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Datasheet for the decision of 7 March 2024

Case Number: T 1107/22 - 3.3.02

Application Number: 14720369.9

Publication Number: 2970123

IPC: C07D213/75, A61P9/00, A61P9/04, A61K9/20, A61K31/496

Language of the proceedings: EN

Title of invention:
CRYSTALLINE DIHYDROCHLORIDE HYDRATE SALT OF OMECAMTIV MECARBIL AND PROCESS FOR ITS PREPARATION

Patent Proprietor:
Amgen Inc.
Cytokinetics, Inc.

Opponent:
KELTIE LLP

Headword:

Relevant legal provisions:
EPC 1973 Art. 56

Keyword:
Inventive step

Decisions cited:
T 0500/16

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 1107/22 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 7 March 2024

Appellant: (Patent Proprietor 1)	Amgen Inc. One Amgen Center Drive Thousand Oaks, California 91320-1799 (US)
Appellant: (Patent Proprietor 2)	Cytokinetics, Inc. 350 Oyster Point Boulevard South San Francisco, CA 94080 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Appellant: (Opponent)	KELTIE LLP No.1 London Bridge London SE1 9BA (GB)
Representative:	Moore, Michael Richard Keltie LLP No.1 London Bridge London SE1 9BA (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 10 February 2022 concerning maintenance of the European Patent No. 2970123 in amended form.**

Composition of the Board:

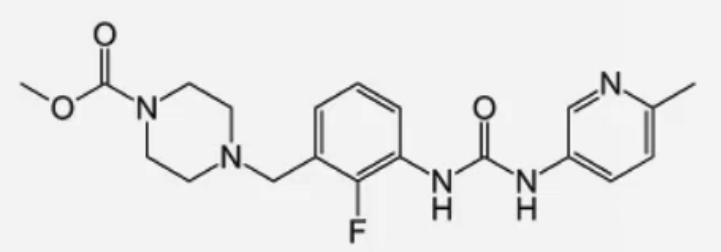
Chairman	M. O. Müller
Members:	S. Bertrand
	L. Bühler

Summary of Facts and Submissions

I. The appeals by the opponent and the patent proprietors lie from the opposition division's interlocutory decision that European patent No. 2 970 123 in amended form according to auxiliary request 1 filed during the oral proceedings on 16 December 2021 met the requirements of the EPC.

II. The patent relates to a dihydrochloride hydrate salt of omecamtiv mecarbil.

Omecamtiv mecarbil is a cardiac-specific myosin activator having the following formula:



III. Since the patent proprietors and the opponent were both appellants and respondents in these appeal proceedings, they are referred to as "patent proprietors" and "opponent" in the following.

IV. The following documents are used in the present decision:

D1 US 2006/0014761 A1

D2 Declaration of Mingda Bi (dated 14 March 2014)

D6 Technical reports of OM entities (filed on 8 January 2021)

D10 Declaration of Dr Chunsheng Qiao (dated 14 October 2021)

D13 Declaration of Dr Fady Malik (dated 13 December 2021)

D13A Curriculum vitae of Dr Fady Malik (dated 13 December 2021)

D13B J.R. Teerlink, et al., The Lancet, 378, 2011, 667-75

V. In the impugned decision, the opposition division's conclusions included the following.

- The subject-matter of claim 1 as granted did not involve an inventive step in view of D1 as the closest prior art.

- The subject-matter of the claims according to auxiliary request 1 filed before the opposition division involved an inventive step in view of D1 as the closest prior art (Article 56 EPC).

VI. In its statement of grounds of appeal, the patent proprietors contested the opposition division's conclusion on inventive step of the subject-matter of claim 1 as granted.

VII. In its statement of grounds of appeal, the opponent submitted that the subject-matter of the claims according to auxiliary request 1 held allowable by the opposition division did not involve an inventive step starting from D1 as the closest prior art.

VIII. With its reply to the opponent's grounds of appeal, the patent proprietors filed auxiliary requests 2 to 13. They commented on the inventive step of the subject-

matter of claim 1 of auxiliary request 1. They also provided submissions on the allowability of the claims according to auxiliary requests 2 to 13.

IX. In its reply to the patent proprietors' grounds of appeal, the opponent contested the patent proprietors' submissions on the inventive step of claim 1 as granted. It relied on documents D14 to D16. However, copies of these documents were not filed.

X. The board summoned the parties to oral proceedings, as requested by the parties, and issued a communication under Article 15(1) RPBA.

XI. Oral proceedings before the board were held in person on 7 March 2024 in the presence of the patent proprietors and the opponent. During the oral proceedings, the patent proprietors withdrew the main request and auxiliary requests 1 to 9. They made auxiliary request 10 their main request.

XII. The parties' requests relevant to the decision were as follows.

The patent proprietors requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the claims of the main request filed as auxiliary request 10 with their reply to the opponent's appeal. The patent proprietors further requested that documents D13, D13A and D13B stay in the proceedings and that D14 to D16 not be admitted and that quotes from these references be disregarded.

The opponent requested that the decision under appeal be set aside and that the patent be revoked in its entirety. The opponent further requested that the

opposition division's decision to admit documents D13, D13A and D13B into the proceedings be overruled.

XIII. The patent proprietors' and the opponent's cases relevant to the present decision are summarised in the reasons below.

Reasons for the Decision

Main request

Inventive step - Claim 1

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

"*1. A dihydrochloride hydrate salt of omecamtiv mecarbil, wherein the salt is crystalline, and wherein the salt is characterized by an X-ray powder diffraction pattern comprising peaks at 6.6, 14.9, 20.1, 21.4, and 26.8 ± 0.2° 2θ using Cu Kα radiation*."

Omecamtiv mecarbil is referred to as "OM" in the following. "Dihydrochloride" is referred to as "diHCl".

Claim 1 of the main request relates to Form A of OM diHCl hydrate.

The aim of the patent is to provide a crystalline form of OM having improved properties such as solubility and stability (paragraph [0007] of the patent).

2. Closest prior art

3. It was common ground that example 3 of D1 is a suitable starting point for inventive step.

Example 3 of D1 (paragraphs [0747] to [0759]) discloses the synthesis of OM free base (see the last formula in paragraph [0756]). OM free base is isolated as a white powder (paragraph [0759]). OM free base is not in the form of a salt.

4. Distinguishing feature

It was common ground between the parties that the distinguishing feature of claim 1 of the main request is the diHCl hydrate salt form of OM. In example 3 of D1, OM is in the form of a free base.

5. Effects achieved by the distinguishing feature and objective technical problem

As submitted by the patent proprietors and shown in the following, the distinguishing feature of Form A of OM diHCl hydrate results in (i) an improved stability of the entity per se, (ii) an improved stability during tabletting, (iii) an improved stability during storage, and (iv) an improved water solubility and bioavailability when compared to the OM free base.

5.1 Stability of the OM diHCl hydrate entity

The patent proprietors relied on D6 and the patent.

Figure 1 of D6 shows three XRPD profiles of Form A of OM diHCl hydrate samples (according to claim 1 of the main request). The lowest curve represents the XRPD profile of a reference standard of Form A of OM diHCl hydrate prior to storage. The middle and upper profiles correspond to the XRPD profiles of Form A of OM diHCl hydrate samples obtained after having been stored at 40°C and 75% relative humidity for one month (middle line) and 30°C and 65% relative humidity for 18 months (top line). In the middle and upper profiles obtained

after storage, no new peaks are visible, relative to the profile on the bottom, obtained prior to storage. It can therefore be concluded that Form A of OM diHCl hydrate according to claim 1 of the main request is storage stable at 40°C and 75% relative humidity for one month and 30°C and 65% relative humidity for 18 months.

In comparison, figure 2 of D6 shows that, for a crystalline form of OM free base (according to D1), "*new peaks start to appear in the XRPD profile which indicates that the original entity is changing*" after nine days at 40°C and 75% relative humidity, i.e. the stability of the crystalline form of OM free base is lower than that of Form A of OM diHCl hydrate according to claim 1 of the main request (see also point 1.5 of D6).

According to paragraphs [0028] and [0029] of the patent, Form A of OM diHCl hydrate (according to claim 1 of the main request) "*remains in substantially the same physical form over 6months* [sic] *at 40°C and 75%RH*". According to paragraph [0035] of the patent, Forms B and C, which are anhydrous forms of OM diHCl (they do not contain any hydrate, paragraph [0031] of the patent), and which are thus not according to claim 1, convert to Form A at ambient conditions (Form B) or under exposure at 15% relative humidity (Form C).

In view of the technical data presented in D6 and in the patent, the board concludes that Form A of OM diHCl hydrate (according to claim 1 of the main request) is more stable than the crystalline form of OM free base of D1 (comparative) and Form B and Form C (both comparative).

The opponent disputed the conclusion that Form A of OM diHCl hydrate was more stable than the crystalline form of OM free base of D1.

It submitted in writing that the data provided by the patent proprietors in D6 was not convincing. Some of the arrows in figure 2 of D6, which were supposed to point to new peaks, did not even show the presence of new peaks. Moreover, the scale on the y-axis in figure 1 of D6 was 20 000 per unit, whereas the scale on the y-axis in figure 2 was 1 000 per unit. The scale in figure 2 was thus twenty-fold more sensitive for the profile of the OM free base, and so it was unsurprising that some very small peaks were visible. Such peaks might well be present also in the middle and upper profiles of figure 1 but would not be visible since in this figure, the scale was twenty fold smaller. The data thus could not be considered sufficient for demonstrating a technical effect.

The board disagrees with the opponent.

The distance between the peak maxima and the base line, i.e. the intensity, in the middle and upper curves of figure 1 of D6 is very high such that any peaks are clearly visible. Without any proof from the opponent, the board therefore does not see any reason to believe that any new peaks arising during storage would not have been visible in these profiles, had there been any.

Therefore, the opponent's allegation that the experimental data of D6 is not sufficient for demonstrating a technical effect is not convincing.

The opponent further submitted that by comparing the information in paragraphs 1.2 and 1.5 of D6, it could be concluded that the storage conditions for Form A of

OM diHCl hydrate and OM free base anhydrate were different, suggesting that the studies were carried out at different times and under different instructions.

The board disagrees.

The temperature and humidity for the storage of both the OM diHCl hydrate according to claim 1 (figure 1) and the OM free base (figure 2) were identical. What differs is the storage time, which was one month for the OM diHCl hydrate and nine days for the OM free base.

If there is no change during the storage of Form A of OM diHCl hydrate after one month, there cannot have been any change after nine days. This is in contrast to the OM free base anhydrate, which changed after a storage of only nine days. It can be thus concluded that the stability of Form A of OM diHCl hydrate is higher than that of OM free base anhydrate.

Finally, the opponent submitted that comparing the methodologies in paragraphs 1.3 and 1.6 of D6 showed that the measurement conditions and sample preparations of Form A of OM diHCl hydrate and OM free base anhydrate were different.

The board is not convinced by the opponent's submission.

First, paragraphs 1.3 and 1.6 of D6 do not disclose the sample preparations, and the opponent did not provide any evidence that the two samples analysed in D6 were prepared differently. Furthermore, even if the diffractometers used are different in paragraphs 1.3 and 1.6 of D6, the opponent did not provide any evidence to support the allegation that a different diffractometer would affect the outcome of the tests

performed on Form A of OM diHCl hydrate and OM free base anhydrate. In the absence of any evidence, the opponent's submission must fail.

5.2 Improved stability on tabletting

The patents proprietors relied on D2. D2 discloses results on the stability of tablets prepared from different forms of OM.

A tablet comprising Form A of OM diHCl hydrate (according to claim 1 of the main request) resulted in 39% conversion of Form A of OM diHCl hydrate to the amorphous form after tabletting (point 3.(iv) on pages 1 and 2 of D2).

When a tablet was produced with OM free base (according to D1), 75% of the OM free base converted to the amorphous form after tabletting. It was not clear from D2 whether the OM free base was already predominantly or partially in an amorphous state. It was thus doubtful whether D2 showed an improved stability on tabletting for Form A of OM diHCl hydrate.

The board does not find this submission convincing. Point 3(i) of D2 refers to "*converted to an amorphous salt form*", meaning implicitly that the initial form of OM free base was crystalline.

Second, the opponent submitted that claim 1 of the main request was not directed to tablets, and therefore the data of D2, which only related to stability in modified release tablet formulations, was not relevant to the claimed invention.

The board does not agree. The above-discussed improved stability on tabletting is an effect obtained with the claimed product and thus can be relied on for inventive

step. As submitted by the patent proprietors, it is not necessary to have use features in a product claim to rely on a technical effect for this use since the product can be claimed *per se*.

The opponent further submitted that no tabletting conditions, no process conditions and no lists of ingredients were provided in the tests carried out in D2. It was not excluded that the study of Form A of OM diHCl hydrate was performed in a different laboratory using different processes and equipment and that the measurements were made using different instruments and at a different time to that of the OM free base. For these reasons, no meaningful comparison of the stability on tabletting of Form A of OM diHCl hydrate with that of the OM free base was possible.

The opponent's allegation is not convincing. The opponent did not provide any evidence that the tests were made in a different laboratory using different processes and equipment. Furthermore, the opponent did not provide any evidence that, even if the tests were made in different environments, this would lead to a non-meaningful comparison of Form A of OM diHCl hydrate with that of the OM free base. In the absence of any evidence, the opponent's attempt to discredit D2 must fail.

5.3 Improved stability of tablets on storage

The patent proprietors referred to point 2 of D6, which compares the stability of tablets comprising Form A of OM diHCl hydrate (according to claim 1 of the main request) versus tablets comprising the OM free base (according to D1).

The tablet comprising Form A of OM diHCl hydrate showed 0% conversion even after six months, whereas under the same conditions, the tablet comprising the OM free base showed a conversion beginning at two weeks (point 2.2 and table 1 of D6).

The opponent disputed the improved stability on storage achieved by a tablet comprising Form A of OM diHCl hydrate. It submitted that, as in the case of D2, the storage conditions used in the two sets of allegedly comparable tests in D6 were completely different and that the data of D6 should be ignored.

The board does not agree. First, in the absence of evidence bringing the improved stability in storage demonstrated by D6 into doubt, the opponent's allegation must fail. Second, D6 uses the same temperature and humidity for the storage, namely 40°C and 75% relative humidity (note of table 1 of D6) for the tablet with Form A of OM diHCl hydrate and that with the OM free base. The board acknowledges that the storage times are different, six months for tablets with OM diHCl hydrate and two weeks and four weeks for the OM free base. However, the fact that the tablet with Form A of OM diHCl hydrate exhibited no conversion after six months can only imply that it did not show any conversion at shorter times such as two or four weeks. It can be thus concluded that tablets comprising Form A of OM diHCl hydrate have a higher stability on storage than tablets comprising the OM free base.

5.4 Improved water solubility and bioavailability

The patent proprietors based their submissions on the water solubility on the results given in the patent, D2, D6 and D10.

Figures 7A and 7B of the patent represent the water solubility of a tablet comprising Form A of OM diHCl hydrate (referred to as "AMG423 HCl") and a tablet comprising OM free base hemihydrate (referred to as "AMG423 hemihydrate") by indicating the amount of the forms of OM dissolved by unit of time at pH 2 (curve with diamonds) or at pH 6.8 (curve with squares). Form A of OM diHCl hydrate (according to claim 1 of the main request, figure 7B) has a higher water solubility at pH 6.8 in comparison with the OM free base hemihydrate (according to D1, figure 7A).

The figures on page 3 of D2 show the dissolution profile of the tablets comprising Form A of OM diHCl hydrate in the lower figure and the tablets comprising OM free base in the upper figure. After 24 hours of *in vitro* dissolution, the tablets comprising Form A of OM diHCl hydrate (according to claim 1 of the main request) is almost 100% with fumaric acid and slightly below 80% with citric acid. This is higher than the values obtained with tablets comprising OM free base (according to D1), namely slightly above 90% with fumaric acid and slightly below 70% with citric acid.

In figure 3 of D6 (page 7), Form A of OM diHCl hydrate (curve with diamonds, according to claim 1 of the main request) provides the highest percentage of OM dissolved in 24 hours when compared to OM free base hemihydrate (curve with bold points, according to D1) and OM free base anhydrate (curve with triangles, according to D1).

As submitted by the patent proprietors, the improved water solubility of Form A of OM diHCl hydrate results in improved bioavailability.

This improved bioavailability is also shown in the studies described in D10. Oral administration of Form A of OM diHCl hydrate (according to claim 1 of the main request) results in a bioavailability of 87.1% (D10, point 4.2, table 5). By contrast, oral administration of OM free base anhydrate (according to D1) results in a bioavailability of 44.8% (D10, point 4.2, table 5).

The opponent did not dispute this effect.

6. Objective technical problem

In view of the above, the objective technical problem is the provision of a form of OM having an increased storage stability, an increased stability on tabletting, an increased stability of tablets on storage and an increased water solubility/ bioavailability.

7. Obviousness

Starting from D1 and when faced with the above objective technical problem, the skilled person would not have found in D1 any teaching towards Form A of OM diHCl hydrate. In fact, D1 does not deal with this objective technical problem.

7.1 The opponent submitted that the improvement in stability of Form A of OM diHCl hydrate was a "bonus effect" that would have inevitably been achieved by following the teaching of D1 when faced with the problem of improving water solubility of the OM free base disclosed in D1. It was common general knowledge that the water solubility of a drug could be increased by forming a salt.

The opponent's submission is not convincing.

It is established case law that a bonus effect arises when the state of the art forces the skilled person to adopt a certain solution, the lack of alternatives leading to a "one-way street" situation (see e.g. T 500/16, Reasons 5.5).

This is, however, as submitted by the patent proprietors, not applicable to the current case where there is no one-way street but rather a number of alternative modifications that could be made to the OM free base of D1. D1 (paragraph [0107]) teaches "pharmaceutical acceptable forms" of compounds of Formula I (generic formula of OM), among which chelates, non-covalent complexes and prodrugs are listed along with pharmaceutical acceptable salts of compounds of Formula I. Furthermore, D1 does not limit the pharmaceutical acceptable salts to hydrochloride salts. Paragraph [0108] of D1 discloses a non-exhaustive list of equivalent pharmaceutical salts including inorganic and organic salts. Hence, the skilled person is not faced with a one-way street. The improved stability is in fact an unexpected technical effect rather than a bonus effect.

7.2 The opponent further submitted that it would have been obvious for the person skilled in the art to arrive at Form A of OM diHCl hydrate having regard to the teaching of document D1. The conditions described in the patent for forming the claimed crystalline diHCl hydrate of OM according to claim 1 of the main request were the same as those described in D1 (paragraph [0109]). Furthermore, D1 (paragraph [0108]) referred to the hydrochloride salt of OM.

The board does not agree.

Paragraph [0109] of D1 discloses that "*[i]n addition, if the compound of Formula I is obtained as an acid addition salt, the free base can be obtained by basifying a solution of the acid salt. Conversely, if the product is a free base, an addition salt, particularly a pharmaceutically acceptable addition salt, may be produced by dissolving the free base in a suitable organic solvent and treating the solution with an acid, in accordance with conventional procedures for preparing acid addition salts from base compounds. Those skilled in the art will recognize various synthetic methodologies that may be used to prepare non-toxic pharmaceutically acceptable addition salts*".

The patent (paragraphs [0039] and [0110]) discloses that the compound of claim 1 of the main request is obtained by adding hydrochloride to an aqueous solution of 2-propanol (isopropyl alcohol).

OM, 2-propanol and hydrochloride are not disclosed in paragraph [0109] of D1.

Paragraph [0108] of D1, as set out above, discloses a list of equivalent pharmaceutical salts including hydrochloride salts ("*hydrochlorate*"). However, as set out above, this paragraph refers to a compound of Formula I and not directly to OM.

Thus, it cannot be concluded that the conditions used for forming the claimed crystalline diHCl hydrate of OM according to claim 1 of the main request are disclosed in D1. Therefore, the opponent's submission is not convincing.

7.3 Finally, the opponent submitted that the patent itself confirmed that Form A of OM diHCl hydrate was the stable polymorph of OM diHCl hydrate, such that Form A would be the form obtained by following the teaching of

D1. The XRPD pattern resulting for the obtained product would inevitably be the same as that now claimed.

The board is not convinced.

It is accepted that the XRPD pattern comprising the peaks identified in claim 1 of the main request is inherent to Form A of OM diHCl hydrate as claimed. However, as set out above, D1 provides neither any disclosure nor motivation on how to prepare a form of OM having both an increased stability and an increased water solubility, let alone a diHCl salt of OM according to claim 1 of the main request.

8. The subject-matter of claim 1 of the main request and, by the same token, of claims 2 to 13, which are dependent on or include the subject-matter of claim 1, therefore involves an inventive step in view of D1 as the closest prior art.

9. Admittance of D13, D13A and D13B

9.1 Documents D13, D13A and D13B were submitted by the patent proprietors before the oral proceedings before the opposition division. D13 is a declaration of Dr Fady Malik, a technical expert. D13A is Dr Fady Malik's curriculum vitae. D13B is a scientific article on the *in vivo* testing of OM as a selective cardiac myosin activator. The opposition division decided to admit documents D13, D13A and D13B into the proceedings (top of page 6 of the decision).

9.2 The opponent requested that the opposition division's decision to admit documents D13, D13A and D13B into the proceedings be overruled.

9.3 During the oral proceedings, the board decided not to overrule the opposition division's decision to admit D13, D13A and D13B into the proceedings.

In drawing its conclusion on inventive step, the board did not take into consideration documents D13, D13A and D13B, and these documents are thus not relevant to the current decision. There is thus no need to give any reason on their admittance.

10. Admittance of the statements of the opponent in points 5.10, 6.4 and 7.4 of its reply to the patent proprietors' grounds of appeal and reliance by the opponent on D14 to D16

10.1 The opponent referred to documents D14 to D16 in its reply to the patent proprietors' grounds of appeal (points 5.10, 6.4 and 7.4 to 7.6).

In points 5.10 and 6.4 of this reply, the opponent referred to page 114 of D14 and submitted that D14 provided evidence that amorphous forms had very different properties from the crystal forms of the same material and that any data demonstrating an improvement in stability (especially in terms of low hygroscopicity) for the crystalline Form A of OM diHCl hydrate could not be extrapolated to the corresponding amorphous form as encompassed by claim 1 as granted.

In points 7.4 to 7.6 of its reply to the patent proprietors' grounds of appeal, the opponent submitted that D14 included a clear teaching that where a drug compound had limited solubility, such that it affected its absorption, it was appropriate to use a more soluble salt form. D14 further taught that the hydrochloride drugs of basic drugs were by far the most common salts. This teaching was supported by D15 (page

1), which disclosed that salt formation had long been used to improve the water solubility of drugs.

Finally, the opponent submitted that D16 provided a medical definition of the term "hydrochlorate". This term was any salt of hydrochloric acid (point 8.2 of the reply to the patent proprietors' grounds of appeal).

10.2 The patent proprietors requested that the statements of the opponent in points 5.10, 6.4 and 7.4 of its reply to the patent proprietors' grounds of appeal and the reliance by the opponent on D14 to D16 not be admitted into the proceedings.

10.3 During the oral proceedings, the board decided not to admit the statements of the opponent in points 5.10, 6.4 and 7.4 of its reply to the patent proprietors' grounds of appeal and the reliance by the opponent on D14 to D16 into the proceedings.

The opponent's statements made in points 5.10 and 6.4 of its reply to the patent proprietors' grounds of appeal that any data demonstrating an improvement in stability for the crystalline Form A of OM diHCl hydrate could not be extrapolated to the corresponding amorphous form were made for claim 1 as granted and do not apply to claim 1 of the current main request. They thus have no relevance for the current decision.

Furthermore, the board accepted, in the opponent's favour, that it was basic chemistry that salt formation was a solution for improving the water solubility of a drug, even without taking into account any statement of the opponent in points 7.4 to 7.6 of its reply to the patent proprietors' grounds of appeal or its reliance on D14 and D15.

Finally, the board accepted, in the opponent's favour, that the term "hydrochlorate" disclosed in D1 was to be understood as a hydrochloride salt, even without taking into account the definition based on D16 as submitted by the opponent in its reply to the patent proprietors' grounds of appeal.

Thus, since the statements of the opponent in points 5.10, 6.4 and 7.4 of its reply to the patent proprietors' grounds of appeal and its reliance on D14 to D16 are not relevant for the current decision on inventive step, there is no need to give any reason on their non-admittance.

11. The objection of lack of inventive step was the only objection raised by the opponent.

12. The board thus concludes that the main request is allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the claims of the main request filed as auxiliary request 10 with the patent proprietors' reply to the opponent's appeal and a description and drawings possibly adapted thereto.

The Registrar: The Chairman:

H. Jenney M. O. Müller

Decision electronically authenticated