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**Datasheet for the decision  
of 27 February 2018**

**Case Number:** T 0156/15 - 3.3.07

**Application Number:** 09007867.6

**Publication Number:** 2106790

**IPC:** A61K9/00, A61K38/28, A61K9/20,  
A61K38/00

**Language of the proceedings:** EN

**Title of invention:**  
Rapid acting drug delivery compositions

**Patent Proprietor:**  
Eli Lilly and Company

**Opponent:**  
Bohmann, Armin K., Dr.

**Headword:**  
Rapid acting compositions/ELI LILLY

**Relevant legal provisions:**  
EPC Art. 76(1), 123(3), 114(2)  
RPBA Art. 13(1), 13(3), 12(2)

**Keyword:**

Main request and auxiliary requests 10-16, 18 - subject-matter extends beyond content of earlier application (yes)  
Late-filed auxiliary requests 1-9, 19 and 20 - admitted (no)  
Auxiliary request 17 - Extension of scope of protection (yes)  
Late submitted documents - admitted (no)

**Decisions cited:**

G 0002/10, T 0005/10, T 1634/09, T 0360/11

**Catchword:**

Expert evidence tends to assist the boards in matters which lie outside their own expertise. However, the opinion of a former board member submitted as expert evidence on the application of Article 76 EPC to the facts of the case cannot add any evidential value to the party's submissions. Indeed, if a Board were swayed on such a matter by the fact that submissions had been made by a former board member, however eminent that person might be, it would attach undue weight to the individual making the argument rather than focus on the argument itself (see point 1.2.3).

The appellant-patent proprietor filed auxiliary request 19 after the Chairman had announced the results of the Board's deliberation on the main request and auxiliary requests 1 to 18, and filed auxiliary request 20 after the Chairman had announced the result of the Board's deliberation on auxiliary request 19. By its behaviour, the appellant-patent proprietor is, as a matter of fact, adjusting its strategy to the results of the Board's deliberation, which puts the appellant-opponent in a position where it is difficult to react. In deciding on the admission of such late-filed requests, respect for the principle of fairness of the procedure might make it immediately apparent that these requests should not be admitted, even without also considering specific criteria for the exercise of the Board's discretion such as *prima facie* allowability (see points 1.3.5 and 1.3.6).



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

Boards of Appeal of the  
European Patent Office  
Richard-Reitzner-Allee 8  
85540 Haar  
GERMANY  
Tel. +49 (0)89 2399-0  
Fax +49 (0)89 2399-4465

Case Number: T 0156/15 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 27 February 2018**

**Appellant:** Eli Lilly and Company  
(Patent Proprietor) Lilly Corporate Center  
Indianapolis, IN 46285 (US)

**Representative:** Potter Clarkson LLP  
The Belgrave Centre  
Talbot Street  
Nottingham NG1 5GG (GB)

**Appellant:** Bohmann, Armin K., Dr.  
(Opponent) Nymphenburger Str. 1  
80335 München (DE)

**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
21 November 2014 concerning maintenance of  
European patent No. 2106790 in amended form.

**Composition of the Board:**

**Chairman** J. Riolo  
**Members:** A. Usuelli  
Y. Podbielski

## **Summary of Facts and Submissions**

- I. European patent No. 2 106 790, based on European patent application No. 09007867.6, was filed as a divisional application of European patent application No. 05728268.3. It was granted on the basis of twelve claims.

Independent claim 1 read as follows:

"1. A composition comprising a therapeutically effective dose of insulin or insulin derivative, ions of acetic acid, ascorbic acid, or citric acid, and a zinc metal chelator effective to dissociate the insulin into monomers or dimmers, in a form suitable for sublingual or subcutaneous administration".

- II. The patent was opposed on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as filed and of the earlier application.

The following document was among those cited during the first-instance proceedings:

D2: WO 97/33531

- III. By an interlocutory decision posted on 21 November 2014, the opposition division decided that the patent as amended in accordance with auxiliary request 1 filed on 6 October 2014 met the requirements of the EPC.

Auxiliary request 1 differed from the patent as granted in an amendment introduced in paragraph [0020] of the

description. Claim 1 of auxiliary request 1 was identical to claim 1 of the patent as granted.

The opposition division reached, *inter alia*, the following conclusions:

- (a) The introduction in claim 1 of the features "*ions of acetic acid, ascorbic acid or citric acid*" did not result in additional subject-matter.
- (b) In view of the information disclosed in paragraphs [0019] and [0020] of the description, it was clear that citric acid could be present in the formulation of claim 1 both as a chelator and as a solubilising agent. Hence, the composition containing insulin and citric acid disclosed in table 8 of D2 anticipated the subject-matter of claim 1 of the patent.
- (c) In view of the amendments introduced in paragraph [0020], citric acid was no longer a suitable chelator and the chelator was not the same substance as the solubilising acid. It followed that the compositions disclosed in document D2 no longer anticipated claim 1.
- (d) Auxiliary request 1 also met the requirements of sufficiency of disclosure and inventive step.

- IV. Appeals were filed against the decision of the opposition division by the patent proprietor (hereinafter: appellant-patent proprietor) and by the opponent (hereinafter: appellant-opponent).
- V. In its statement setting out the grounds of appeal the appellant-patent proprietor requested that the decision

under appeal be set aside and the opposition rejected or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 1 to 10 filed with the grounds of appeal.

Auxiliary request 1 was the same request as that considered by the opposition division to meet the requirements of the Convention.

- VI. In a communication pursuant to Article 15(1) RPBA issued on 11 January 2018, the Board observed that the parent application did not mention the presence of ions in the insulin compositions or indicate that they would have been inevitably formed from the corresponding acids. It then came to the preliminary conclusion that claim 1 of the patent and claim 1 of auxiliary requests 1 to 8 and 10 did not comply with Article 76(1) EPC. As to claim 1 of auxiliary request 9 the Board observed that the presence of ions was no longer a mandatory feature of the claim whereas it had been in the patent as granted. Accordingly, auxiliary request 9 was considered not to comply with Article 123(3) EPC.
- VII. Responding to the communication of the Board in a letter dated 26 January 2018, the appellant-patent proprietor withdrew the previous main request (patent as granted) and requested that previous auxiliary request 1 (text of the patent found allowable by the opposition division) be considered the new main request. With the same letter it filed amended auxiliary requests 1-9. Auxiliary requests 2-10 filed with the statement setting out the grounds of appeal were renumbered as auxiliary requests 10-18.

In the course of the oral proceedings held on 27 February 2018 the appellant-patent proprietor filed auxiliary requests 19 and 20.

Claim 1 of the main request was identical to claim 1 of the patent as granted (see point III above).

Claim 1 of auxiliary request 1 read as follows:

"1. A composition, which has been prepared in a solution, comprising a therapeutically effective dose of insulin or insulin derivative, ions of citric acid, and a zinc metal chelator effective to dissociate the insulin into monomers or dimers, in a form suitable for subcutaneous administration".

Claim 1 of auxiliary request 2 differed from claim 1 of auxiliary request 1 in the replacement of the feature "ions of citric acid" with the feature "citric acid".

Claim 1 of auxiliary requests 3 to 9 all related to a composition "which has been prepared in a solution", said composition comprising, *inter alia*, a therapeutically effective dose of insulin or insulin derivative and ions of citric acid.

Claim 1 of auxiliary requests 10 to 16 and 18 all related to a composition comprising a therapeutically effective dose of insulin or insulin derivative, ions of acetic acid, ascorbic acid or citric acid (or only ions of citric acid in auxiliary request 14) and a zinc metal chelator.

Claim 1 of auxiliary request 17 related to a composition suitable for sublingual or subcutaneous administration comprising a therapeutically effective

dose of insulin or insulin derivative, an acid selected from acetic acid, ascorbic acid or citric acid and a zinc metal chelator.

Claim 1 of auxiliary request 19 read as follows:

"1. A composition comprising a therapeutically effective dose of insulin or insulin derivative, ions of citric acid, and a zinc metal chelator effective to dissociate the insulin into monomers or dimers, in a form suitable for subcutaneous administration".

Claim 1 of auxiliary request 20 read as follows:

"1. A composition comprising a therapeutically effective dose of a dry powdered insulin or insulin derivative, mixed with a diluent containing water or saline, citric acid, and a zinc metal chelator effective to dissociate the insulin into monomers or dimers, in a form suitable for subcutaneous administration".

VIII. With a letter dated 15 February 2018 the appellant-patent proprietor filed the following documents:

D42: Technical declaration of Dr John Beals

D43: Opinion from Dr. rer.nat. Dipl. Biol. Ursula Kinkeldey, former member of a technical Board of Appeal of the EPO, Chair of the first biotech Board of Appeal of the EPO and member of the Enlarged Board of Appeal of the EPO.

IX. The arguments of the appellant-patent proprietor, as far as they are relevant to the decision, can be summarised as follows:



(a) Late-filed evidence and requests

D42 and D43 had been filed as expert evidence in response to the Board's communication. In that communication the Board had expressed its preliminary opinion that neither claim 1 of the patent nor claim 1 of the then pending auxiliary requests 1 to 8 and 10 complied with the requirements of Article 76(1) EPC. In that assessment it differed from the decision of the opposition division. That had come as a surprise to the appellant-patent proprietor and it was thus only at that point in time that it had been able to respond to this new assessment. Given that the communication had only been issued on 11 January 2018 the appellant-patent proprietor had not been in a position to provide the additional evidence any earlier.

The main request and auxiliary requests 1-9 had also been filed in response to the communication and thus at the earliest opportunity. As regards auxiliary requests 19 and 20, these had been filed in direct response to the conclusions reached by the Board during the oral proceedings.

(b) Article 76(1) EPC

The parent application did not contain any explicit reference to the presence of ions in the insulin compositions. However, it referred to acetic acid, ascorbic acid and citric acid and the skilled person knew that these acids were partially ionised in the presence of water. Thus, the introduction of the term "ion" did not provide any new teaching and complied with Article 76(1) EPC. Compositions for sublingual administration could also be in liquid form. This was clear from, for instance, page 11 (line 7) of the

original description. Hence, the concerns expressed by the Board as to the presence of ions in the solid sublingual compositions were not justified. Moreover the presence of minor amounts of water was unavoidable even in dry formulations. This would have caused the hydrolysis of the acids. The skilled person would therefore have assumed that ions were also present in dry formulations.

(c) Auxiliary request 17 - Article 123(3) EPC

The compositions defined in this request inevitably contained some water that caused the hydrolysis of the acids, thereby forming the corresponding ions. Hence, this request did not cover compositions that did not include ions of acetic acid, ascorbic acid or citric acid. The requirements of Article 123(3) EPC were therefore met.

X. The arguments of the appellant-opponent, as far as they are relevant to the decision, can be summarised as follows:

(a) Late-filed evidence and requests

Both D42 and D43 had been filed so late (less than two weeks prior to the oral proceedings) that it had not been possible for it to prepare an adequate response. The professional expertise of Dr Beals was so extensive that he could hardly be regarded as a person skilled in the art and his evidence in this regard was thus not convincing. As to D43 there was no need to rely on an expert for the arguments presented therein. Accordingly, D42 and D43 should not be admitted into the proceedings.

Auxiliary requests 1-9, 19 and 20 were not to be admitted. Auxiliary requests 1-9 did not address the concerns expressed by the Board in its preliminary opinion, but raised new issues instead and thus increased the complexity. Auxiliary request 19 was clearly late filed and also did not overcome the shortcomings expressed in the preliminary opinion of the Board. Auxiliary request 20 showed much the same shortcomings as auxiliary request 19.

(b) Article 76(1) EPC

The parent application did not contain any reference to the ions of acetic acid, ascorbic acid or citric acid. It only concerned the acids as such. Furthermore, there was no evidence that some water was always present in the pharmaceutical compositions and that this water was sufficient to cause the formation of the ions by hydrolysis of the acids. Hence, the introduction in claim 1 of the feature "ions" did not comply with the requirements of Article 76(1) EPC.

(c) Auxiliary request 17 - Article 123(3) EPC

The compositions defined in claim 1 of this request comprised acetic acid, ascorbic acid or citric acid whereas the granted patent referred to the ionic forms of these substances. Thus, claim 1 contravened the requirements of Article 123(3) EPC since it did not relate to the same subject-matter as the patent.

XI. The appellant-patent proprietor requested that the appellant-opponent's appeal be dismissed and the patent maintained on the basis of the request considered by the opposition division to meet the requirements of the Convention or, in the alternative, that the patent be

maintained on the basis of one of auxiliary requests 1-9, filed with letter dated 26 January 2018, or one of auxiliary requests 10-18, filed with the statement setting out the grounds of appeal (as auxiliary requests 2-10), or one of auxiliary requests 19 and 20, filed during the oral proceedings.

- XII. The appellant-opponent requested that the decision under appeal be set aside and the patent revoked. It furthermore requested that neither auxiliary requests 1-9, 19 and 20 nor documents D42 and D43 be admitted into the proceedings.

## **Reasons for the Decision**

### Admission of late-filed evidence and requests

#### 1.1 Preliminary considerations

Documents D42 and D43 were filed by the appellant-patent proprietor less than two weeks before the day of the oral proceedings. Both documents concern the question whether the requests on file fulfil the requirements of Article 76(1) EPC. Auxiliary requests 1 to 9 and auxiliary requests 19 and 20 were filed around one month before the oral proceedings and during the oral proceedings respectively. The admissibility of these documents and requests was objected to by the appellant-opponent.

- 1.1.1 The appellant-patent proprietor argued that D42 and D43 had been filed as expert evidence in response to the Board's communication, which had come as a surprise to it since the Board's opinion was not in line with the decision of the opposition division.

The appellant-patent proprietor had thus only been able to respond at that point in time.

A similar argument was made with regard to the filing of new requests. The appellant-patent proprietor regarded itself as having only been able to file amended claims once it knew the Board's opinion on the matter. Thus it had filed amended auxiliary requests 1-9 as a response to the Board's communication and auxiliary requests 19 and 20 during the oral proceedings in response to the opinion the Board had communicated to the parties in the course of the oral proceedings.

- 1.1.2 There are two fundamental flaws in the approach of the appellant-patent proprietor. The first is that it had been surprised by the Board's communication. The specific issue under Article 76(1) EPC, namely whether the replacement of the feature "acids" with "ions" was compatible with Article 76(1) EPC, had been discussed before the opposition division, the opposition division had decided on it and the appellant-opponent objected to, *inter alia*, that part of the decision in its statement setting out the grounds of appeal (point IV., page 7 ff.). The Board's communication thus did not raise any new issue. What the appellant-patent proprietor regarded as surprising was that the Board had expressed a preliminary opinion which differed from the conclusion reached by the opposition division in its decision. That, however, cannot be a surprise. If a decision of the opposition division is appealed, then it is a very real possibility that the Board will disagree with that decision. A party must take that possibility into account from the very moment an appeal is filed and act accordingly.

Secondly, the "reactive approach" of the appellant-patent proprietor is incompatible with the judicial nature of appeal proceedings, in particular those which are inter-partes proceedings. All parties to appeal proceedings have a right to know from the start of these proceedings the essential aspects of the case they have to meet. It is thus a requirement under Article 12(2) RPBA that the statement setting out the grounds of appeal and the reply contain a party's complete case. That includes not only the reasons why the appealed decision should be reversed, amended or upheld, but also all the facts, arguments and evidence relied on. Anything filed thereafter, with the exception of an answer to a communication filed pursuant to directions of the Board, is regarded as having been filed late (see also CA/133/02, page 12, paragraph 1), unless it could not have been filed earlier.

- 1.1.3 Article 114(2) EPC and Article 13(1) RPBA confer discretion on the Board whether or not to admit late-filed facts, evidence and requests. Article 13(1) RPBA identifies particular criteria for the exercise of discretion (complexity of new subject-matter, current state of the proceedings, need for procedural economy) and the case law of the boards has established additional ones, such as sound reasons for filing the document or request so late and the requirement that claims be convergent.

In the Board's view, the overarching consideration when exercising discretion and applying the criteria mentioned above must always be that the proceedings are fair. Where one party approaches the proceedings in such a way that it mainly reacts to communications or opinions of the Board rather than to the submissions of

the other party, it seeks an unfair advantage over the other party, which would, if such behaviour were allowed, be forced to react repeatedly, sometimes even at very short notice.

1.2 Admission of D42 and D43

1.2.1 Both D42 and D43 address issues which had formed part of the appeal proceedings from the start. This, and the fact that they were filed less than 2 weeks prior to the oral proceedings, already speaks against their admission into the proceedings.

1.2.2 The technical declaration D42 contains a considerable number of facts and assertions to which the appellant-opponent must have an adequate opportunity to reply. The Board does not consider that the appellant-opponent would have such an opportunity without adjournment of the oral proceedings. An adjournment, however, would be contrary to the principle of procedural economy and has also not been requested by the parties. The Board thus decides not to admit D42 into the proceedings (Article 114(2) EPC and Article 13(1) and (3) RPBA).

1.2.3 In the introductory part of opinion D43, which was submitted as expert evidence, the author explains that the brief given by the appellant-patent proprietor was to provide an "opinion on whether the claims and amended description of the European Patent EP 2 106 790 (EP790) as currently on file as main request according to the submissions of the patentee of 26 January 2018 fulfil the requirement of Article 76 EPC in view of the preliminary opinion of Board 3.3.07 of 11 January 2018". The appellant-patent proprietor confirmed for the Board that there was nothing in the

opinion that could not equally have been submitted by its representative. Thus the important point about the opinion lay in the fact that it had been presented by a former member of a technical Board of Appeal and of the Enlarged Board of Appeal.

Expert evidence tends to assist the boards in matters which lie outside their own expertise. However, the opinion of a former board member on the application of Article 76 EPC to the facts of the case cannot add any evidential value to the party's submissions. Indeed, if a board were swayed on such a matter by the fact that submissions had been made by a former board member, however eminent that person might be, it would attach undue weight to the individual making the argument rather than focus on the argument itself. The Board thus decides, in exercising its discretion under Article 114(2) EPC, not to admit the opinion into the proceedings. It does not, however, object to the appellant-patent proprietor relying on the arguments presented therein; indeed it regards these arguments as party submissions.

- 1.3 Admission of auxiliary requests 1 to 9, 19 and 20
  - 1.3.1 Auxiliary requests 1-9 were filed with a letter dated 26 January 2018 and thus just over one month before the oral proceedings. Apart from the complexity of the new subject-matter considered and the current state of the proceedings, the need for procedural economy is an essential criterion when a board exercises discretion pursuant to Article 13(1) RPBA whether or not to admit late-filed requests into the proceedings. As is established case law of the Boards of Appeal, such procedural economy implies that amended requests, especially when filed very late, should at least be



*prima facie* allowable in order to be admitted. This means that the claims must be likely to overcome the objections in response to which the request has been filed and must not give rise to new objections (see e.g. T 5/10, T 1634/09, T 360/11 and Case Law of the Boards of Appeal, 8<sup>th</sup> edition, IV.E.4.2.2).

- 1.3.2 Claim 1 of each of auxiliary requests 1 to 9 specifies that the insulin composition "has been prepared in a solution" (see point VII above).

In its letter of 26 January 2018 the appellant-patent proprietor did not provide any basis in the parent application for the introduction of this process feature in claim 1. During the oral proceedings it argued that the feature "has been prepared in a solution" could be derived from a passage on page 18 of the description (lines 16 to 27) relating to the preparation of formulation for subcutaneous administration. The Board notes that this passage describes a process of several steps which comprises the preparation of two separate compositions, namely a solution containing, *inter alia*, citric acid and EDTA and a powder containing insulin in lyophilised form. These two compositions are then mixed prior to administration. Hence, several steps of this process disclosed on page 18, such as the preparation of insulin in lyophilised form, have not been included in claim 1 of auxiliary requests 1 to 9. In other words, the amendment introduced in claim 1 of these requests is based on the isolation of a single step of a more general process. Thus, the passage on page 18 does not provide a clear basis pursuant to Article 76(1) EPC for the introduction of the feature "has been prepared in a solution".

1.3.3 It follows that the amendments introduced in claim 1 of auxiliary requests 1 to 9 give rise to further issues concerning Article 76(1) EPC. In view of the above, auxiliary requests 1 to 9 are not admitted into the appeal proceedings.

1.3.4 Auxiliary request 19 relates to a composition in a form suitable for subcutaneous administration which comprises insulin, ions of citric acid and a zinc metal chelator. The Board notes that the parent application does not contain any passage that *prima facie* provides clear support for a composition combining the features recited in claim 1 of auxiliary request 19. Additionally, in the absence of any indication as to the nature of the solvent and the pH of the solution it appears doubtful whether the feature "suitable for subcutaneous administration" necessarily implies that the citric acid is ionised, as maintained by the appellant-patent proprietor. Thus, auxiliary request 19 does not *prima facie* overcome the deficiency under Article 76(1) EPC observed in relation to the main request (see point 2.1 below). In conclusion, auxiliary request 19 gives rise to new issues and does not *prima facie* overcome the deficiencies observed in relation to the previous requests.

Auxiliary request 20 adds features which are taken from the description to claim 1. In particular, the feature "dry powdered insulin or insulin derivative" has not formed part of any of the previous requests. It therefore poses new questions which cannot reasonably be considered by the Board or the appellant-opponent without an adjournment of the oral proceedings.

In view of the above, the Board decides not to admit auxiliary requests 19 and 20 into the appeal proceedings.

- 1.3.5 Having regard to the specific circumstances in which auxiliary requests 19 and 20 were submitted, the Board would like to add the following remarks.

Auxiliary requests 19 and 20 were filed at a very late stage in the oral proceedings. When exercising its discretion the Board must weigh up all the circumstances of the case. The later the claims are submitted, the stricter the criteria to be applied (Case Law of the Boards of Appeal, 8<sup>th</sup> edition, IV.E. 4.1.3, with reference to the cases cited therein). Moreover, when new sets of claims are filed during the oral proceedings the Board should take particular care to ensure that their admission does not compromise the other parties' ability to adequately defend their case. In other words, the admission of a new request should not favour the patent proprietor over the opponents.

- 1.3.6 In the present case, the appellant-patent proprietor filed auxiliary requests 19 after the Chairman had announced the results of the Board's deliberation on the main request and auxiliary requests 1 to 18, and filed auxiliary request 20 after the Chairman had announced the result of the Board's deliberation on auxiliary request 19. Both parties were aware of the Board's preliminary position on the issues under Article 76(1) and 123(3) EPC in view the communication it had issued on 11 January 2018 and so its conclusions at the oral proceedings were not surprising. By its behaviour, the appellant-patent proprietor is, as a matter of fact, adjusting its strategy to the results of the Board's deliberation, which puts the

appellant-opponent in a position where it is difficult to react. The adoption of this tactic provides an advantage to the appellant-patent proprietor over the appellant-opponent which is hard to reconcile with the principle of fairness of the procedure. In deciding on the admission of such late-filed requests, respect for this principle of fairness might make it immediately apparent that these requests should not be admitted, even without also considering the specific criteria for the exercise of the Board's discretion such as *prima facie* allowability (see also point 1.1.3 above). In the present case, the Board considers that the admission of auxiliary requests 19 and 20 could, in principle, have been refused even without considering whether these requests clearly overcome the deficiencies under Article 76(1) and 123(3) EPC.

2. Main request

2.1 Article 76(1) EPC

2.1.1 Claim 1 of the main request is identical to claim 1 as granted (see point VII above). The insulin compositions defined in claim 1 of this request comprise ions of acetic acid, ascorbic acid or citric acid. The parent application discloses compositions comprising the acids of these substances without any mention of their ionic forms. The appellant-patent proprietor argues that the acids would inevitably be present, at least partially, in these compositions in ionised form.

2.1.2 The Board observes that claim 1 refers to, *inter alia*, pharmaceutical forms which are suitable for sublingual administration. Although these forms may also be liquid, it is clear that they are usually in the form of dry solid powders. Indeed paragraph [0034] of the

patent states that the compositions may be in form of a dry powder which is typically delivered buccally or sublingually.

In a dry composition, an acid is normally in a non-ionised form. Thus, in the absence of any indication as to the presence of ions, the skilled person would assume that the dry powder compositions described in the parent application contain acetic acid, ascorbic acid or citric acid rather than their ionic forms.

2.1.3 The appellant-patent proprietor expresses the view that the residual amount of water which is present in the dry powder would cause the formation of the ions from the acids.

2.1.4 In this regard the Board notes that there is no indication in the parent application that the sublingual compositions in dry powder form contain an amount of water which is sufficient to cause the ionisation of the acids. It is stressed that the ions of acetic acid, ascorbic acid or citric acid are essential components of the compositions of claim 1 of the main request. However, according to the position of the appellant-patent proprietor, in the context of the parent application the presence of these essential components is to be derived from the assumption that water, which is present in a dry powder (if at all) only in negligible amounts, would cause the ionisation of the acids.

The Board considers that if an essential component of a composition is present not because it is added as such but because it is formed in a rather fortuitous manner, this should be explained in the original application.

However, there is no teaching in the parent application that supports the explanation provided by the appellant-patent proprietor with regard to the formation of the ions in the dry powder sublingual compositions.

2.1.5 The assessment of Article 76(1) EPC is to be based on the "gold standard". This standard requires that the subject-matter of a claim of a divisional application be based only on what the skilled person would directly and unambiguously derive from the earlier application (see G 2/10, point 4.3 of the Reasons). The technical considerations put forward by the appellant-patent proprietor in support of the position that the sublingual compositions of claim 1 inevitably contain the ionic form of the acids, cannot be directly and unambiguously derived from the earlier application.

2.1.6 In view of the above the Board concludes that the main request does not comply with the requirements of Article 76(1) EPC.

### 3. *Auxiliary requests 10 to 16 and 18*

3.1 Claim 1 of each of these requests relates to compositions comprising ions of acetic acid, ascorbic acid or citric acid (or only ions of citric acid in auxiliary request 14). Accordingly, these requests do not fulfil the requirements of Article 76(1) EPC for the same reasons given above in respect of the main request.

4. *Auxiliary request 17*

4.1 Article 123(3) EPC

- 4.1.1 Claim 1 of auxiliary request 17 relates to compositions containing an acid selected from acetic acid, ascorbic acid or citric acid. The granted patent relates to compositions containing ions of acetic acid, ascorbic acid or citric acid.

Since the presence of the ionic form of the acids is no longer a mandatory feature of claim 1 of auxiliary request 17, there is an extension of the scope of protection conferred by the patent. This is because auxiliary request 17 covers compositions that are not included in the scope of the patent, namely the compositions that do not contain the ionic form of the acids.

- 4.1.2 In the appellant-patent proprietor's opinion the compositions defined in claim 1 of auxiliary request 17 would inevitably contain ions of acetic acid, ascorbic acid or citric acid since the presence of water would cause the ionisation of the acids.

However, as discussed in relation to the main request, claim 1 also covers compositions suitable for sublingual administration which are typically formulated as dry solid powders. There is no indication in the patent that any residual water present in these formulations would cause the ionisation of the acids. Hence, the argument of the appellant-patent proprietor is unconvincing.

Therefore, the subject-matter of claim 1 of auxiliary request 17 does not meet the requirements of Article 123(3) EPC.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated