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Datasheet for the decision of 5 March 2020

Case Number: T 1443/15 - 3.3.01

04783095.5 Application Number:

Publication Number: 1667682

A61K31/445, C07D401/04 IPC:

Language of the proceedings: ΕN

Title of invention:

POLYMORPHIC FORMS OF 3-(4-AMINO-1-OXO-1,3 DIHYDRO-ISOINDOL-2-YL)-PIPERIDINE-2,6-DIONE

Patent Proprietor:

CELGENE CORPORATION

Opponents:

Generics [UK] Limited Teva Pharmaceutical Industries Ltd.

Headword:

Lenalidomide polymorph/CELGENE

Relevant legal provisions:

EPC Art. 123(2), 111(1) RPBA Art. 12(4), 13(1) RPBA 2020 Art. 11

Keyword:

Main request - admitted (yes) - added subject-matter (no) - remitted (yes)

Late-filed objections - admitted (no)



Beschwerdekammern

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Chambres de recours

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Case Number: T 1443/15 - 3.3.01

DECISION
of Technical Board of Appeal 3.3.01
of 5 March 2020

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 24 June 2015

revoking European patent No. 1667682 pursuant to Article 101(2) and Article 101(3) (b) EPC

Composition of the Board:

Chairman A. Lindner

Members: J. Molina de Alba

M. Blasi

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Summary of Facts and Submissions

- I. The present appeal by the patent proprietor (appellant) lies from the opposition division's decision revoking European patent No. 1 667 682.
- II. Two oppositions had been filed against the patent on the grounds that the claimed subject-matter lacked novelty and inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed (Article 100(a), (b) and (c) EPC).
- III. The decision was based on the patent as granted and the claims of six auxiliary requests.

In the decision, the opposition division considered that the patent as granted and auxiliary requests 1 and 2 added subject-matter. Auxiliary requests 3-6 were not admitted into the proceedings because they contained the same deficiency of added subject-matter as claim 6 of auxiliary request 2.

Furthermore, the opposition division rejected the patent proprietor's request to hear opponent 2's expert, Prof. Dr Kirschning, as a witness or, alternatively, to exclude him from the oral proceedings before the opposition division in case the board of appeal were to consider it necessary to hear him.

IV. With the statement of grounds of appeal the appellant maintained the main request (patent as granted) and auxiliary requests 1 and 2 on which the decision was

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based. In addition, it filed eight sets of claims as auxiliary requests 3-10 and document D32.

- V. In their respective responses to the statement of grounds of appeal, opponents 1 and 2 (respondents 1 and 2, respectively) objected to the admission of auxiliary requests 3-10 and document D32 into the proceedings.
- VI. The board scheduled oral proceedings in line with the parties' requests. In the communication accompanying the summons, the board informed the parties that it was inclined to agree with the decision under appeal that claims 1 and 9 of the main request and claims 1 and 6 of auxiliary request 1 comprised added subject-matter.
- VII. With a letter dated 5 December 2019, respondent 2 withdrew its request for oral proceedings and announced that it would not attend the oral proceedings.
- VIII. On 9 January 2020, the appellant withdrew its main request and auxiliary requests 1 and 2, and made auxiliary request 3 its main request. Auxiliary requests 4-10 were maintained.

Independent claims 1, 4, 6, 9, 13, 14, 19, 27, and 29-32 of the new main request read as follows:

- "1. Crystalline 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione hemihydrate having an X-ray powder diffraction pattern comprising peaks at 16, 18, 22 and 27 degrees 20."
- "4. Crystalline 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione dihydrate having an X-ray powder diffraction pattern comprising peaks at 20, 24.5 and 29 degrees 20."

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- "6. Crystalline 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione, which has an X-ray powder diffraction pattern comprising peaks at 8, 14.5, 16, 17.5, 20.5, 24 and 26 degrees 20."
- "9. A solid form of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione comprising the crystalline 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6 dione of any one of claims 1-8, wherein the crystalline 3-(4-amino-1-oxo-1,3 dihydroisoindol-2-yl)-piperidine-2,6-dione is present at greater than 80% by weight of the solid form."
- "13. A mixture of the crystalline 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione of any one of claims 1-3 and the crystalline 3-(4-amino-1-oxo-1,3 dihydroisoindol-2-yl)-piperidine-2,6-dione of any one of claims 4-5."
- "14. A composition comprising amorphous 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)piperidine-2,6-dione and the crystalline 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)piperidine-2,6-dione of any one of claims 1-8."
- "19. A pharmaceutical composition comprising the crystalline 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione of any one of claims 1-8 or the solid form of any one of claims 9-12 or the composition of any one of claims 14-18, and a pharmaceutically acceptable excipient, diluent, or carrier."
- "27. Use of a therapeutically or prophylactically effective amount of the crystalline 3-(4-amino-1-

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oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione of any one of claims 1-8 in the preparation of a pharmaceutical composition for the treatment or prevention of a cancer."

- "29. Use of a therapeutically or prophylactically effective amount of the crystalline 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione of any one of claims 1-8 in the preparation of a pharmaceutical composition for the treatment or prevention of undesired angiogenesis, an inflammatory disease, an autoimmune disease, or an immune disease."
- "30. Use of a therapeutically or prophylactically effective amount of the crystalline 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione of any one of claims 1-8 in the preparation of a pharmaceutical composition for the treatment or prevention of a myelodysplastic syndrome."
- "31. Use of a therapeutically or prophylactically effective amount of the crystalline 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione of any one of claims 1-8 in the preparation of a pharmaceutical composition for the treatment or prevention of a myeloproliferative disease."
- "32. Use of a therapeutically or prophylactically effective amount of the crystalline 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione of any one of claims 1-8 in the preparation of a pharmaceutical composition for the treatment or prevention of a blood-borne tumor."
- IX. Oral proceedings were held before the board on 5 March 2020 in the absence of respondent 2.

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X. The appellant's arguments, where relevant to the present decision, may be summarised as follows:

Admission of the main request (Article 12(4) RPBA 2007)

The set of claims of the main request differs from that of auxiliary request 2 on which the decision is based only in that claim 6 has been deleted. It was filed with the statement of grounds of appeal as auxiliary request 3. Thus, the main request overcomes the objection that led to the revocation of the patent, and it was filed at the earliest possible opportunity. Therefore, it should not be excluded from the appeal proceedings.

The claims of the main request could not have been filed in the opposition proceedings. Claim 6 of then auxiliary request 2 was filed to overcome the addedmatter objection raised by opponent 2 in its notice of opposition (point 3.8) against claim 13 as granted. Despite the fact that auxiliary request 2 had been on file for two years prior to the oral proceedings in opposition, the objection against claim 6 was raised for the first time at those oral proceedings. The division, however, did not give the appellant the opportunity to file an amended request; it announced its conclusion that claim 6 of auxiliary request 2 added subject-matter and immediately afterwards, without pausing, it announced that the remaining auxiliary requests were not admitted into the proceedings and that the patent was revoked. This is apparent from the last two paragraphs of the minutes of the oral proceedings in opposition.

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Added subject-matter (Article 123(2) EPC) - claims 1, 4 and 6 of the main request

The removal of the word "approximately" before the diffraction peaks in claims 1, 4 and 6 does not add subject-matter. These peaks were extracted from the XRPD patterns in Figures 6, 23 and 1 of the application as filed, respectively. They were rounded to integers or half-integers and qualified with the word "approximately" to reflect the margin of error in the measure.

The skilled person understands that a specific diffraction value in XRPD may vary within a margin of error depending on the specificity of each sample. Although this variation was expressed in the application as filed by the word "approximately", it was superfluous and could be removed without changing the breadth of the claims. Most importantly, the removal of "approximately" did not result in claims encompassing any additional polymorph.

Admission of additional added-matter objections

The added-matter objections raised by respondent 1 at the oral proceedings before the board which were not directed to the deletion of the word "approximately" in claims 1, 4 and 6, had not been raised in the opposition proceedings. Therefore, they should not be admitted into the appeal proceedings.

XI. The respondents' arguments, where relevant to the present decision, may be summarised as follows:

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Admission of the main request (Article 12(4) RPBA 2007)

The objection against claim 6 of auxiliary request 2 discussed at the oral proceedings before the opposition division is derived from the objection against claim 13 as granted raised by respondent 2 in its notice of opposition (point 3.8). It was self-evident from the basis in the application as filed cited by the appellant that claim 6 added subject-matter. Thus, the appellant should have expected the objection to be discussed at the oral proceedings. Furthermore, the objection and the way to overcome it (deleting the claim) were straightforward and did not require long deliberations.

In addition, at the oral proceedings, the opposition division did not prevent the appellant from filing claims of further auxiliary requests or from expressing its intention to do so if the auxiliary requests on file were found to add subject-matter. The appellant simply chose not to use this right.

Hence, as the appellant could and should have filed the present main request in the opposition proceedings, the request should not be admitted into the appeal proceedings.

Added subject-matter (Article 123(2) EPC) - claims 1, 4 and 6 of the main request

The diffraction peaks in claims 1, 4 and 6 were extracted from their respective XRPD patterns in Figures 6, 23 and 1. In those patterns, the peaks did not appear at exact 20 values; they were rounded and qualified as being approximate. In consequence, the removal of the word "approximately" results in lists of

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peaks at exact 2Θ values, which is information for which there is no basis in the application as filed.

Admission of additional added-matter objections

The added-matter objections raised by respondent 1 at the oral proceedings before the board had been previously raised in relation to the claims of the patent as granted, either in respondent 2's letter dated 13 May 2014 or in respondent 1's reply to the statement of grounds of appeal. The objections are directly applicable to the claims of the main request and should therefore be admitted.

XII. The parties' final requests were as follows:

- The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of the claims of the main request, filed as auxiliary request 3 with the statement of grounds of appeal dated 4 November 2015, or, alternatively, on the basis of any of the sets of claims filed on 4 November 2015 as auxiliary requests 4-10.
- Respondent 1 requested that the appeal be dismissed or, alternatively, that the case be remitted for further prosecution. Furthermore, it requested that auxiliary requests 4-10 not be admitted into the proceedings.
- Respondent 2 had additionally requested in writing that the opposition division's decision not to hear Prof. Dr Kirschning as a witness be confirmed.

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XIII. At the end of the oral proceedings, the board's decision was announced.

Reasons for the Decision

- 1. The revised version of the RPBA ("RPBA 2020") entered into force on 1 January 2020 and applies to appeals pending on that date (see Article 24(1) and Article 25(1) RPBA 2020). Accordingly, any reference to the RPBA in this decision concerns RPBA 2020 unless otherwise indicated.
- 2. The appeal is admissible. It complies with the requirements pursuant to Articles 106 to 108 and Rule 99(2) EPC.
- 3. The oral proceedings before the board took place in the absence of respondent 2, who had been duly summoned but chose not to attend, as announced with the letter dated 5 December 2019. In accordance with Rule 115(2) EPC, the board decided to continue the proceedings in the absence of respondent 2. Furthermore, pursuant to Article 15(3) RPBA, the board was not obliged to delay any step in the proceedings, including its decision, by reason only of respondent 2's absence at the oral proceedings. In line with this provision, respondent 2 was treated as relying on its written case. Hence, the board was in a position to announce a decision at the conclusion of the oral proceedings, in accordance with Article 15(6) RPBA.

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- 4. Admission of the main request (Article 12(4) RPBA 2007)
- 4.1 The set of claims of the main request, filed as auxiliary request 3 with the statement of grounds of appeal, results from the deletion of claim 6 in auxiliary request 2 on which the appealed decision was based. The opposition division considered that that claim added subject-matter, which ultimately led to the revocation of the patent.
- The respondents have not contested that the main request was an adequate response to the decision under appeal or that it was filed at the earliest possible opportunity after the decision was issued. The matter of dispute is rather whether the request could and should have been filed during the opposition proceedings and, therefore, whether the board should hold it inadmissible pursuant to Article 12(4) RPBA 2007 (for its applicability to the present case, see Article 25(2) RPBA 2020).

It has not been disputed that the added-matter objection against claim 6 of then auxiliary request 2 was raised for the first time at the oral proceedings before the opposition division. This was also explicitly confirmed by respondent 1 at the oral proceedings before the board. The respondents' position was rather that the appellant should have expected the objection to be raised at the oral proceedings in view of the added-matter objection raised against claim 13 as granted by respondent 2 in its notice of opposition (point 3.8). Therefore, the appellant could and should have filed a claim request addressing this issue during the opposition proceedings. In particular, the respondents maintained that the opposition division did

not prevent the appellant from filing a further claim request at the oral proceedings, the appellant simply did not wish to do so.

4.3 The board is not convinced by those arguments. As noted by the appellant, the set of claims of then auxiliary request 2 had been filed about two years before the oral proceedings held on 7 May 2015. Between the filing of the claims of auxiliary request 2 and the oral proceedings, respondent 2 and the opposition division raised multiple added-matter objections against the then main request and auxiliary requests 1, 3, 4 and 5 (see respondent 2's letter dated 13 May 2014, section 2, and the communication annexed to the summons to oral proceedings, section II.2a). Respondent 1 did not raise any added-matter objection during that period (see the letter dated 13 April 2015). Thus, an added-matter objection was never raised against then auxiliary request 2, let alone against its claim 6. In addition, the respondents and the opposition division raised objections of lack of novelty, lack of inventive step and lack of sufficiency of disclosure.

Having regard to the numerous objections raised by the respondents and the opposition division against all the claim requests then on file and the fact that no added-matter objection had been raised against the claims of then auxiliary request 2, the board fails to see why the appellant should have expected added subject-matter to be discussed at the oral proceedings in relation to claim 6 of auxiliary request 2. This is even more so the case considering that claim 6 of auxiliary request 2 had already been a response to the added-matter objection raised in respondent 2's notice of opposition against claim 13 as granted and that the latter objection had not been pursued further against the

claims of then auxiliary request 2 in the written proceedings during opposition. Hence, before the oral proceedings of 7 May 2015, the appellant had had no reason to file further amendments in relation to claim 6 of auxiliary request 2.

4.4 In this situation, where the objection that would lead to the revocation of the patent was raised for the first time at the oral proceedings, it was the opposition division's duty to ensure that the appellant could fairly prepare and respond to the new objection with arguments and/or amendments.

From the minutes of the oral proceedings before the opposition division (see page 2, paragraphs 2 and 3), it would appear that the appellant was sufficiently prepared to discuss claim 6 and the basis of its subject-matter in the application as filed, and, accordingly, that it had been given the opportunity to defend its position with arguments. The appellant has not complained in that respect. What the board needed to establish, however, is whether the appellant also had been given the opportunity to respond to the new objection by filing amendments, if it had so wished.

On this point, the minutes of oral proceedings are of little help because they do not contain any pointer suggesting that the appellant had indeed been given the opportunity to file amendments. For instance, they are silent on whether the opposition division had asked the parties for confirmation of their requests before announcing its final decision. Recording this procedural step would have been particularly important because the decision was based on an objection raised for the first time at the oral proceedings. Thus, although the respondents are right in that the

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opposition division had no obligation to suggest that the appellant file a further claim request, the division should at least have made sure that the appellant had the opportunity to do it if it so wished, and this should have been reflected in the minutes.

The minutes of the oral proceedings before the opposition division do not allow the board to conclude that the appellant had the opportunity to file amendments to overcome the objection in relation to then auxiliary request 2, raised for the first time during the oral proceedings. Therefore, it cannot be established that the set of claims of the main request, filed as auxiliary request 3 with the statement of grounds of appeal and which addresses this very objection by way of amendment (deleting claim 6), could have been presented in the proceedings before the opposition division. Consequently, the claims of the main request could not be held inadmissible pursuant to Article 12(4) RPBA 2007 and had to be taken into account by the board.

5. Added subject-matter (Article 123(2) EPC) - claims 1, 4 and 6 of the main request

The XRPD peak lists defining the polymorphs of claims 1, 4 and 6 were disclosed on page 9, line 8; page 12, line 17; and page 8, line 12 of the application as filed, respectively. They were extracted from their respective XRPD patterns reproduced in Figures 6, 23 and 1 of the application, rounded to integers or half-integers, and qualified with the word "approximately".

It is generally accepted that the skilled person understands that any specific value obtained empirically is subject to a margin of error. Thus, the

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skilled person would have read the peaks in claims 1, 4 and 6 as being approximate even in the absence of the word "approximately". Consequently, the word "approximately" was superfluous and could be removed without adding any new technical information.

Furthermore, the board agrees with the appellant that the removal of "approximately" does not result in XRPD patterns which encompass new polymorphs. The peak list in claim 1 defines only form B of lenalidomide, irrespective of whether or not the word "approximately" is present. The same is true for the peak lists in claims 4 and 6 in relation to forms E and A of lenalidomide, respectively.

In consequence, claims 1, 4 and 6 of the main request do not add subject-matter within the meaning of Article 123(2) EPC.

- 6. Admission of additional added-matter objections
- At the oral proceedings before the board, respondent 1 raised added-matter objections against claims 2, 5, 7, 9-12, 15-18 and 21-38 of the main request. The objections were essentially the following:
 - claims 2, 5 and 7: the word "about" has been removed compared with the application as filed;
 - claims 9-12: page 6, lines 2-4 of the application as filed defines the amount of one polymorphic form and the amount of "other polymorphic forms"; in claims 9-12, the amount of "other polymorphic forms" has been removed;

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- claims 15-18: due to their dependency on claim 14, which in turn depends on claims 1-8, claims 15-18 define a mixture of amorphous lenalidomide with a certain amount of the specific crystalline forms A, B and E; there is no basis in the application as filed for that combination of features;
- claims 21-26: these claims define selections from two lists, namely a specific dosage form and a specific amount of active agent;
- claims 27-38: due to their dependency on claims 1-8, claims 27-38 define selections from two lists, namely a specific therapeutic indication and a specific polymorphic form.
- Respondent 1 contended that the objections had been raised in both the opposition and the appeal proceedings against analogous claims in the patent as granted. In this respect, it referred to respondent 2's letter dated 13 May 2014 (section 2) and to respondent 1's reply to the statement of grounds of appeal (pages 4-6).
- 6.3 The claims as granted correspond to the claims of the main request as follows:

As granted	Main request
6, 12, 18	2, 5, 7
20-23	9-12
26-29	15-18
32-37	21-26
38-49	27-38

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- 6.4 The added-matter objections raised against the claims as granted in the letter dated 13 May 2014 were the following:
 - In relation to claims 6, 12 and 18, the letter referred to the objections raised in the notice of opposition, which contained added-matter objections against claims 6, 12 and 18 but not on the ground that the word "about" had been removed (see points 3.4, 3.8 and 3.9 of respondent 2's notice of opposition).
 - The objection against claims 20-49 was formulated in a very general manner; specifically, it mentioned only that the claims contained a selection from two lists, namely a dosage form (e.g. a tablet) and an amount of active ingredient (e.g. 25 mg). This objection may be associated with claims 32-37 as granted (claims 21-26 of the main request).
- In view of the above, out of the objections raised by respondent 1 at the oral proceedings before the board, only the one directed to claims 21-26 could be derived from the letter dated 13 May 2014. An inspection of the notices of opposition and the opposition division's communication sent in preparation for the oral proceedings reveals that none of the other new objections had been raised throughout the opposition proceedings. Hence, only the objection against claims 21-26 may be considered to have been raised in the opposition proceedings.

In relation to the latter, the board however notes that the objection against claims 32-37 as granted was not pursued in the written proceedings before the board. It

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was raised for the first time against claims 21-26 of the main request at the oral proceedings before the board. Raising this objection changed respondent 1's case at a very late stage of the appeal proceedings. Its admission appeared unfair towards the appellant and would have been detrimental to procedural economy since it would have required that the appellant be given the opportunity to adequately react to these objections. Therefore, the board decided not to admit it into the appeal proceedings (Article 13(1) RPBA 2007).

The objections against claims 2, 5, 7, 9-12, 15-18 and 27-38 had not been raised in the opposition proceedings. The objection in relation to the removal of the word "about" was raised for the first time with respondent 2's reply to the statement of grounds of appeal (page 7, paragraph 4). The remaining objections were raised by respondent 1 in its reply to the statement of grounds of appeal (pages 3-5).

It is nevertheless apparent that they could and should have been raised against the corresponding claims in the patent as granted from the outset in the opposition proceedings. A further opportunity for the respondents to raise these objections during the opposition proceedings arose when the appellant filed the sets of claims of auxiliary requests 1 and 2 together with its reply to the notices of oppositions. The objections would also have applied since the claims of the present main request are those of auxiliary request 2 with claim 6 of the latter having been deleted. Thus, albeit late in opposition, this further opportunity arose still during opposition proceedings and not only at the appeal stage.

Hence, the objections against claims 2, 5, 7, 9-12,

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15-18, and 27-38 raised in the respondents' replies to the appeal were held inadmissible by the board pursuant to Article 12(4) RPBA 2007.

7. Remittal - Article 111(1) EPC and Article 11 RPBA

Concerning the question of whether the claimed subjectmatter met the requirements of the EPC, the decision
under appeal was confined to an assessment of added
subject-matter under Article 100(c) and
Article 123(2) EPC, respectively. The issues have been
overcome in the set of claims of the main request
before the board (see points 4-6 above). Accordingly,
pursuant to Article 111(1), second sentence, EPC, the
board has discretion over whether to exercise any power
within the competence of the department which was
responsible for the decision appealed or to remit the
case to that department for further prosecution.

The appellant and respondent 1 requested that the case be remitted to the opposition division if the board found that any of the claim requests on file fulfilled the requirements of Article 123(2) EPC. Respondent 2 did not take a position on this issue.

Having regard to the board's function to review the decision under appeal and given that two of the parties have explicitly requested remittal, the remaining party has not objected to remittal and the opposition division did not rule on the issues of novelty, inventive step and sufficiency of disclosure, the board considers that special reasons present themselves to remit the case to the opposition division for further prosecution pursuant to Article 11 RPBA.

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- 8. Remaining issues
- 8.1 In the light of the above, there was no need for the board to decide on the admission of auxiliary requests 4-10 and document D32 into the proceedings, or on the opposition division's decision not to hear Prof. Dr Kirschning.

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8.2 Since a reimbursement of the appeal fee under Rule 103(1)(a) EPC is not dependent on the filing of any request, the board considered the matter ex officio in view of the appellant's allegations of substantial procedural violations presented in writing.

However, there was no reason for the board to order a reimbursement of the appeal fee. It had not been argued by the appellant nor was it apparent to the board that the decision taken in relation to the then main request (patent as granted) was tainted with a substantial procedural violation. The appellant lodged the appeal, defending the patent as granted as main request in the statement of grounds of appeal. Therefore, the events surrounding the new objection in relation to claim 6 of then auxiliary request 2 cannot be considered as having forced the appellant to lodge an appeal. A causal link to the filing of the appeal can therefore not be established.

That the appeal could be allowed was primarily the consequence of the appellant's changed position in that it no longer defended the patent as granted as the main request (see section VIII). Accordingly, a reimbursement of the appeal fee would not have been equitable in the present circumstances and the requirements of Rule 103(1)(a) EPC are thus not met.

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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 for further prosecution.

The Registrar:

The Chairman:



M. Schalow A. Lindner

Decision electronically authenticated