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Datasheet for the decision of 27 February 2013

Case Number: T 0493/09 - 3.3.04

Application Number: 96936938.8

Publication Number: 858343

IPC: A61K 38/21, A61K 38/19, A61K 38/18

Language of the proceedings: EN

Title of invention:
Continuous low-dose cytokine infusion therapy

Patent Proprietor:
Merck Sharp & Dohme Corp.

Opponents:
Sandoz AG
Krauss, Jan B.

Headword:
Hepatits C/MERCK SHARP & DOHME CORP.

Relevant legal provisions:
EPC Art. 54, 113(1), 123(2)(3)
RPBA Art. 13(1)

Keyword:
"Violation of the right to be heard (no)"
"Late submissions - admitted (no)"
"Main request: amendments - allowable (yes); novelty (no)"

Decisions cited:
T 0301/87, T 0853/02, T 1459/05

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0493/09 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 27 February 2013

Appellant I: (Opponent 2)
Sandoz AG
Lichtstrasse 35
CH-4056 Basel (CH)

Representative:
Breuer, Markus
Henkel, Breuer & Partner
Patentanwälte
Erika-Mann-Straße 23
D-80636 München (DE)

Appellant II: (Opponent 3)
Krauss, Jan B.
Forrester & Boehmert
Pettenkoferstrasse 20-22
D-80336 München (DE)

Representative:
Krauss, Jan B.
Boehmert & Boehmert
Pettenkoferstrasse 20-22
D-80336 München (DE)

Respondent: (Patent Proprietor)
Merck Sharp & Dohme Corp.
126 East Lincoln Avenue
Rahway, NJ 07065-0907 (US)

Representative:
Taormino, Joseph
HOFFMANN EITLE
Patent- und Rechtsanwälte
Arabellastraße 4
D-81925 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 19 December 2008 concerning maintenance of European patent No. 858343 in amended form.**

Composition of the Board:

Chairman: C. Rennie-Smith
Members: R. Morawetz
G. Alt

Summary of facts and submissions

I. The appeals by opponent O2 (hereinafter "appellant I") and opponent O3 (hereinafter "appellant II") lie against the interlocutory decision of the opposition division posted on 19 December 2008, whereby European patent No. EP 0 858 343 was maintained in amended form on the basis of the main request filed by fax on 24 November 2008.

II. The patent at issue has the title "Continuous low-dose cytokine infusion therapy". It was granted on European patent application No. 96936938.8 which originated from International patent application No. PCT/US1996/017085 published as WO 1997/016204 (hereinafter "application as filed").

Claim 1 as granted read as follows:

"1. The use of interferon alpha in the manufacture of a medicament for treating a hepatitis C viral infection in a human, wherein said medicament is to be administered to the human in an amount of the interferon alpha of from 2 million IU per week to 10 million IU per week; wherein the administration maintains serum concentrations of the interferon alpha at a steady state for the duration of the treatment."

III. The patent was opposed under Article 100(a) EPC 1973 on the grounds of lack of novelty (Article 54 EPC 1973) and lack of inventive step (Article 56 EPC 1973), under Article 100(b) EPC 1973 and under Article 100(c) EPC 1973 on the ground of added subject-matter (Article 123(2) EPC 1973).

IV. The opposition division maintained the patent in amended form on the basis of the main request (which is identical to the present main request). Claim 1 of the main request reads as follows (amendments compared to claim 1 as granted indicated in bold by the board):

"1. The use of interferon alpha**-2b** in the manufacture of a medicament for treating a **chronic** hepatitis C viral infection in a human, wherein said medicament is to be administered to the human **for at least 4 weeks** in an amount of the interferon alpha**-2b** of from 2 million IU per week to 10 million IU per week; wherein the administration maintains serum concentrations of the interferon alpha**-2b** at a steady state for the duration of the treatment."

V. The opposition division decided that the claims of the main request found a basis in the application as filed. The opposition division considered that new Article 101(3)(b) EPC did not alter the established practice that during opposition proceedings unamended parts of the patent could not be attacked under Article 84 EPC. Accordingly it did not allow any discussion of the feature "steady state" under Article 84 EPC during the oral proceedings (see minutes, page 2, end of first paragraph). The opposition division took the view that no steady state could be achieved when the half life of the drug was much smaller than the interval of administration. None of the documents cited by the appellants were considered to anticipate the subject-matter of the main request since they did not disclose an administration which would maintain interferon alpha-2b at a "steady state".

VI. Appellant I filed its statement of grounds on 29 April 2009 and submitted that the opposition division violated its right to be heard by not allowing for a discussion of the feature "steady state" under Article 84 EPC and requested that the interlocutory decision be set aside, the patent be revoked and the fee for filing the appeal be reimbursed.

VII. Appellant II also filed its statement of grounds on 29 April 2009 and submitted substantial arguments why the main request lacked basis in the application as filed, lacked novelty and lacked an inventive step.

VIII. The respondent filed its response to the statements of grounds of appeal of both appellants on 4 September 2009.

IX. On 7 August 2012 appellant II filed a further written submission, which was said to be in response to the respondent's reply of 4 September 2009, together with three additional documents (OD43 to OD45). This submission made substantial observations (see pages 1 to 32) on all the issues raised in the statements of grounds of appeal of both appellants, summarised the appellant's conclusions (see page 32), and finally stated (see page 33): "Thus, there are multiple reasons, each of which warrants revocation of the patent. Since these reasons have not been adequately considered in the Opposition Proceedings, it is requested that the interlocutory decision be set aside, the patent be revoked in its entirety, and the fee for filing the appeal fee be reimbursed."

X. By a communication of 29 November 2012 the parties were summoned to oral proceedings to be held on 27 February 2013.

XI. In a letter of 4 January 2013 appellant I informed the board that it would not attend the oral proceedings.

XII. By its letter of 25 January 2013 the respondent informed the board that it did not maintain its request for oral proceedings and would not attend the oral proceedings.

XIII. On 7 February 2013 the board issued a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) in which it introduced document (D46) in the appeal proceedings and expressed its provisional, non-binding views on some of the relevant issues.

XIV. In a letter of 25 February 2013 appellant II informed the board that it would not attend the oral proceedings.

XV. Oral proceedings were held on 27 February 2013 in the absence of the parties.

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

(OD11) Arzneimittelwirkungen, Mutschler E., 1991, pages 42-44

(OD14) Causse X. et al., Gastroenterology 1991, vol. 101, pages 497-502

(OD15) Davis G.L. et al., N Engl J Med 1989, vol. 321, pages 1501-1506

(OD16) Marcellin, P. et al., Hepatology 1991, vol. 13, pages 393-397

(D46) Pharmacokinetics, 1982, second edition, Milo Gibaldi and Donald Perrier, pages 113 to 143

XVII. The submissions by the appellants can be summarized as follows:

Violation of the right to be heard (Article 113(1) EPC)

Appellant I submitted that the opposition division violated its right to be heard by not allowing it to present arguments at oral proceedings under Article 84 EPC with regard to the feature "steady state". Article 101(3)(b) EPC did not allow the unamended parts of a patent amended during opposition proceedings not to meet the requirements of the Convention.

Decision T 1459/05 of 21 February 2008 supported the view that features, present in the claims as granted might be subject to a revocation for formal reasons, i.e. in respect of Article 84 EPC, if the claims have been amended.

Main (sole) request
Amendments (Articles 100(c) and 123(2) EPC) - claim 1

The combination of the features in claim 1 could not be directly and unambiguously derived from the application as filed.

Interpretation of claim 1

In the decision under appeal the term "steady state" had been interpreted to cover both a "true steady state" and a "pseudo steady state", as defined in document (OD11). Document (OD11) referred to "pseudo-steady state" as a state wherein the serum concentrations fluctuated between maximal and minimal concentrations. Document (OD11) further taught that a pseudo-steady state might be achieved by administering a drug in administration intervals shorter than the half life of the drug. This did not exclude the administration of a drug in an interval longer than the half life of the drug from achieving a steady state. As a consequence, "steady state" did not just relate to a state which could be reached via drop-infusion or via repeated administration of a drug in intervals shorter than the half life of the drug. The term "steady state" was to be construed in the broadest possible sense (cf. decision T 882/01, reasons 4). In the absence of a clear teaching as regarded possible administration intervals in the patent description any administration leading to a state in which the drug came to oscillate between unknown minimal and maximal concentrations resulted in a steady state in the sense of the opposed patent. The patent specification did not contain any teaching with respect to any deviations within the "steady state" during the time of treatment, such deviations were thus comprised within the "steady state" during the time of treatment. The patent had to be construed to mean that any long term pharmacotherapy would lead to steady state serum concentrations.

Novelty (Article 54 EPC)- claim 1

Any mode of administration upon which the drug oscillated between an unknown minimum and an unknown maximum inevitably led to a steady state. Documents (OD14), (OD15), and (OD16) disclosed that at the date of priority of the patent in suit the recommended therapy of chronic hepatitis C was 1 to 3 MIU interferon alpha given three times a week for 6 months, which corresponded to an administration of interferon alpha in the range from 2 to 10 MIU per week as defined in claim 1. Consequently these documents anticipated the subject-matter of claim 1.

XVIII. The submissions by the respondent can be summarized as follows:

Violation of the right to be heard (Article 113(1) EPC)

The purpose of Article 101(3)(b) EPC was clear from the Special Edition No. 4 of the Official Journal of the EPO, 2007. Article 101(3)(b) EPC did not provide any basis whatsoever for re-examining the principles laid down in the established case law such as decision T 301/87 with regard to the examination of Article 84 EPC in opposition. In the present case, the feature "steady state" was in claim 1 as granted and had not been added or amended. Decision T 1495/05 was irrelevant to the present case.

Main (sole) request
Amendments (Articles 100(c) and 123(2) EPC) - claim 1

Support for claim 1 could be found in the application as originally filed in claims 1, 3, 11 to 13 and 19 as well as page 8, lines 19 to 23, the paragraph bridging pages 9 and 10; page 11, line 26 to page 12, line 2 and the example, especially page 13, lines 21 to 23.

Interpretation of claim 1

The interpretation of the term "steady state" to mean a "serum concentration oscillating between a minimum and a maximum concentration" or a state in which "drug concentration oscillates between an unknown minimum and an unknown maximum concentration" was completely far-fetched. Based on the description per se and the common general knowledge as exemplified by document (OD11) the meaning of the term "steady state" was clear and excluded an understanding of the term "steady state" by the average skilled person as one in which the serum concentrations of interferon could vacillate, for example, over a 50-fold level within 40 hours.

Novelty (Article 54 EPC)- claim 1

The original application contained a discussion on page 3 of various prior art documents including documents (OD14) to (OD16), and expressed a need to improve hepatitis C therapy over the therapy disclosed in these documents. Thus, the application as filed did not understand, and the average skilled person would not have understood, the teaching in these documents to represent a "steady state" within the meaning of the

patent because the application differentiated itself from the teaching in these documents. None of the documents (OD14) to (OD16) anticipated the claimed subject-matter because none of these documents described the administration of interferon alpha-2b wherein the administration maintained serum concentrations of interferon alpha-2b at a steady state for the duration of the treatment as required by claim 1 of the main request.

XIX. Appellants I and II have requested that the decision under appeal be set aside, that the patent be revoked and that their appeal fees be reimbursed.

XX. The respondent has requested that the appeals be dismissed.

Reasons for the decision

Violation of the right to be heard (Article 113(1) EPC)

1. Appellant I submitted that it followed from Article 101(3)(b) EPC that after amendment during opposition proceedings **all** parts of a patent - and thus also parts which had not been amended - had to meet the requirements of the Convention including Article 84 EPC. Therefore the opposition division had violated its right to be heard by not allowing it to present arguments at oral proceedings under Article 84 EPC with regard to the feature "steady state".

2. Article 101(3)(b) EPC stipulates that if the opposition division is of the opinion that, taking into

consideration the amendments made by the proprietor of the European patent during the opposition proceedings, the patent and the invention to which it relates do not meet the requirements of this convention, it shall revoke the patent.

3. Article 101(3)(b) EPC has no counterpart in the EPC 1973, but is a new Article introduced with the EPC 2000 to add a clarifying point, see Special Edition No. 4 OJ EPO 2007. It is stated with regard to Article 101(3)(b) EPC on page 110 that "*New Article 101(3)(b) EPC adds a clarifying point. If the proprietor of the patent requests amendments during the opposition proceedings, the opposition division examines whether, with reference to all the provision of the EPC, the substantive requirements for maintaining the patent are met. If the examination shows that they are, the patent is maintained as amended. If these requirements are not met, the patent is revoked. Article 102(1) EPC 1973 provided for revocation of the patent only if the grounds for opposition prejudiced its maintenance. This meant that, strictly speaking, Article 102(1) EPC 1973 did not provide the legal basis for revoking the patent if the patent as amended did not meet, for example, the requirements of Articles 84 or 123(3) EPC or Rules 27 or 29 EPC 1973. In such cases it has been the practice of the EPO to revoke the patent under Article 102(3) EPC 1973, even though this provision does not expressly so provide.* ***For the purpose of clarification, new Article 101(3)(b) EPC expressly provides for the revocation of the patent as amended.***" (Emphasis added).

4. Thus, Article 101(3)(b) EPC was not formulated to provide for a complete examination of the claims of a patent in opposition proceedings once claims are amended, as alleged by appellant I. Rather it was the intention of the legislator to provide with Article 101(3)(b) EPC a legal basis for revoking a patent if a specific amendment introduced into the patent during opposition proceedings did not meet the requirements of the EPC. This legal basis was missing in the EPC 1973. It was not the intention of the legislator to change the established principles laid down in the case law with regard to the examination of Article 84 EPC in opposition proceedings. These principles remain valid even after the entry into force of the revised EPC.

5. In accordance with established case law, when amendments were made to a patent during opposition proceedings, Article 102(3) EPC 1973 required them to be examined to ascertain if the EPC 1973, including Article 84 EPC, was contravened as a result. However, Article 102(3) EPC 1973 did not allow objections to be based upon Article 84 EPC 1973 if they did not arise out of the amendment made. It was held that it would seem somewhat absurd if making a minor amendment were to enable objections outside Article 100 EPC 1973 to be raised which had no connection with the amendment itself (Case Law of the Boards of Appeal of the European Patent Office, 6th edition 2010, VII.D.4.2; see in particular decision T 301/87, OJ EPO 1990, 335; headnote 1, points 3.6 to 3.8 of the reasons).

6. In the present case, the feature "steady state" has not been added or amended during opposition proceedings but

was already present in claim 1 as granted (see sections II and III, above). Moreover, the amendments made to claim 1 during the opposition proceedings have not changed the context in which the feature "steady state" is used. Therefore objections as to lack of clarity against the feature "steady state" are inadmissible because they represent an attempt to raise an objection under Article 84 EPC - which is not a ground of opposition - against claim 1 as granted (cf decision T 853/02 of 26 November 2004, point 3.1.1. of the reasons).

7. In the board's judgement therefore the opposition division had no power to examine the clarity of the feature "steady state" in claim 1 and appellant I had no right to raise an objection under Article 84 EPC against this feature. Accordingly, the opposition division did not violate appellant I's right to be heard when it decided not to hear it on the issue of clarity of the feature "steady state" and appellant I's request for reimbursement of the appeal fee is rejected.

8. Appellant I also submitted that in line with decision T 1459/05 of 21 February 2008 features, which were already present in the claims as granted, might be subject to a revocation for formal reasons, i.e. in respect of Article 84 EPC, if the claims had been amended.

9. The board notes that also in decision T 1459/05, *supra*, (see point 4.3.1 of the reasons) it was held that Article 101(3)(a) EPC does not permit an objection under Article 84 EPC that does not relate directly to an amendment made in opposition proceedings. In the

case underlying decision T 1495/05, *supra*, claim 1 as granted had been combined with its dependent claim 4 and the amendment considered under Article 84 EPC was the feature added to claim 1. As set out above, in the present case the term "steady state" was present in claim 1 as granted and has not been added or amended during opposition proceedings. The board concludes therefore that decision T 1459/05, *supra*, is not relevant to the present case.

Main (sole) request

Amendments (Articles 100(c) and 123(2)(3) EPC) - claim 1

10. The board is satisfied that claim 1 finds a basis in the application as filed in claims 1, 3, 11 to 13 and 19 as well as page 8, lines 19 to 22, the paragraph bridging pages 9 and 10; page 11, line 26 to page 12, line 2 and the example. In view of the decision on novelty (Article 54 EPC), see below, the board considers it unnecessary to provide a detailed reasoning for its finding.

11. The appellants did not raise an objection under Article 123(3) EPC. The board is also satisfied that the amendments made in claim 1 (see section IV, above) limit the scope of claim 1 vis-à-vis the scope of the claims as granted.

Interpretation of claim 1

12. In the decision under appeal the opposition division interpreted the term "steady state" on the basis of paragraphs [0026], [0029], and [0035] of the patent in

suit and in the light of document (OD11) to cover both a "true steady state" and a "pseudo steady state", as defined in document (OD11). Based on document (OD11) the opposition division moreover considered that no "steady state" could be achieved when the half-life of a drug was much smaller than the interval of administration.

13. It is undisputed that the specification of the patent in suit does not provide a definition of the term "steady state". It is established jurisprudence of the Boards of Appeal that, absent a definition of a particular term in the specification, terms should be given their normal meaning in the relevant art (Case Law of the Boards of Appeal of the European Patent Office, 6th edition 2010, section II.B.5.3.3). It is also established jurisprudence of the Boards of Appeal that the skilled person, when considering a claim, should rule out interpretations which are illogical or which do not make technical sense. He/she should try, with synthetical propensity, i.e. building up rather than tearing down, to arrive at an interpretation of the claim which is technically sensible and takes into account the whole disclosure of the patent. The patent must be construed by a mind willing to understand, not a mind desirous of misunderstanding. However, this means only that technically illogical interpretations should be excluded but does not require that a term which is broad needs to be interpreted more narrowly (*ibid.*, section II.B.5.1).

14. Hence, the board considers it necessary to arrive at an interpretation of the term "steady state" and consequently of the feature "*wherein the administration*

maintains serum concentrations of interferon alpha-2b at a steady state for the duration of the treatment" in claim 1 which is technically sensible and takes into account the whole disclosure of the patent.

15. The board agrees with the respondent (see its letter of 14 October 2005, page 10, paragraphs 1 to 4) that the normal meaning of the term "steady state" is as follows:

"Steady state" is a widely used term in the art, encompassed in the common general knowledge of the skilled person having e.g. a scientific or medical background. It describes the state of a system wherein an input (e.g. drug administration to a subject) and a corresponding output (e.g. elimination of the drug from the subject by excretion/metabolism) are in an equilibrium."

16. The board considers moreover that the term "steady state" in itself does not indicate anything about rate and extent of accumulation of a drug in the serum. In fact, rate and extent of accumulation of a drug are a function of the relative magnitudes of the dosing interval and the half-life of the drug. "Steady state" therefore neither means that the plasma concentration of a drug is necessarily constant over time nor that fluctuations are minimal but merely that a balance between input and output has been achieved. This understanding is confirmed by e.g. document (D46), see page 113, first paragraph to page 117, last paragraph, which - being a textbook - can be considered to represent the common general knowledge in the field of pharmacokinetics. The board can therefore not accept respondent's argument that the term "steady state"

excludes the possibility that the serum concentrations of interferon alpha-2b can vacillate.

17. The same understanding is derivable from document (OD11), which was considered by the opposition division to represent the common general knowledge of the skilled person. According to document (OD11), a "steady state" can be reached by either repeatedly or constantly administering a drug. Thus, repeated administration of a drug leads to a "steady state" wherein the amount of the drug eliminated during a dosing interval corresponds to the amount of drug taken up from the previous dose (see paragraph bridging columns on page 42). The plasma levels oscillate between a maximum and a minimum (trough) concentration, a condition termed "pseudo-steady-state" or simply "steady state" (see document (OD11), page 42, right column, first full paragraph, paragraph bridging columns on page 43 and legend to figure A 2-26). On the other hand, administration of the drug by continuous drip infusion leads to a plasma concentration which is constant at "steady state" (see document (OD11), page 44, left hand column, first full paragraph to right hand column, first paragraph). Regardless of whether a drug is administered intermittently or continuously, the time till reaching the steady state drug concentration is about five drug half-lifes (see document (OD11), page 44, right hand column, lines 6 to 8).

18. As to the meaning given to the term "steady state" in the patent, paragraph [0026] is of importance. It discloses that "[t]*he terms "continuous administration" and "continuous infusion" are used interchangeably*

herein and mean maintaining a steady state serum level of interferon throughout the course of the treatment period. This can be accomplished by constantly or repeatedly injecting substantially identical amounts of interferon, e.g., at least every hour, 24 hours a day, seven days a week, such that a steady state serum level is achieved for the duration of the treatment."

19. The board concludes that the disclosure of the patent is therefore in keeping with the common understanding of the skilled person that a "steady state" can in principle be achieved by continuous or repeated administration of a drug, see points 15 to 17 above.

20. It is noted that the time intervals indicated in paragraph [0026] of the patent are merely illustrative, and do not restrict the scope of claim 1 in any way. The board also adds that nowhere in the patent is it specified that the fluctuations in the serum concentration of interferon alpha-2b are to be kept within certain, narrow ranges, let alone that the interferon concentration needs to be kept constant during the duration of the treatment. The patent is moreover silent as to the pharmacokinetic parameters of interferon alpha-2b (e.g. its half-life, its elimination kinetics, etc.) or as to how these parameters would have to be adapted to the administration regime, e.g. to avoid any oscillation of the interferon concentration for the duration of the treatment.

21. Applying the principles laid out above (see point 13) leads the board to conclude that the feature "*wherein the administration maintains serum concentrations of*

interferon alpha-2b at a steady state for the duration of the treatment" in claim 1 of the main request is to be interpreted to mean that (i) the administration is e.g. by constant injection, for example by drip infusion and also that (ii) the administration is by repeated injection of substantially identical amounts of interferon alpha-2b, whereby the feature does not define the dosing interval. This understanding is technically sensible (see points 15 to 17 above) and takes into account the whole teaching of the patent (see points 18 to 20 above).

22. Finally, the board points out that document (OD11) discloses (see page 42, left hand column, lines 9 to 11) that if the half-time of a drug is small, e.g. 3 h, in relation to the dosing interval, e.g. 24 h, a drug is eliminated completely in the dosing interval. Document (OD11) does however not teach that a "steady state" can only be reached if a drug, let alone interferon alpha-2b, is administered in intervals that are shorter than its half-life. That a steady state can be reached even if the dosing interval is much greater than the half-life can also be derived from document (D46), page 113, first paragraph to page 125, third paragraph. It belongs to the common general knowledge that the minimum (trough) concentration at steady state approaches zero if the dosing interval is much greater than the half-life of a drug (document (D46), page 117, last paragraph).

23. Contrary to the decision under appeal the board sees therefore no justification to interpret the term "steady state" narrowly to mean that interferon

alpha-2b has to be administered in intervals that are shorter than its half-life.

Novelty (Article 54 EPC)- claim 1

24. As set out above, see point 21, claim 1 has to be construed to mean that administration of interferon alpha-2b by repeated injection of substantially identical amounts of interferon alpha-2b maintains serum concentrations of interferon alpha-2b at a steady state regardless of the dosing interval.

25. Therefore the board considers that the established prior art treatment of chronic hepatitis C in human patients with interferon alpha-2b at a dose of 3×10^6 international units (IU) three times a week for 24 weeks (see paragraph [0006] of the patent in suit and documents (OD14) to (OD16) cited therein) discloses a treatment which falls within the scope of claim 1. The same compound, i.e. interferon alpha-2b, is administered to the same patients, i.e. humans, for the treatment of the same disease, i.e. chronic hepatitis C viral infection, for the same time, i.e. for at least 4 weeks, in an amount of 9 million IU per week and thus an amount which falls within the amount of 2 million IU per week to 10 million IU per week, and wherein the administration is such that it maintains serum concentrations of the interferon alpha at a steady state for the duration of the treatment, namely 3×10^6 IU thrice weekly. For the avoidance of any doubt it is noted that, according to established practice, disclosure of a particular method of treatment of the human or animal body by therapy as disclosed in documents (OD14) to (OD16) is considered to disclose

the feature relating to the manufacture of a medicament. Therefore page 497, left hand column, first paragraph of the abstract of document (OD14); page 1501, left hand column, first paragraph of the abstract and page 1502, left hand column, paragraph entitled treatment of document (OD15); and page 393, left hand column and page 394, left hand column, first paragraph of document (OD16) anticipate the subject-matter of claim 1.

26. The respondent submitted that the original application contained a discussion on page 3 of various prior art documents including documents (OD14) to (OD16) and expressed a need to improve hepatitis C therapy over these documents. In its view the application as originally filed did not understand, and the average skilled person would not have understood, the teaching in these documents to represent a "steady state" within the meaning of the patent because the application differentiated itself from the teaching in these documents.

27. According to established case law of the Boards of Appeal (Case Law of the Boards of Appeal, 6th edition 2010, section I.C.5.3.1) a claimed invention lacks novelty unless it includes at least one technical feature which distinguishes it from the state of the art. It has been established above, see point 25, that documents (OD14) to (OD16) disclose all technical features of claim 1. In the absence of any technical feature that would distinguish the claimed subject-matter from the state of the art respondent's argument must fail.

28. The board concludes that claim 1 lacks novelty and therefore the main request fails the requirements of Article 54 EPC. Accordingly, the patent cannot be maintained on the basis of this request and in the absence of another, allowable claim request the patent has to be revoked.

Admission of appellant II's written submissions of 7 August 2012

29. The only written submissions which are necessarily taken into account in appeal proceedings are those referred to in Article 12(1) RPBA (to the extent they are relevant and comply with Article 12(2) RPBA - see Article 12(4) RPBA). Those are an appellant's notice and statement of grounds of appeal and the respondent's reply which should each contain a party's complete case (see Articles 12(1)(a)(b) and 12(2) RPBA). Any other submissions, unless answering a communication from the board (see Article 12(1)(c) RPBA and again subject to Article 12(4) RPBA), are amendments to a party's case and admissible only at the board's discretion (see Article 13(1) RPBA). Those provisions of the RPBA quite clearly foresee only one written submission from each party supplemented as necessary by answers to communications (if any) from the board. They do not foresee, and there is no right to, the filing of a response to the reply or any other written submissions.

30. The board finds appellant II's written submissions of 7 August 2012 and the new documents OD43 to OD45 filed therewith inadmissible. Appellant II made no attempt to explain why the board should exercise its discretion to admit these submissions into the proceedings. The

entire submissions being inadmissible, the additional request made therein for reimbursement of appellant II's appeal fee is *ipso facto* inadmissible.

31. Even if it were not inadmissible (see point 30 above), appellant II's request for reimbursement of its appeal fee would be bound to fail for lack of adequate substantiation. Its only reason for requesting such reimbursement was that its reasons for seeking to set aside the decision under appeal had "not been adequately considered in the Opposition Proceedings". That is no more than the fundamental argument which any appellant makes, at least implicitly if not explicitly, in any appeal proceedings. It does not begin to explain (as required by Rule 103(1)(a) EPC) either how a substantial procedural violation occurred or how, by reason of such a violation, it would be equitable to reimburse the appeal fee.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

3. The request of appellant I for reimbursement of the appeal fee is rejected.

The Registrar: The Chairman:

P. Cremona C. Rennie-Smith