding of lack of novelty had already been presented by the then opponent. There were thus no extraordinary developments in the case history of the first instance proceedings. The auxiliary requests should not be admitted.

Concerning auxiliary requests 3a, 4a, 5a, 6, which were allegedly filed in response the board's communication pursuant to Article 15(1) RPBA, it was a crucial point that these claim requests introduced further complexities, were filed very late in the proceedings and were used by the appellant to introduce claim requests which could not be admitted pursuant to Article 12(4) RPBA. Consequently, these claim requests should not be admitted.

XII. The final requests of the parties were as follows:

The appellant requested:
-that the decision under appeal be set aside;
-that the case be remitted to the opposition division for further examination of inventive step of any claim request found to meet the requirements of added subject-matter and novelty;
-that, in case the board would not remit the case to the opposition division, the patent be maintained on the basis of the main request, submitted in the oral proceedings before the opposition division and re-submitted with the grounds of appeal;
-alternatively, that the patent be maintained on the basis of the main request with an amended description or on the basis of auxiliary requests 1 to 3, 3a, 4, 4a, 5, 5a or 6, auxiliary requests 1 to 3, 4 and 5 submitted with the grounds of appeal and auxiliary requests 3a, 4a, 5a and 6 submitted with the letter dated 3 May 2019;
-that the arguments of the respondent regarding Article 123(2) EPC, which were presented in the first instance proceedings and only reiterated in the appeal proceedings, not be admitted into the appeal proceedings.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request - novelty (Article 54 EPC)*

2.1 Claim 1 of the main request defines a method of detecting a biological marker in a sample:

After a) contacting the sample with a first binding agent and forming a first complex,

step b) specifies "contacting the first complex of a) with at least one second binding agent which is a second molecule that specifically binds to the first binding agent such that a second complex is formed, wherein the at least one second binding agent is linked to at least one first polymer;"

this is then followed by step c), contacting with a third binding agent linked to a second polymer, wherein a detectable agent is introduced, and finally by a step of detection.

2.2 The respondent cited documents (1), (2), (3), (6) and (8) (in the form of a family document, document (9)) as novelty-destroying for the subject-matter of claim 1.

There is agreement between the parties that the steps other than step b) of the method defined in claim 1 are disclosed in these documents.

2.2.1 Document (1) describes the detection of hepatitis C virus in samples. As a first step, the samples are contacted with a fluorescein-conjugated, purified IgG fraction (first binding agent), leading to the formation of a first complex (first step corresponding to step a)), followed by contact with a mouse monoclonal antibody (second step corresponding to step b)). This second complex is then contacted with goat anti-mouse immunoglobulins conjugated to peroxidase-labeled polymer (third step corresponding to

step c)) and finally the peroxidase is detected in a colour reaction (page 497, right-hand column, second paragraph).

2.2.2 The decisive point in coming to a decision on novelty is thus whether the mouse monoclonal antibody used in the second step (corresponding to step b) of claim 1 of the main request) represents a "second binding agent" linked to "at least one first polymer".

An antibody is a biopolymer consisting of four chains. An antigen binding site is situated in the Fab region formed by specific parts of these chains. The light and heavy chains making up the antibody are polypeptides. Polypeptides are biopolymers consisting of a polyamide backbone having various side chains, depending on the specific monomers, in the form of amino acids. All the parts of the antibody are linked to each other, either by covalent amide bonds or by covalent disulfide bonds. There is thus no doubt that an antibody is a large molecule comprising binding sites and polymeric units. In the absence of any specific definition as to (i) the type of binding agent, (ii) the type of polymer and (iii) the type of linkage in step b) of claim 1 cited above, there is no doubt that any antibody fulfils these three requirements.

2.3 Reference has been made to the "mind willing to understand", to the description and to the "artificial" identification of a "link" in a naturally occurring molecule.

2.3.1 With regard to the "mind willing to understand", the board notes that the terms used in the definition of claim 1 of the main request are clear, albeit very broad. An antibody clearly fulfils the broadly defined

subject-matter. Moreover, the use of an antibody for detecting a biological marker in a sample is not only technically feasible, but one of the most specific and precise ways to do so. In fact, antibodies are used for precisely this purpose in the prior art.

2.3.2 The description of the patent in suit confirms the board's view that an antibody is in fact a binding agent linked to a polymer. Paragraph [0036] states that the second binding agent refers to a second molecule which specifically binds to a first binding agent. This molecule may be an antibody. In the description of the patent in suit, the term "antibody" does not exclusively describe a natural, full-length antibody but includes "a part thereof", meaning "any fragment which can still bind antigen, for example, an Fab, $F(ab')_2$, Fv, scFv" (paragraph [0033]). It is thus clear that the binding agent may be any fragment of an antibody that specifically binds to a probe. The list of possible polymers in the description of the patent in suit, and in the amended description page filed in appeal, lists various natural and synthetic homo- and heteropolymers, including biopolymers such as poly amino acids, polynucleotides and various polysaccharides (paragraph [0047]). The description does not limit the type of linkage to any particular chemistry. It merely conveys the impression that covalent linking is present, which is the case for an antibody.

2.3.3 The appellant has referred to paragraph [0089] of the patent in suit, where it is stated that "Many methods of forming polymeric conjugates are known in the art and can be used to make the polymeric conjugates of the invention". From this passage the appellant draws the conclusion that the patent in suit is limited to

situations in which the second binding agent is synthetically linked to the first polymer.

While it is true that paragraph [0089] refers to various ways of forming a covalent bond between an agent or a molecule and a polymeric backbone, this does not change the fact that claim 1 of the main request merely specifies as mandatory the presence of a link of some kind, whenever and however formed, between a binding agent and a polymer. An antibody is a naturally occurring macromolecule consisting of a binding site covalently linked to a non-binding (bio)polymeric part. The "link" is not an artificially introduced mental image, but a (bio)chemical reality.

2.4 Given the conclusion that any antibody, including in particular the mouse monoclonal antibody described in document (1), represents a second binding agent linked to a first polymer, the disclosure of document (1) describes directly and unambiguously all the technical features of claim 1 of the main request.

2.5 The subject-matter of claim 1 of the main request lacks novelty (Article 54 EPC). The same applies to claim 1 of the main request with amended page 9 of the description, as this amendment has no bearing on the conclusion that an antibody fulfils the requirements of step b).

3. *Auxiliary requests 1 and 2 - novelty (Article 54 EPC)*

The respective claim 1 of auxiliary requests 1 and 2 is identical to claim 1 of the main request.

Consequently, the subject-matter of these claims is not

novel, for the reasons given under point 2 above.

4. *Admission of claim requests*

4.1 *Admission of auxiliary requests 3, 4 and 5*

4.1.1 The patent was revoked for non-compliance with Rule 80 EPC and Article 123(2) EPC by the main request. The auxiliary request was found to meet the requirement of Article 123(2) EPC, but lacked novelty. Both the main request and the auxiliary request were filed during oral proceedings before the opposition division. The appellant did not file a request to deal with the issue of novelty during the oral proceedings, although it was given the opportunity to do so. With the statement of grounds of appeal, the appellant maintained its main request and submitted five auxiliary requests. It asserted that auxiliary request 3 addressed issues related to novelty, auxiliary request 4 addressed issues related to inventive step and auxiliary request 5 further limited a certain technical feature. These requests were said to be in response to the reasoning of the opposition division in the decision under appeal, which was based on a change from its preliminary opinion.

4.1.2 According to Article 12(1) and (4) RPBA, the notice of appeal and the statement of grounds of appeal form the basis of the appeal proceedings and shall be taken into account by the board. However, Article 12(4) RPBA gives the board discretion not to admit requests into the appeal proceedings which could have been presented in the first instance proceedings. The admission of auxiliary requests into proceedings therefore hinges on the question of whether a party to appeal proceedings was in a position to make its submission earlier, and

whether it could have been expected to do so under the circumstances.

4.1.3 It is thus necessary to look again at the first instance proceedings.

(a) The opposition division gave a positive preliminary opinion on the novelty of claim 1 of the then pending auxiliary requests 1 and 2 in its annex to the summons to oral proceedings (dated 16 September 2014, see item 61). The feature that the second binding agent must comprise a polymer was considered to render the scope of claim 1 novel.

(b) In response to the summons, the patent proprietor filed an amended main request and six auxiliary requests (letter dated 19 February 2015).

(c) In response to the new claim requests, the opponent provided detailed remarks in its letter dated 8 April 2015. Starting on page 53 of this letter, the opponent discussed in detail its interpretation of certain terms and presented its line of argument concerning novelty in view of documents (1), (2), (3), (6) and (8)/(9), thus reiterating in more detail arguments already presented in its notice of opposition (see, for example, page 33 of the notice of opposition).

(d) At the beginning of the oral proceedings before the opposition division, held on 22 April 2015, the proprietor withdrew all of its claim requests and replaced them by a single set of claims. When these claims were found to contravene the requirements of Rule 80 EPC and Article 123(2) EPC, the proprietor

filed an auxiliary request, which was then found to lack novelty (time: 18:55, item 14.3 of the minutes of the oral proceedings before the opposition division). The patent proprietor was asked if it wished to submit any further requests, to which it replies in the negative at 19:10 hours, after a break of 15 minutes (item 15.1 of the minutes).

(e) A written decision was issued on 9 September 2015. The reasoning regarding novelty followed the general lines of argument set out in the opponent's letter of 8 April 2015, which had been discussed during oral proceedings (item 14.1 of the minutes).

From the chronology of the first instance proceedings, it is thus entirely clear that the patent proprietor had been aware of the line of argument of the opponent in respect of novelty. When given the possibility to file a further claim request to deal with the lack of novelty, the patent proprietor chose not to do so. The board cannot accept that this manner in which the patent proprietor handled the case was due only to the late hour. No argument concerning the time of the day is recorded in the minutes of the oral proceedings before the opposition division. Furthermore, no request for adjournment of the oral proceedings had been made.

To sum up, the patent proprietor had the opportunity to respond to the finding of lack of novelty in the opposition proceedings, but chose not to do so. Furthermore, the finding of lack of novelty was based on arguments that had been in the proceedings from the beginning and had been reiterated by the opponent in writing shortly before the oral proceedings. The patent proprietor was thus well aware of the opponent's line of argument. The board notes that the preliminary

opinion of the opposition division had been clearly marked as "non-binding" (see title).

Consequently, the patent proprietor not only could, but should have responded to the finding of lack of novelty by submitting a further claim request during oral proceeding before the opposition division.

Since claim requests that deal with the issue of novelty (and as a consequence with the issue of inventive step) could and should have been filed in the first instance proceedings, the board, exercising its discretion, decided not to admit auxiliary requests 3 to 5 into the proceedings (Article 12(4) RPBA).

4.2 *Admission of auxiliary requests 3a, 4a, 5a and 6*

It is asserted that auxiliary requests 3a, 4a, 5a and 6 were all filed in response to issues addressed by the board in its communication pursuant to Article 15(1) RPBA, and could not therefore have been filed earlier. In particular, they were filed in response to the observation of the board that the respective independent product claims of all claim requests then on file do not define conjugates, unlike granted claims 47 and 82.

4.3 However, in addition to adding the term conjugates back to the respective independent product claims again in auxiliary requests 3a, 4a and 5a and deleting of the product claims in auxiliary request 6, additional features are added to the respective method claims 1, similar to those in auxiliary requests 3, 4 and 5. Addition of these features is clearly not in response to any possible objection to the independent product claims. Admission of auxiliary requests 3a, 4a, 5a or 6

would therefore, in view of the non-admittance of the requests on which they are based, also give the proprietor an undue advantage at this late stage in the proceedings.

Consequently, the board decided not to admit auxiliary requests 3a, 4a, 5a and 6 into the appeal proceedings (Article 13(1) RPBA).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated