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**Datasheet for the decision
of 17 June 2010**

Case Number: T 1898/07 - 3.3.04

Application Number: 97952621.7

Publication Number: 0948358

IPC: A61K 47/18

Language of the proceedings: EN

Title of invention:

Stable liquid interferon formulations

Patentee:

Biogen Idec MA Inc.

Opponents:

- 01: Sandoz AG
02: BIOCEUTICALS Arzneimittel AG
03: BioGeneriX AG

Headword:

Interferon Formulations/BIOGEN

Relevant legal provisions:

- EPC Art. 54, 56, 84, 123(2), 123(3)
EPC R. 80
RPBA Art. 12, 13

Keyword:

"Admissibility of auxiliary requests 13 and 14 - (no)"

"Main request and auxiliary requests 1-10 amendments -
Article 123(2) (yes), Article 123(3) (no)"

"Auxiliary requests 11, 12 and 15 amendments, clarity (yes),
novelty (no)"

"Auxiliary request 16 amendments, clarity, novelty, inventive
step - yes"

Decisions cited:

G 0002/88, T 0059/87, T 0148/87, T 0049/89, T 0402/89,
T 0506/91, T 0686/91, T 0190/99, T 0835/00, T 0579/01,
T 0604/01, T 0352/04, T 0221/06, T 0316/08, R 0002/08,
R 0011/08, R 0003/09, R 0012/09

Catchword:

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Case Number: T 1898/07 - 3.3.04

DECISION
of the Technical Board of Appeal 3.3.04
of 17 June 2010

Appellant:
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 11 September 2007
revoking European patent No. 0948358 pursuant
to Article 102(1) EPC 1973.**

Composition of the Board:

Chairman: C. Rennie-Smith
Members: M. Wieser
 G. Alt

Summary of Facts and Submissions

I. The appeal was lodged by the Patent Proprietor (Appellant) against the decision of the Opposition Division, whereby the European patent No. 948 358 was revoked pursuant to Article 102(1) EPC 1973.

II. The patent had been granted with a set of sixty-nine claims. Claims 1, 3, 12 and 13 read:

"1. A liquid composition comprising an interferon and an amino acid stabilizing agent selected from the group consisting of acidic amino acids, arginine and glycine; wherein the amino acid stabilizing agent is present at between 0.3% and 5% w/v; wherein the liquid composition has not been reconstituted from lyophilized interferon; and wherein the liquid composition is not further lyophilized.

3. The liquid composition of claim 1, wherein said liquid composition is contained within a vessel, and wherein at least one surface of the vessel in contact with the liquid composition is coated with a material inert to interferon.

12. The liquid composition of claim 3, wherein said at least one surface of the vessel is coated with a material selected from the group consisting of silicone and polytetrafluoroethylene.

13. The liquid composition of claim 12, wherein the vessel is a syringe."

Besides claim 1, the set of granted claims contained three other independent claims. Claim 32 referred to a liquid pharmaceutical composition and claims 43 and 58 each referred to a method for stabilizing interferon in a liquid pharmaceutical composition.

- III. The patent had been opposed by three parties (Respondents I to III) under Article 100(a) EPC, on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), Article 100(b) and Article 100(c) EPC.
- IV. The Opposition Division decided to revoke the patent because it found that neither the main request nor any of auxiliary requests 1A to 1D and 2 to 5 before it met the requirements of the EPC.
- V. The Appellant's Notice of Appeal filed on 8 November 2007 contained a request to set aside the decision under appeal to the extent it rejected its main request and auxiliary requests (see section IV above) and then stated:

"We further request: (i) maintenance of the patent in suit on the basis of the patentee's main request, or if this is not possible, on the basis of any one of the above-mentioned auxiliary requests or a combination thereof or any one of the auxiliary requests that will be filed with the patentee's statement of grounds of appeal;...".

There was also a request for oral proceedings.

VI. The statement of grounds of appeal filed by faxed letter on 21 January 2008 contained a section headed "1. Requests" which, after requests to set aside the decision of the Opposition Division and maintain the patent on the basis of the main request filed with the Patentee's letter of 17 February 2006, read as follows (the numbering being that of paragraphs of the Appellant's letter):

"1.3 In the event that the Board of Appeal is contemplating any other decision, however, Patentee requests that the patent should be maintained on the basis of any one, or a combination, of Auxiliary Requests 1A-1D as filed herewith, or on the basis of Auxiliary Request 2, as filed herewith, together with an appropriately amended description. These requests are identical to the requests that were considered at the Oral Proceedings before the Opposition Division on 21 June 2007, except that for Auxiliary Request 1C, Claim 48 has been cancelled, and for Auxiliary Request 2, the corresponding Claim 42 has been cancelled.

1.4 Should it be necessary to consider the Auxiliary Requests 1A-1D, then Patentee requests that these be considered or combined as appropriate, having regard to the reasoning behind the decisions that are being addressed. Auxiliary Requests 1A-1C relate to separate and independent allegations under Article 123(2) EPC (see paragraphs 13.1.1 (a), 13.1.2 and 13.1.1 (b) of the OD's Decision). For this reason, it may be appropriate to combine one or more of the Auxiliary Requests 1A-1C, optionally in combination with

Auxiliary Request 1D, depending upon the decisions of the Board of Appeal during the appeal procedure.

1.6 In addition, Patentee reserves the right to: (i) expand on the present submissions both in writing and at any subsequent oral proceedings; (ii) make amendments to the Main Request, or to any of the Auxiliary Requests, in order to deal with any deficiencies that the Board of Appeal considers to be present in an otherwise allowable set of claims; and (iii) file one or more additional Auxiliary Requests should the Board consider that the patent cannot be maintained on the basis of any one of the current claim requests."

VII. Respondent I (Opponent 1) filed a reply by faxed letter dated 16 June 2008 in which it observed that the extent of the appeal proceedings is determined by the notice of appeal in which the Appellant had requested maintenance of the patent on the basis of considerably more limited requests than those of the granted claims and that the Appellant was not entitled to revert to the granted claims or to make requests going beyond the requests set forth in the notice of appeal. Otherwise the letter referred to the party's submissions during the opposition proceedings.

VIII. Respondent III (Opponent 3) also filed a reply on 16 June 2008 in which it presented substantive arguments against the case in the grounds of appeal (see section XXI below).

IX. The Appellant filed written submissions dated 13 July 2009 in response to the reply of Respondent III.

X. The Board issued a provisional opinion in its communication dated 20 January 2010 sent together with the summons to oral proceedings. The communication opened with the following remarks:

"1. This communication is sent pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal. Any opinions expressed herein are provisional and are not binding on the Board in arriving at its decision.

This communication raises some, but not necessarily all, of the issues that will be considered at the oral proceedings. This is not an invitation to the parties to make further submissions, unless they consider it necessary to do so.

2. The final date for receipt of any written submissions is two months before the date of the oral proceedings.

The attention of the parties is drawn to the fact that pursuant to Article 114(2) EPC facts and evidence which are not submitted in due time by the parties concerned may be disregarded by the Board. With regard to the basis of the appeal proceedings and amendments to a party's case, Articles 12 and 13 of the Rules of Procedure of the Boards of Appeal (RPBA) should be noted."

The communication then summarised the decision under appeal and the parties' requests, observing that the Appellant's requests were (at that time) the same as before the Opposition Division except that claim 48 of

auxiliary request 1C and claim 42 of auxiliary request 2 had been cancelled.

The Board's communication then expressed provisional views on issues arising from the decision under appeal as follows.

The Board was not convinced by the Appellant's arguments with regard to two issues, namely that the Opposition Division was wrong to have held (in point 13.1.1(a) of its decision) that the feature "... wherein the amino acid stabilizing agent is present at between 0.3% and 5% w/v; ..." had no basis in the application as originally filed, and to have held (in point 13.1.2 of its decision) that claim 28 contravened the requirements of Article 123(2) EPC as it covered liquid pharmaceutical compositions which had been reconstituted from lyophilised interferon-beta. This had the effect that, according to the Board's preliminary opinion, none of the Appellant's main or auxiliary requests 1A, 1B, 1C and 1D seemed to meet the requirements of Article 123(2) EPC.

The Board had not yet formed an opinion on the subject-matter discussed in points 13.1.1(b) ("the liquid composition does not comprise serum albumin") and 13.2 ("A packaged kit", Article 123(3) EPC) of the decision under appeal.

The Board was also not yet convinced by the Appellant's arguments against the Opposition Division's decision (in point 16) that claims referring to a liquid composition in a syringe which is contained in a packaged kit, wherein the composition comprises an

interferon-beta and glycine as a stabilising agent did not meet the requirements of Article 56 EPC as their subject-matter was obvious in the light of the disclosure of document (2), representing the closest state of the art, when combined with any of documents (5), (7) or (10). Thus, the Board's preliminary opinion was that the subject-matter of the claims of the main request and of auxiliary requests 1A, 1B and 1C did not involve an inventive step.

Lastly, the Board was not yet convinced that the subject-matter of claims referring to interferon-beta containing compositions stabilized by arginine was obvious in the light of the disclosure in document (6) in combination with any of documents (5), (7) or (10), as decided by the Opposition Division (in point 17 of the decision under appeal).

- XI. Respondent II (Opponent 2) filed a letter dated 16 March 2010 stating it would not attend the oral proceedings and withdrew its request therefor. In fact, it had made no such request and filed no other submissions throughout the appeal proceedings.
- XII. Respondent III filed written submissions dated 14 April 2010 containing substantive arguments on the issues on which the Board had said, in its communication, it had either not yet formed a view or on which its provisional opinion was not against the Appellant.
- XIII. The Appellant filed a letter dated 19 April 2010 containing written submissions and enclosing a main and eighteen auxiliary requests which were the subject of three pages of explanation and a table (Annex A to the

letter). The submissions were in summary as follows (the numbering being that of paragraphs of the Appellant's letter).

1.1 The previous main request was maintained.

1.2 As a precaution, if the Board contemplated any other decision, the Appellant requested that the patent be maintained on the basis of any one, or any combination, of auxiliary requests 1A - 1E, 2, 2bis, 2ter, 2quater, 2quinquies, 3, 3bis, 3ter, 3quater, 3quinquies, 4, 5, or 6 all enclosed with the letter of 19 April 2010 and in each case with a description to be amended as appropriate.

1.3 In addition, the Appellant requested the opportunity at the oral proceedings to make minor amendments to any of these requests in order to deal with any alleged deficiencies that the Board considered to be present in an otherwise allowable set of claims. Such minor amendments might include e.g. the deletion of one or more claims from a request that would be accepted in the absence of those claims.

2.2 Auxiliary request 1E was filed as a precaution in case the Board, which had not yet issued a preliminary opinion confirming the Opposition Division's conclusion that the disclosure of the patent was enabling, took the view that the requirements of Article 83 EPC were not satisfied.

2.3 The Appellant requested that, if it had to rely on auxiliary requests 1A - 1E, these be considered and/or combined as appropriate, having regard to the reasoning

behind the decisions being addressed. It asked the Board to note that auxiliary requests 1A - 1C related to separate and independent objections under Article 123(2) EPC and accordingly it might well be appropriate to combine one or more of these requests, optionally in combination with auxiliary request 1D (relating to the Opposition Division's decision under Article 56 EPC) and/or with auxiliary request 1E, depending on the decisions taken by the Board on each of these separate issues at the oral proceedings.

2.4 The separate and independent nature of the various objections necessitated this approach of identifying the possible amendments that might be made as separate auxiliary requests 1A - 1E, which would then be combined, as appropriate, depending on the decisions of the Board. This approach was to be preferred over filing an individual request for each of the five separate amendments and the 26 possible combinations thereof.

3.1 A new auxiliary request 2 had been filed to address the concerns of the Board whose preliminary opinion had agreed with paragraphs 13.1.1a and 13.1.2 of the decision under appeal. It was a combination of the original main request and original auxiliary requests 1A and 1B (which respectively addressed the objections that there was no basis in the application as filed for the specific range of % w/v recited in Claims 1 and 37 of the main request nor for the omission from Claim 28 of the main request of a requirement that the claimed liquid composition has not been reconstituted from lyophilised interferon).

3.2 As the Board had not yet formed any preliminary opinion on the issue of the reference in the claims to the omission of serum albumin, as a precaution auxiliary request 2bis incorporated the amendments of auxiliary request 1C into auxiliary request 2.

3.3 In view of the Board's comments as to the alleged lack of an inventive step for the embodiments of the main request in which glycine, by itself, is employed as an amino acid stabilizing agent, in auxiliary request 2ter the feature specified in Claim 12 of auxiliary request 2bis (i.e. the presence of a salt where the amino acid stabilizing agent is glycine) had been incorporated into Claim 1 of that earlier request.

3.4 Also in view of the Board's preliminary opinion, auxiliary request 2quater incorporated a requirement that the amino acid stabilizing agent is arginine into auxiliary request 2bis (i.e. combining that request with auxiliary request 1D).

3.5 Because the Board had not issued any opinion on sufficiency of description (see 2.2 above), the Appellant filed auxiliary request 2quinquies which incorporated the amendments made in auxiliary request 1E (concerning a specific pH range) into auxiliary request 2quater.

4.1 As the Board had not issued a preliminary opinion on the objection to the reference in the main request to "a packaged kit", the Appellant was left in the difficult position of not knowing whether the Board would be satisfied with the overall format of auxiliary requests 2, 2bis, 2ter, 2quater and 2quinquies (wherein

Claim I is directed to "a packaged kit"), or if the Board would prefer the format advanced at the oral proceedings before the Opposition Division and found to meet the requirements of Article 123(3) EPC (in which Claim 1 is directed to "a liquid composition . . . wherein the liquid composition is contained within a syringe . . . and wherein the syringe is contained in a packaged kit").

4.2 Thus auxiliary requests 3, 3bis, 3ter, 3quater, and 3quinquies were filed to take account of this uncertainty. These were identical to auxiliary requests 2, 2bis, 2ter, 2quater and 2quinquies except that they employed the overall format of claims that was accepted by the Opposition Division, rather than the format used in the main request.

5.1 Finally, auxiliary requests 4, 5 and 6 were resubmitted as a precautionary measure. These were identical to auxiliary requests 2, 4 and 5 before the Opposition Division except that in auxiliary request 4 Claim 42 had been deleted.

XIV. At the oral proceedings held before the Board on 17 June 2010, after the Board had refused the main request and auxiliary requests 1 to 12, the Appellant filed new auxiliary requests 13 and 14 and requested that these be admitted into the proceedings and considered next (with the effect that its other remaining requests would be renumbered auxiliary requests 15 to 20).

XV. The final requests submitted by the parties at the oral proceedings on 17 June 2010 were as follows:

The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or one of auxiliary requests 1 to 12 filed on 19 April 2010 (originally filed as auxiliary requests 1A to 1E, 2 to 2quinquies, 3 and 3bis), or auxiliary requests 13 and 14 filed during the oral proceedings, or auxiliary requests 15 and 16 filed on 19 April 2010 (originally filed as auxiliary requests 3ter and 3quarter).

Moreover, the Appellant contended that there was a procedural defect by the Board of Appeal which, in refusing to admit auxiliary requests 13 and 14 into the proceedings, had contravened the provisions in Article 112a(2)(c) and (d). An objection pursuant to Rule 106 EPC was raised during the oral proceedings.

The Respondents I and III requested that the appeal be dismissed. Respondent II made no requests.

XVI. Claim 1 of Appellant's main request read as follows:

"A packaged kit for parenteral administration of an interferon-beta, the kit containing a syringe pre-filled with a liquid composition comprising the interferon-beta and an amino acid stabilizing agent selected from the group consisting of acidic amino acids, arginine and glycine; wherein the amino acid stabilizing agent is present at between 0.3% and 5% w/v; wherein the liquid composition has not been reconstituted from lyophilized interferon; and wherein the liquid composition is not further lyophilized, wherein the liquid composition does not comprise serum

albumin, and wherein the syringe has a head space flushed with an inert gas" (emphasis added by the Board).

Claim 1 of each of auxiliary requests 1 to 10 referred to a packaged kit and started with the four lines highlighted above.

XVII. Claim 1 of Appellant's auxiliary request 11 read as follows:

"A liquid composition comprising an interferon-beta and an amino acid stabilizing agent selected from the group consisting of 0.5% to 5% (w/v) arginine-HCl, 0.50% to 2.0% (w/v) glycine, and 1.47% to 2.94% (w/v) glutamic acid; wherein the liquid composition has not been reconstituted from lyophilized interferon; wherein the liquid composition is not further lyophilized, wherein the liquid composition does not comprise serum albumin, wherein the liquid composition is contained in a syringe, wherein the syringe has a head space flushed with an inert gas, and wherein the syringe is contained in a packaged kit."

Claim 1 of auxiliary request 12 differed from claim 1 of auxiliary request 11 by

- deletion of the feature "wherein the liquid composition does not comprise serum albumin".

Claim 1 of auxiliary request 15 differed from claim 1 of auxiliary request 11 by

- deletion of the feature "wherein the liquid composition does not comprise serum albumin"; and
- addition of the feature "and wherein if the amino acid stabilizing agent is glycine, then the liquid composition further comprises a salt".

XVIII. Claim 1 of auxiliary request 16 differed from claim 1 of auxiliary request 11 by

- deletion of the feature "wherein the liquid composition does not comprise serum albumin"; and
- definition of the amino acid stabilizing agent as being "0.5% to 5% (w/v) arginine-HCl".

Dependent claims 2 to 22 of auxiliary request 16 referred to preferred embodiments of the liquid composition according to claim 1. Claim 23 and claims 24 to 32 dependent thereon referred to a method for preparing a liquid pharmaceutical composition and claim 33 and claims 34 to 41 dependent thereon referred to a method for stabilizing interferon in a liquid pharmaceutical composition.

XIX. The following documents are referred to in this decision:

(2) EP-A-0 270 799

(6) EP-B-0 163 111

(7) EP-B-0 736 303

(19) WO 94/26 302

(32) EP-B-1 017 413

(33) Communication of the Examining Division of the EPO
in case EP 98 950 074.9 dated 10 May 2001 (granted
as EP-B-1 017 413; document (32))

XX. The arguments of the Appellant, in writing and at the oral proceedings, can be summarised as follows.

Admissibility of auxiliary requests 13 and 14

These requests should not come as any surprise because the Appellant had given warning of possible combinations of claims from other requests. The request to file such combinations or further amended requests had been made and maintained throughout the proceedings.

In a case where several issues had to be decided, the Appellant had been faced with a situation where it did not know the Board's view on all those issues. To cover every possibility the Appellant would have had to file some two hundred requests but chose instead to file a limited number and turn to combinations or amended request according to how the Board might decide particular issues.

If the Appellant was not allowed to bring forward new requests until all its previously-filed requests had been dealt with, it could be forced into the position where it obtained less protection for its invention than it could by these new requests.

If the Board did not admit these new requests, the Appellant would be denied the right to be heard pursuant to Article 113 EPC. Therefore, if the Board refused to admit these requests, the Appellant would file a petition for review by the Enlarged Board of Appeal on the grounds contained in Article 112a(2)(c) and (d) EPC.

In response to the suggestion of Respondent I, the Appellant said it would not withdraw its other requests and replace them with these new requests.

Main request and auxiliary requests 1 to 10

A skilled person willing to understand the application as published immediately recognized that all ranges of ingredients of the disclosed liquid composition were given as % (w/v). Any other interpretation would be absolutely illogical and unusual. Moreover, the application as published clearly contained a basis for liquid compositions free of serum albumin.

The scope of protection conferred by a claim referring to a packaged kit containing a syringe pre-filled with a liquid composition was restricted when compared to a claim referring to the liquid composition per se. Deciding differently would contradict the case law of the Boards of Appeal (for example T 579/01 of 30 June 2004) and require referral of questions to the Enlarged Board of Appeal.

Auxiliary requests 11, 12 and 15

The amendments to the claims were occasioned by objections under Article 54 EPC, which was a ground for opposition under Article 100 EPC. The claims were clear and the extent of protection they conferred was limited with regard to the claims as granted.

Document (2) did not disclose liquid compositions contained in a syringe which was comprised in a packaged kit and therefore did not anticipate the subject-matter of the claims.

Auxiliary request 16

In order to arrive at the claimed subject-matter, a skilled person had to make a selection from two lists disclosed in document (6). According to established case law, such disclosure was not novelty destroying.

When applying the problem-and-solution approach, document (2) and not document (6) had to be considered as representing the closest state of the art. The problem to be solved was the provision of an alternative, long-time stable, easy to produce and to apply, liquid composition of interferon-beta. The skilled person would have had no reason to turn to document (6) which was concerned with an absolutely unrelated technical problem.

XXI. The arguments of the Respondents, in writing and at the oral proceedings, can be summarised as follows.

Admissibility of auxiliary requests 13 and 14

Respondent I argued that these requests were very late-filed. The Appellant claimed that it presented its requests as it did to avoid filing some two hundred requests and to see what the Board of Appeal might decide. However, the Board was not an advisory committee. The Respondent would have had more sympathy with the Appellant if it had offered to withdraw its other requests and replace them with these new requests.

Respondent II argued that these requests were broader than any others remaining on file. The Appellant had known at least from receipt of the Board's preliminary opinion that it might be limited to a set of claims based on arginine (as all the other remaining claims were) but had not then filed the requests it now wanted to introduce. The Appellant had chosen how to conduct its case and should not be allowed to change its requests at such a late stage. The attempt to introduce these new requests was an abuse of procedure.

Main request and auxiliary requests 1 to 10

The ranges disclosed on page 2 and in claim 1 of the application as published were given as % (w/w). There was no basis for these specific ranges as % (w/v) in the entire application as published.

The extent of protection conferred by a claim referring to a packaged kit containing various components differed from the extent of protection conferred by a claim referring to one of these components, with the effect that an act which did not infringe the patent as granted became an infringing act as a result of an amendment after grant.

Auxiliary requests 11, 12 and 15

The amendments to the claims were not occasioned by a ground for opposition and therefore contravened the requirements of Rule 80 EPC. Features defining a composition by way of a specific container comprising it were not clear and could, moreover, have the effect that the extent of protection conferred by such a claim extended beyond that conferred by a claim referring to the composition per se.

Document (2) disclosed all technical features of the liquid composition, the subject-matter of claim 1 of each of auxiliary requests 11, 12 and 15, and was therefore novelty destroying for these requests.

Auxiliary request 16

Document (6) anticipated the claimed subject-matter which thus contravened the requirements of Article 54 EPC.

The skilled person would not hesitate to apply the findings of document (6) with regard to interferon-gamma to another interferon, namely interferon-beta. As solubilisation and stabilization were based on very similar physical principles, document (6) was a good starting point for the assessment of inventive step and could be considered to represent the closest state of the art. The claimed subject-matter was obvious, either in the light of the disclosure in document (6) alone or in combination with document (2). Any attempt of the Appellant to argue in favour of inventive step based on

a solution of a problem not stated in the claims must fail.

Reasons for the Decision

Admissibility of auxiliary requests 13 and 14

1. The Appellant was correct in its submission that it had throughout the appeal proceedings requested to file further requests consisting of "combinations" of actual requests (see sections V; VI 1.4; XIII 2.3, 2.4; and XX above) and either requested, or claimed to "reserve the right", to file additional or amended auxiliary requests (see sections VI 1.6; XIII 1.3; and XX above). It is also clear from its submissions that the Appellant considered this approach was required for various reasons - the large number of objections it had to deal with (see section XIII 2.4 above); the absence in the Board's communication of a provisional opinion on every one of those objections (see sections XIII 3.2, 3.5 and 4.1; and XX above); and its expectation that at the oral proceedings it would receive, rather than one final decision after all the parties had been heard, a number of decisions on individual issues and individual claims within requests followed by the opportunity to file new auxiliary requests, whether "combinations" or amendments of previous requests (see sections VI 1.4 and 1.6; XIII 1.3 2.3, 2.4 and 4.1 above). However, the Appellant's view of appeal procedure was unfortunately mistaken.

2. The matter is governed by Articles 12 and 13 RPBA (which were referred to by the Board in its

communication - see section X above). In particular Article 12(2) RPBA requires that a party's statement of grounds of appeal (or reply - the requirement applies equally to both sides of an *inter partes* case) contains its complete case; and Article 13(1) RPBA requires that any amendment to a party's case after it has filed its grounds of appeal or reply - and a new set of claims is clearly such an amendment - is admissible, not as of right, but at the Board's discretion.

3. As the Board has recently observed (see T 316/08 of 26 May 2010, Reasons, point 19), the fact that Article 12(1)(c) RPBA provides that appeal proceedings shall be based on, in addition to the grounds of appeal and reply, any communication sent by the Board and any answer thereto, cannot mean that any new requests filed with such an answer are *per se* admissible since otherwise parties could withhold less preferred requests until after obtaining the Board's provisional opinion on more preferred requests: a tactic which would largely negate the function and value of provisional opinions but on which the Appellant in this case relied heavily. Article 12(4) RPBA requires the Board to take into account everything presented by the parties under Article 12(1) RPBA if and to the extent it relates to the case under appeal and meets the requirements in Article 12(2) RPBA, which includes the complete case requirement. Thus the Board is quite clearly not required to take into account anything which does not satisfy that requirement, such as requests which could have been filed with the statement of grounds of appeal but were not.

4. In the present case, it follows axiomatically from the Appellant's own submissions on possible further auxiliary requests in the form of "combinations" or amendments of existing requests that it had foreseen other requests than those it actually filed. Accordingly, it is implicit in its own case that it could have filed such other requests (including auxiliary requests 13 and 14) either with its statement of grounds of appeal or, at the very latest, in response to the Board's communication. Similarly, it is implicit that the statement of grounds of appeal did not contain the Appellant's complete case.

5. The Appellant's arguments can be conveniently dealt with by reference to the recent jurisprudence of the Enlarged Board of Appeal relating to procedural questions raised in petition proceedings under Article 112a EPC. The Appellant argues that it did not know the Board's opinion on all the issues in the appeal, that it did not want to file a large number of requests, that it had constantly requested to file further requests or combinations of existing requests, and that these would depend on the decisions taken by the Board on each of these separate issues at the oral proceedings. The Appellant clearly expected that the Board would announce a separate decision on each such issue and then allow the Appellant to tailor its requests to the new situation which might then arise. However, as the Enlarged Board observed in R 12/09 (of 15 January 2010, see Reasons, point 11):

"It is for each party to make its own case and for a Board then to decide on the basis of the parties' submissions. In doing so a Board should not in *inter*

partes proceedings assist one of the parties by giving it a hint in advance, either during oral proceedings (see R 11/08 of 6 April 2009, Reasons, point 14) or in a communication (R 3/09 of 3 April 2009, Reasons, point 5.1). A party which wants a decision in its favour must play a full part in proceedings and submit arguments in support of its case on its own initiative and at the appropriate time (see R 2/08 of 11 September 2008, points 8.5 and 9.10). It is part of the professional task of representatives to decide independently - that is, without assistance from the Board - how to pursue their cases (see T 506/91 of 3 April 1992, Reasons, point 2.3 cited with approval in R 11/08 of 6 April 2009, Reasons, point 10)."
(Translation by the Board from the German text of the decision.)

6. The present case bears a close resemblance to R 11/08 of 6 April 2009 in which, in proceedings before a Board of Appeal, the petitioners (as the Patentees appealing against a revocation decision) had filed a main and fifteen auxiliary requests and further stated in their grounds of appeal that they were ready to file further auxiliary requests to solve potential problems by deleting claims from or combining claims of different auxiliary requests and, as a precautionary measure and to avoid numerous further auxiliary requests, they also requested that the patent be maintained based on at least one of the independent claims of any of the auxiliary requests. (This last request was referred to in the Enlarged Board's decision as "the general request".) The Board of Appeal had dismissed the general request (which it called a "pick and mix" approach) because it would have required the Board to

assist the Appellants by giving them a "pre-decision" before they finalised their requests (see T 221/06 of 24 July 2008, reasons, points 2.3 and 2.4).

7. The Enlarged Board dismissed the Appellants' arguments (as petitioners) that their approach only called for deleting one or more claims and avoided filing many further requests by observing that such arguments in themselves showed that the requests in question were not immediately ascertainable (see Reasons, point 12). To the argument that the Appellants' approach was the only way to obtain the broadest possible protection in the face of numerous objections, the Enlarged Board observed the objections were to the claims the patentees themselves had put forward and there was no explanation why the conventional approach, of a sequence of specific requests in descending order of preference, had not been possible (see Reasons, point 13). Further, the Enlarged Board held it was inherent in the petitioners' further argument - that many variants of their requests were needed because the Board had not supplied an opinion on various issues - that, if the Board had provided such views, it would thereby have assisted the petitioners to frame their requests. The Enlarged Board concluded that the petitioners' complaint was in effect that the Board in question was, quite properly, impartial (see Reasons, point 14).

8. The Board follows those views of the Enlarged Board in the present case in which the Appellant's arguments are very substantially the same. The Board could not assist the Appellant to frame further requests by giving "pre-decisions" at various points during the oral

proceedings - indeed, despite its earlier hopes that the Board would take decisions on each of separate issues at the oral proceedings, the Appellant conceded at the oral proceedings that it was not entitled to any provisional opinion from the Board. To the extent such an opinion is given in a communication, it is intended to assist both or all parties and if, as in the present case, that communication records that the Board has not yet been convinced by an argument or has not yet formed an opinion on an issue, that can only mean what it says - that the Board is as yet undecided even on a provisional basis - and carries no implicit offer of a further opinion before the proceedings are concluded.

9. The function of the Board is to hear the parties' cases and only thereafter to decide. It is not, as the Appellant appeared to believe, to say which of two or more alternatives it prefers (see section XIII 4.1 above) or to suggest deletions of claims from otherwise acceptable requests (see section XIII 1.3 above) or to provide interim decisions so as to allow a patentee to combine requests (see section XIII 2.3 above). To the extent a Board provides any opinion before its final decision, it can quite clearly only be provisional and not binding, as indeed the law states (see Article 17(2) RPBA). In the present case, this was also expressly stated in the Board's communication (see section X above) which also drew the parties' attention to the provisions of Articles 12 and 13 RPBA which include the complete case requirement and the provisions on amendment of a party's case (see points 1 to 3 above).

The Appellant argued that, if it was not allowed to file auxiliary requests 13 and 14 which it produced at

the oral proceedings, it would be disadvantaged by being denied the right to be heard. The Board's view is quite to the contrary namely that, if it had complied with the Appellant's approach, it would have inevitably assisted the Appellant to the disadvantage of the respondents.

Accordingly, the Appellant's request to introduce auxiliary requests 13 and 14 at the oral proceedings was denied.

Main request and auxiliary requests 1 to 10

Amendments - Article 123(2) EPC

10. The only objections raised by the Respondents and dealt with by the Board during the entire appeal procedure with regard to claim 1 of these requests concerned the following two features:

"wherein the amino acid stabilizing agent is present at between 0.3% and 5% w/v" in claim 1 of the main request and of auxiliary requests 2, 3, 4, and 5; and

"wherein the liquid composition does not comprise serum albumin" in claim 1 of the main request and of auxiliary requests 1, 2, 4, 5 and 6.

11. Claim 1 of the original application, published as WO 98/28 007, reads:

"A liquid composition comprising an interferon and a stabilizing agent at between about 0.3% and 5% by weight which is an amino acid selected from the group

consisting of acidic amino acids, arginine and glycine, wherein the liquid composition has not been previously lyophilized."

The same wording can be found on page 2, lines 25 to 28 of the application as published.

12. The Respondents argued that, according to the general understanding of a skilled person, this disclosure referred to 0.3% to 5% on a weight/weight (w/w) basis, which was different from the range indicated in claim 1, namely "0.3% to 5% w/v" (weight/volume). The application as published did not provide a basis for this newly introduced feature with the consequence that a claim containing it contravened the requirements of Article 123(2) EPC.

The Respondent also argued that this was obvious from the French translation of the application as published and from prior art document (32), a European patent referring to liquid formulations containing interferon-beta. Claim 1 of document (32) contained a disclaimer excluding the presence of arginine or glycine in a weight percentage between 0.3 and 5%. It was clear from document (33), a communication of the Examining Division, that the disclaimer was added to exclude the disclosure of the present application as published (WO 98/28 007).

13. Claim 1 refers to a liquid composition. The indication of the amount of a component contained in this liquid composition in % w/w (gram/100 gram) would be most unusual and unpractical. Especially in the case of liquid compositions for pharmaceutical use where the

practitioner and/or the patient have to know the exact amount of an active substance contained in the volume to be administered, the indication of constituent amounts on a w/w basis is very unlikely.

In the passage directly following page 2, lines 25 to 28 (see point 11 above), the application as published discloses preferred embodiments of the claimed invention wherein the amounts of all ingredients of the liquid compositions are indicated as weight/volume (w/v) (page 3, lines 1 to 11); the same applies to page 11, lines 13 to 19. The description of all liquid formulations in the examples of the application as published indicates the amount of their ingredients as % (w/v) (pages 14 to 16; examples 1 to 9 starting on page 18).

14. The Board is convinced that a skilled person willing to understand the application as published and trying to arrive at an interpretation which is technically sensible and takes into account the whole disclosure (cf. decision T 190/99 of 6 March 2001) will arrive at the conclusion that the application as filed, whenever it refers to the amount of an ingredient contained in the liquid formulations, indicates it as w/v.

15. As the language of the original application as published is English, Respondents' argument that the interpretation of a technical term used therein should be considered in the light of the text of its French translation is without merit.

The Board does not see how a disclaimer in another patent, which is aiming to exclude the disclosure of

the patent in suit, should have any bearing on the Board's decision on the allowability of an amendment in the present case.

Thus, the feature "wherein the amino acid stabilizing agent is present at between 0.3% and 5% w/v" in claim 1 of the main request and of auxiliary requests 2, 3, 4, and 5 does not violate the requirements of Article 123(2) EPC.

16. The sentence bridging pages 1 and 2 of the application as published discloses that pharmaceutical interferon compositions for clinical use commonly contain interferon as a lyophilized preparation in combination with complex organic excipients and stabilizers such as human serum albumin.

On page 4, first paragraph, various advantages of the claimed liquid formulations over lyophilized products are given. In point (ii) it is said that "**replacement** of complex excipients with simple amino acids makes it possible to monitor finished product quality more closely" (page 4, lines 3 to 5; emphasis added by the Board). In table 1 and on pages 14 and 15, four "preferred formulations" are disclosed; none of them contains human serum albumin or another complex organic excipient or stabilizer. However "alternate formulations" disclosed on table 2 on page 16 contain human serum albumin and Pluronic F-68.

According to page 4, lines 23 to 25, it is a **further object** of the invention to use simple amino acids as alternate stabilizers besides commonly used serum albumin.

17. The Board arrives at the conclusion that the application as published, according to a first aspect of the invention, discloses liquid compositions comprising interferon beta and an amino acid stabilizing agent wherein the amino acid replaces complex excipients and does not therefore contain human serum albumin. According to a second embodiment the liquid compositions contain an amino acid stabilizer in addition to commonly used serum albumin.

Therefore, the feature "wherein the liquid formulation does not comprise human serum albumin" in claim 1 of the main request and of auxiliary requests 1, 2, 4, 5 and 6 does not violate the requirements of Article 123(2) EPC.

Amendments - Article 123(3) EPC

18. Claim 37 (and claims 38 to 40 dependent thereon) of the application as published refer to a kit for parenteral administration of a liquid interferon formulation. Contrary to this, claims 1 to 69 as granted do not contain such claim. The independent claims as granted refer to a liquid composition (claim 1), to a liquid pharmaceutical composition (claim 32) and to methods for stabilizing interferon in a liquid pharmaceutical composition (claims 43 and 58).

Claim 1 of Appellant's main request and of each of auxiliary requests 1 to 10 refers to "[A] packaged kit for parenteral administration of an interferon-beta, the kit containing a syringe pre-filled with a liquid

composition comprising the interferon-beta and an amino acid stabilizing agent ...".

19. Article 123(3) EPC provides that during opposition proceedings the claims of the European patent may not be amended in such a way as to extend the protection conferred upon grant. The object of Article 123(3) EPC is to prevent any procedural situation where an act which does not infringe the patent as granted becomes an infringing act as a result of an amendment after grant (cf also T 59/87, OJ EPO 1988, 347, reasons point 2; T 604/01 of 12. August 2004, reasons point 2.3). In accordance with the established case law of the Boards of Appeal (cf. T 49/89 of 10 July 1990, reasons point 3.2.2; T 402/89 of 12 August 1991, reasons point 2), the Board holds that the legal notion "protection conferred" in Article 123(3) EPC refers to the totality of protection established by the claims as granted and not necessarily to the scope of protection within the wording of each single claim as granted. Under Article 123(3) EPC, the patentee is generally allowed to redraft, amend or delete the features of some or all claims and is not bound to specific terms used in the claims as granted as long as the new wording of the claims does not extend the scope of protection conferred as a whole by the patent as granted (and does not violate the requirements under Article 123(2) EPC). Thus, in order to assess any amendment under Article 123(3) EPC after grant, it is necessary to decide whether or not the totality of the claims before amendment in comparison with the totality of the claims after amendment extends the protection conferred.

20. There are basically two different types of claims, namely claims to a physical entity (e.g. product, apparatus) and claims to a physical activity (e.g. method, process, use). These two basic types of claims are referred to as the two possible "categories" of claims. Within these two basic types of claims various sub-classes are possible (e.g. a compound, a composition, a machine; or a manufacturing method, a process of producing a compound, a method of testing, etc.); (see decision of the Enlarged Board of Appeal G 2/88, OJ EPO 1990, 93).

Decision G 2/88, which was relied on by the Appellant in order to substantiate its argument that in the present case the scope of protection has not been expanded, is concerned with the considerations to be taken into account when deciding, with regard to Article 123(3) EPC, on the admissibility of amendments involving a change of category (from a "compound" claim to "use of that compound in a composition for specified purpose").

That situation differs from the one underlying the present case. Here claim 1 of the main request refers to a physical entity (a packaged kit). Also claims 1 and 32 of the claims as granted refer to a physical entity, namely a liquid composition, and belong therefore to the same "category". Claims 43 and 58 of the granted claims refer to a physical activity.

The relevant change in claim 1, from a liquid composition to a packaged kit, is not therefore a change in "category", but a change of sub-class within the same "category".

21. The Appellant argued that a claim referring to a packaged kit containing the liquid composition of claim 1 as granted is in fact narrower in scope than a claim referring to the liquid composition, as this claim encompasses the liquid formulation in any possible container, vessel, package or reservoir. Moreover, granted claim 3 already referred to a liquid composition contained in a vessel, which according to claim 13 was defined as being a syringe.

22. The Board agrees with the Appellant in so far as the scope of protection covered by a claim referring to a physical entity should be considered to encompass the physical entity in any possible package or container. However, it is self-evident that "a packaged kit" is a different physical entity than "a liquid composition". It must not be overlooked that claim 1 of the main request is not directed to "a liquid composition contained in a packaged kit" but to "a packaged kit containing a syringe pre-filled with a liquid composition." In the Board's view the content of a package is not a characterising feature of the package per se. This has the consequence that the scope of protection covered by claim 1 of the main request also encompasses the "packaged kit", being a box, package or other container, whether it comprises a syringe pre-filled with the liquid composition according to the present invention or not.

Thus, a procedural situation is created where an act, for instance the production of the box, package or other container, which did not infringe the patent as granted becomes an infringing act as a result of an

amendment after grant (cf T 59/87 and T 604/01, supra). Exactly this situation should be prevented by the requirements of Article 123(3) EPC.

23. The Appellant submitted that a negative decision on this issue would be contradictory to the case law of the Boards of Appeal and would therefore require a referral of questions to the Enlarged Board of Appeal according to Article 112(1)(a) EPA.

It referred in this respect to decision T 579/01 of 30 June 2004, taken by this Board in a different composition.

In this case independent claim 1 and dependent claims 2 to 6 of the new main request were directed to a "vegetable plant", while the respective claims as granted were directed to a "cell in a vegetable plant". The Board said that in the understanding of the skilled person the term "a cell of a plant", not being qualified as "isolated", included various physiological and morphological states of such a cell, including both differentiated and undifferentiated states. The cells in the different states in which they existed in a (developing) plant fell within the protection conferred by the claim to the "cell of a vegetable plant" as granted, and the protection conferred by such claim also extended to such cells in a plant. Furthermore, the biological notion "cells of a plant" encompassed such differentiated cells which were morphologically and functionally organised to constitute a plant. That implied that morphologically and functionally organised aggregates of plant cells, e.g. plants, likewise fell within the protection conferred by the granted claim to "a cell of a plant". The Board also decided that **any**

plant as subject-matter of claim 1 of the new main request fell within the protection conferred by a claim to "a cell of a plant", and finally that the "plant" now claimed was characterised by the same genetic features as recited in the granted claim to "a cell of a plant". The Board also decided that any plant as subject-matter of claim 1 of the new main request fell within the protection conferred by a claim to "a cell of a plant", and finally that the "plant" now claimed was characterised by the same genetic features as recited in the granted claim to "a cell of a plant".

This situation differs drastically from the present one, where it goes without saying that a liquid composition does not differentiate and develop into a packaged kit, and that these two entities are not characterised by the same genetic features.

Accordingly decision T 579/01 (supra) does not apply to the present case.

24. A further decision referred to was T 352/04 of 11 October 2007. In this case claim 1 as granted referred to a hair conditioner, characterised by its components, while amended claim 1 referred to the hair conditioner characterised by its components, wherein the conditioner took the form of an aerosol hairspray or of a non-aerosol hairspray **with** a mechanically driven spraying device ("... oder wobei das Mittel in Form eines Non-Aerosol-Haarsprays **mit** einer mechanisch betriebenen Sprühvorrichtung vorliegt"; emphases added by this Board).

Both claim 1 as granted and claim 1 as amended refer to a hair conditioner, thus they belong to the same subclass within the same "category" of claims (see point (11) above).

As this situation differs from the present one (see point (11) above, third paragraph), decision T 352/04 (supra) has no bearing for the main request.

25. In the light of the above considerations (see especially point (22) above), the Board arrives at the decision that the patent according to Appellant's main request has been amended in a way as to extend the protection it confers.

The main request violates the requirements of Article 123(3) EPC. The same applies to auxiliary requests 1 to 10.

26. Having reached this decision without seeing any contradiction to the relevant case law of the Boards of Appeal, the Board has no reason to consider the referral of questions to the Enlarged Board of Appeal according to Article 112(1)(a) EPC.

Auxiliary requests 11, 12 and 15

Amendments - Articles 123(2) and 123(3) EPC, Rule 80 EPC

Clarity - Article 84 EPC

27. Both, the claims as granted and those of auxiliary request 11 relate to a liquid composition. The Respondents have not put forward any objection under Article 123(2) EPC. The Board also has none.

28. The claims differ from the claims as granted in so far as the amino acid stabilizing agents contained in the liquid formulation have been defined and their amount has been reduced and adapted to the application as published.

Furthermore, when compared with claim 1 as granted, claims 1 and 37 of auxiliary request 11 have been amended by adding a feature requiring that the syringe containing the liquid composition is contained in a packaged kit. Whether or not this feature is a technically characterizing feature of the claimed liquid formulations will have to be decided when dealing with the issues of novelty and inventive step (Articles 54 and 56 EPC). However, the Board is convinced that it does not contribute to an extension of protection conferred by the claims when compared to the claims as granted.

29. The Board is aware of decision T 352/04 of Board 3.3.07 (supra) where it was decided that a claim to a hair conditioner characterised by its components, wherein the conditioner took the form of an aerosol or a non-aerosol spray **with** a mechanically driven spraying device ("... oder wobei das Mittel in Form eines Non-Aerosol-Haarsprays **mit** einer mechanisch betriebenen Sprühvorrichtung vorliegt"; emphasis added by this Board) contravened the requirements of Article 123(3) EPC as the scope of protection has been extended when compared to the claims as granted which referred to the hair conditioner characterised by its components only.

In point 2.9 of the decision Board 3.3.07 held that the introduction of the mechanical spraying device into claim 1 had the effect that a further physical entity which was absolutely independent from the cosmetic composition was covered by the claim with the unavoidable consequence that the scope of protection was extended.

It is clear from point 2.9.2, first sentence that Board 3.3.07 was of the opinion that the scope of protection of amended claim 1 encompassed a mechanically driven spraying device containing a cosmetic hair conditioner. This interpretation of the claim corresponds with the actual wording of claim 1 of the present main request (a packaged kit containing a syringe pre-filled with the liquid composition).

The present Board can only assume that this interpretation of the amended claim in case T 352/04, which in fact still referred to a hair conditioner, resulted from its specific language, referring to a hair conditioner in the form of a non-aerosol **with** a spraying device.

This specific language is not part of the claims of auxiliary request 11, which refer to a liquid composition, or a method for preparing it, wherein the liquid is contained in a syringe which is contained in a kit. The Board is therefore of the opinion that decision T 352/04 does not apply to the present case.

30. Article 84 EPC is not in itself a ground for opposition under Article 100 EPC. Accordingly, in opposition/appeal procedures the examination of the

requirements of Article 84 EPC is restricted to newly introduced features, i.e. features not already present in the claims as granted.

The only new feature contained in the claims of auxiliary request 11 which was not present in the claims as granted is the one requiring that "the syringe is contained in a packaged kit". The Board is satisfied that the meaning of this feature in itself is clear and does not give rise to a violation of the requirements of Article 84 EPC.

31. The Appellant has introduced these amendments as attempts to overcome objections raised under Articles 54 and 56 EPC which both are grounds for opposition under Article 100 EPC. It is not a requirement of Rule 80 EPC that such attempts are successful.
32. Accordingly, auxiliary request 11 meets the requirements of Articles 84, 123(2) and 123(3) EPC and Rule 80 EPC.

The same applies to auxiliary request 12, wherein claim 1 no longer contains the feature "wherein the liquid composition does not comprise serum albumin" (see points 7 and 8 above) and wherein claims 28 to 36 of auxiliary request 11 have been deleted and to auxiliary request 15, which contains a further additional feature in independent claims 1 and 28, which is disclosed in claim 15 as granted and causes a further restriction of the scope of protection.

Novelty - Article 54 EPC

33. Claim 1 of auxiliary request 11 refers to a liquid composition which
- (a) comprises an interferon-beta,
 - (b) comprises an amino acid stabilizing agent selected from the group consisting of 0.5% to 5% (w/v) arginine-HCl, 0.50% to 2.0% (w/v) glycine, and 1.47% to 2.94% (w/v) glutamic acid,
 - (c) has not been reconstituted from lyophilized interferon,
 - (d) is not further lyophilized,
 - (e) does not comprise serum albumin,
 - (f) is contained within a syringe,
 - (g) wherein the syringe has a head space flushed with inert gas, and
 - (h) wherein the syringe is contained in a package.

Feature (e) is not present in claim 1 of auxiliary request 12 and 15. Claim 1 of auxiliary request 15 contains the following additional feature

- (i) wherein if the amino acid stabilizing agent is glycine, then the liquid composition further comprises a salt.
34. The claims shall define the matter for which protection is sought in terms of the technical features of the invention (Rule 43(1) EPC).

The primary aim of the wording used in a claim must therefore be to satisfy such requirements, having regard to the particular nature of the subject

invention, and having regard also to the purpose of such claims. It follows that the technical features of the invention are the physical features which are essential to it. When considering the two basic types of claims (e.g. claims to physical entities and claims to physical activities; see point (20) above), the technical features of a claim to a physical entity are the physical parameters of the entity (decision G 2/88 supra, point 2.5).

In the present case, the physical parameters defining the structure of the claimed liquid formulation are described in features (a), (b), (e) and (i) (see point (33) above).

35. According to established case law of the Boards of Appeal, a product can also be defined in a claim in terms of a process for its production ("product-by-process" claim). However, such claims are admissible only if the product itself fulfils the requirements of patentability (see Case law of the Boards of Appeal of the EPO, 5th Edition 2006, chapter II.B.6).

The combination of product parameters and process parameters in one and the same claim has been considered to be admissible (decision T 148/87 of 24 November 1989).

In the present case feature (c) is considered to refer to the process of producing the claimed liquid composition (see point (33) above).

36. Feature (d), referring to a process step, performed, or rather not performed, on the claimed entity after

providing it in the claimed form, does not contribute to the characterisation of the claimed physical entity.

Features (f), (g) and (h) characterise a container, i.e. a syringe, filled with the claimed physical entity and a further container, i.e. a packaged kit, comprising the syringe. The features do not define the claimed product but describe merely the form in which it is presented.

It follows that features (d), (f), (g) and (h) are not technical features of the claimed liquid formulation in the sense of Rule 29(1) EPC and decision G 2/88 (supra). These features will not be taken into consideration for the examination of novelty under Article 54 EPC.

37. Document (2) refers to pharmaceutical compositions of recombinant beta-interferon and formulation processes. The disclosed formulations are for parenteral administration (page 12, line 25) and are in liquid form or lyophilized (page 22, lines 5 to 6 and claim 3). According to claim 2, the compositions comprise an additional solubilising or stabilizing agent. The list of these additional stabilising agents disclosed on page 24, first full paragraph, includes glycine.

Example 15 (see page 66, lines 12 to 28) discloses a liquid composition containing interferon beta and 2% w/v glycine. The composition does not comprise serum albumin and has not been reconstituted from lyophilized interferon.

Consequently, the subject-matter of claim 1 of auxiliary request 11 is anticipated by the disclosure in document (2).

38. The same applies to the subject-matter of claim 1 of auxiliary request 12.

The pH of the liquid composition according to example 15 of document 2, containing 2% w/v glycine, which by its nature is an acid, is raised to about 6.0 with NaOH, which is a base (page 66, lines 22 to 23).

It belongs to the basic general knowledge of a chemist that upon mixture of an acid with a base a salt is formed, in the present case sodium glycinate.

Therefore, the subject-matter of claim 1 of auxiliary request 15 is also anticipated by the disclosure in document (2).

39. Auxiliary requests 11, 12 and 15 do not meet the requirements of Article 54 EPC.

Auxiliary request 16

40. The requirements of Articles 84, 123(2) and 123(3) EPC and of Rule 80 EPC are met for the reasons given in points (27) to (32) above.

None of the Respondents had put forward an objection under Article 83 EPC, sufficiency of disclosure. The Board has no such objection either.

Novelty - Article 54 EPC

41. The amino acid stabilizing agent contained in the liquid composition according to the claims of auxiliary request 16 is defined as being 0.5% to 5% (w/v) arginine-HCl. The only document discussed with regard to the issue of novelty of claims 1 to 41 of auxiliary request 16 was document (6).

This document refers to a method for increasing the solubility of lyophilized interferon of any of types alpha, beta or gamma, in water using an amino acid selected from a group of eight amino acids and salts thereof. The list includes arginine (page 2, lines 26 to 32 and claims 1 and 2).

Examples 1 to 3 and 5 describe the reconstitution of lyophilized interferon-gamma in distilled water and an amino acid solution containing arginine-HCl (3% (w/v) in example 1; 4% (W/v) in example 3).

42. Thus, document (6) does not contain an explicit disclosure of a liquid solution containing interferon-beta and arginine.

According to established case of the Boards of Appeal, in cases where two classes of substances are required to prepare the claimed end product, and examples of individual entities in each class were given in two lists of some length, the substance resulting from the reaction a specific pair from the two lists could be regarded for patent purposes as a selection and, hence, as new (see Case Law of the Boards of Appeal of the EPO, 5th Edition 2006, Chapter I.C.4.1.1(b)).

43. The subject-matter of claims 1 to 41 of auxiliary request 16 is therefore novel and meets the requirements of Article 54 EPC.

Inventive step - Article 56 EPC

Closest prior art

44. In accordance with the problem and solution approach, the boards have developed certain criteria for identifying the closest prior art to be treated as a starting point. After the relevant prior art has been identified, careful consideration must be given to the question whether, in the case concerned, the skilled person, taking into account all the available information on the technical context of the claimed invention, would have had good reason to take this prior art as the starting point for further development. The boards have repeatedly pointed out that the closest prior art for assessing inventive step is normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications. A further criterion for the selection of the most promising starting point is the similarity of the technical problem.
45. It follows that a prior art disclosure not mentioning a technical problem which is at least related to that derivable from the specification under examination does not normally qualify as the closest prior art, however

many technical features it may have in common with the claimed subject-matter (cf. T 686/91 of 30 June 1994, point 4 and T 835/00 of 7 November 2002, point 4).

46. In the present case the subjective technical problem the invention sets out to solve is the provision of a liquid formulation of interferon-beta permitting storage for a long period of time and facilitating storing and shipping prior to administration. Said liquid formulation should be easily made and administered having eliminated lyophilisation and reconstitution steps (application as published, page 4, lines 18 to 22 and paragraph [0017] of the patent).
47. In view of the principle referred to in point 37 above, document (6) which was considered as closest prior art in the decision under appeal (see point 17 thereof) cannot be accorded that status because it does not mention any of the problem aspects of the claimed invention but instead relates to a method for solubilisation of lyophilized interferon. No incentive can thus be gained from document (6) by the skilled person with regard to the achievement of the objectives of the patent in suit.
48. Instead the Board considers document (2) to represent the closest state of the art because it relates to the provision of highly stable liquid pharmaceutical compositions suitable for parenteral administration comprising interferon-beta and an additional solubilising/stabilizing agent. The liquid compositions disclosed are said to have a good shelf life (see page 12, lines 25 to 31, page 22, lines 5 to 6 and page 68, lines 18 to 19).

Obviousness

49. With respect to the closest prior art disclosed in document (2) which discloses carbohydrate stabilizing agents and non-carbohydrate stabilizing agents including for example human serum albumin and glycine (document (2), page 24, lines 11 to 23), the technical problem objectively to be solved by the patent in suit is the provision of an alternative form of a liquid interferon-beta formulation which can be stored for a long period and which is easily made and administered.

Considering the results of the experiments disclosed in the patent (especially examples 6 to 9), the Board is satisfied that this problem has been solved by the subject-matter claimed.

50. The Respondents' argument that this was not the problem underlying the invention because it was not mentioned in the claims is without merit. According to the Board's knowledge there is no legal basis in the EPC requiring an Applicant to state the problem underlying its invention in the claims.

51. The subject-matter of claim 1 of auxiliary request 16 is distinguished from the disclosure in document (2) by the fact that arginine-HCl is used as stabilizing agent.

Document (2) itself does not contain any hint that would motivate a skilled person to amend the disclosure and to replace the stabilising agents disclosed therein by arginine-HCl.

52. The Respondents argued that a skilled person, knowing that solubilisation and stabilisation both rely on similar physical principles, namely the prevention of aggregate formation, would turn to document (6) and replace the amino acid glycine disclosed in document (2) by the amino acid arginine. The skilled person would not be prevented from doing so by the fact that the examples of document (6) refer to the reconstitution of lyophilized interferon-gamma, rather he/she would assume that these results can be easily transferred to the use of a different interferon, namely interferon-beta.

53. The application as published highlights at various positions the strong correlation between the ionic (charged) character of the used amino acid and its ability to stabilize interferon beta (cf. page 10, line 31 to page 11, line 4 and page 26, lines 11 to 20).

Document (6), while referring to a technical problem entirely unrelated to the one underlying the patent in suit, discloses the use of eight different amino acids and salts thereof for increasing the reconstitution of lyophilized interferon. The group of eight different amino acids indicated in claim 1 contains amino acids with electrically charged side chains such as arginine, histidine and lysine, but also amino acids with polar uncharged side chains, such as glutamine.

Concerning Respondents' argument that experimental results obtained for the solubilisation of interferon-gamma are of high significance also for other

interferons and will therefore be considered for the solution of the problem underlying the present patent, the Board notes that this view is not commonly shared in the art. Document (7), relating to stabilization of aqueous solutions containing interferon-alpha using a non-ionic detergent and benzyl alcohol, refers on page 2, lines 27 to 29 to document WO 94/26 302, which is document (19) in the present case. It is highlighted that document (19) discloses aqueous interferon-gamma solutions containing the same preservatives, but that it does not contain any suggestion to make a substitution of interferon-gamma for interferon-alpha.

Thus, even in the unlikely event that a skilled person, trying to solve the problem underlying the patent in suit, would turn to document (6) at all, which is aiming at a different purpose, he/she would get no hint or suggestion, first, to chose from a list of eight different amino acids one with charged side chains and, second, to use it for the stabilization of liquid compositions comprising interferon-beta.

54. The Board, therefore, arrives at the decision that a skilled person, trying to solve the problem underlying the patent would not arrive at the subject-matter of claims 1 to 41 of auxiliary request 16 in an obvious way, whether by combining the teaching in document (2) with the disclosure in document (6) or in any other prior art document on file.

The subject-matter of auxiliary request 16 involves an inventive step and meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of claims 1 to 41 of auxiliary request 16 filed on 19 April 2010 and a description and figures to be adapted thereto.

The Registrar

The Chairman

E. Görgmaier

C. Rennie-Smith