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**Datasheet for the decision
of 30 May 2022**

Case Number: R 0008/21

Appeal Number: T 0777/17 - 3.3.04

Application Number: 09711390.6

Publication Number: 2249859

IPC: A61K38/09, A61P35/00, A61P35/04

Language of the proceedings: EN

Title of invention:
Treatment of metastatic stage prostate cancer with degarelix

Patent Proprietor:
Ferring B.V.

Opponent:
Generics (UK) Ltd (trading as Mylan)

Headword:
Petition rejected as clearly inadmissible

Relevant legal provisions:
EPC Art. 112a(2)(c), 112a(2)(d), 113, 113(1), 116(1)
EPC R. 104, 106, 107(1), 107(2), 109(2)
RPBA 2020 Article 15(2)(c)(ii), 15(2)(c)(iv)

Keyword:
Obligation to raise objections - objection raised (no)
Petition for review - clearly inadmissible

Decisions cited:
R 0004/08, R 0008/12

Catchword:

-



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Case Number: R 0008/21

D E C I S I O N
of the Enlarged Board of Appeal
of 30 May 2022

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Decision under review:

**Decision T 0777/17 of the Technical Board of
Appeal 3.3.04 of the European Patent Office of
22 September 2020.**

Composition of the Board:

Chairman: I. Beckedorf
Members: T. Bokor
B. Stolz

Summary of Facts and Submissions

- I. The patent proprietor filed a petition for review under Article 112a EPC of decision T 0777/17 of the Technical Board of Appeal 3.3.04 (hereinafter the "Board") dated 22 September 2020, which set aside the contested decision of the Opposition Division and revoked European patent No. 2249859, essentially for lack of inventive step.

Overview of the proceedings leading to the petition

- II. In the proceedings before the Opposition Division the opposition had been rejected, and subsequently the opponent appealed, arguing insufficient disclosure under Article 100(b) EPC and lack of inventive step under Article 100(a) EPC.
- III. Concerning the written stage of the appeal proceedings before the Board, the following facts are relevant for the petition:
 1. During the appeal proceedings the opponent submitted documents D26 and D27 to support their arguments on the lack of inventive step and of sufficiency of disclosure. Documents D17 and D23, which were already in the proceedings, were also mentioned by the opponent in the discussion on the meaning of the variable IU/L in the patent, as part of the sufficiency debate.
 2. On 27 July 2020 the Board issued a preliminary opinion in preparation for oral proceedings summoned for 22 September 2020 and stated that the Board expected a revocation of the patent, either for insufficiency of disclosure or lack of inventive

step, for all requests. Among other issues, the Board also addressed the possible meaning of the variable IU/L and stated that its precise meaning in the patent was not clear for the skilled person, as an argument on sufficiency.

3. In two letters dated 20 and 21 August 2020, the proprietor requested postponement of the oral proceedings. It was submitted that the proprietor's US counsel would be unable to travel to Germany, due to the Covid situation, and his presence was seen as necessary.
4. The opponent, referring to Article 15(2)(c)(ii) RPBA 2020, argued that the oral proceedings should not be postponed. The Board informed the parties in a communication dated 11 September 2020 that the oral proceedings would not be postponed, referring to Article 15(2)(c)(iv) RPBA 2020.
5. On 15 September 2020 the proprietor requested that the oral proceedings be conducted by videoconference. The request was reasoned as follows: *"We remain of the opinion that the presence of our client, [the US counsel], is essential to our case. As you know, he is in the US and unable to travel to Germany. Thus, we request VICO proceedings in order for [the US counsel] to be able to attend the hearing."* The opponent agreed to the videoconference on the same day. On 18 September 2020 the professional representative submitted the names of the persons taking part in the oral proceedings in addition to the European representative, including the US counsel. The list

of names was accompanied with the following remark:
"For completeness, we note that it was always our intention to attend the in-person hearing with all of the above listed members."

- IV. The request for holding the oral proceedings by videoconference was granted and the oral proceedings before the Board were held on 22 September 2020 in the form of a videoconference. The persons indicated in advance participated on behalf of the proprietor.
- V. According to the minutes, the discussion during the oral proceedings was structured as follows:
- i. In a first round, inventive step was discussed for the main request. During the discussion the opponent requested non-admission of an allegedly new argument of the proprietor concerning a direct effect of degarelix on cancer cells. After deliberation the Board gave its finding on the lack of inventive step and that the new argument was not relevant. Its admission was not decided.
 - ii. In a further round, the admission of the auxiliary request 2 was discussed, and the request was admitted. Thereafter inventive step was discussed, and the admission of another new line of argument submitted by the proprietor concerning the role of the haemoglobin level and its link to the hormone refractory stage. After the Board's deliberation the proprietor's new line of argument was not admitted and the request was found to lack an inventive step.
 - iii. After the Board's finding on auxiliary request 2, there was another break on request of the

proprietor. After the break, according to the minutes, the proprietor made the following statements: *"they did not want to submit further arguments regarding any of the lower ranking auxiliary requests"* and *"requested the board to record in the minutes of the oral proceedings and in the decision that the respondent had requested that the oral proceedings be postponed, which had however been rejected, and that the rejection had been detrimental to their case."*

- iv. The minutes mention that this request was followed by deliberation of the Board, but thereafter the Board did not announce any decision on this request. Instead, the opponent was asked for further comments on the lower-ranking requests, on which they had none. The Chairman invited the parties to state their final requests. The proprietor stated that the claim requests as discussed and presented in the oral proceedings were maintained and repeated the request to record in the minutes the petitioner's statement concerning the rejected postponement, as set out in the previous point.
 - v. The Chairman asked once more if there were further comments, closed the debate and announced the revocation of the patent.
- VI. In the written decision, the Board's reasons correspond to the decisions made at the oral proceedings, both in respect of inventive step and the admission issues. Reasons for not postponing the oral proceedings are also given (points 2 to 4 of the Reasons). There is no mention of the request to record the proprietor's statement in

the minutes (see points V. iii. and V. iv. above). The decision mentions documents D26 and D27 as part of the parties' submissions, but they are not mentioned in the reasons.

Overview of the proceedings before the Enlarged Board

VII. The reasoned petition was filed on 7 June 2021, and the prescribed fee was paid on the same day. The petitioner submits that a fundamental violation of Article 113(1) EPC within the meaning of Article 112a(2)(c) EPC and further fundamental procedural defects within the meaning of Article 112a(2)(d) EPC occurred in the appeal proceedings. The petitioner's right to oral proceedings under Article 116(1) EPC was impaired, and the parties before the Board were not equally treated. These petition grounds were based on multiple independent objections, set out in more detail below.

Objection 1: refusal of the Board to postpone the oral proceedings (cf. point III. 4. above) and holding oral proceedings by videoconference against the will of the proprietor (points 2.1.2 and 2.1.3 of the petition). The petition also mentions that the oral proceedings were riddled with various problems, and as a result, the proprietor was unable to present its complete case (point 2.1.4 of the petition).

Objection 2: non-admission of new arguments in respect of the main request (point 2.2.1 of the petition), concerning a direct effect of degarelix on cancer cells (cf. point V. i. above).

Objection 3: non-admission of new arguments in respect of the auxiliary requests 2 (point 2.2.2 of the petition),

concerning the link between the haemoglobin level of 130g/l and the hormone-refractory stage of cancer (cf. point V. ii. above).

Objection 4: In contrast to the non-admitted arguments of the patentee, the opponent was permitted to raise new arguments (point 2.2.3 of the petition). The new arguments were based on late-filed documents D26 and D27, and also on D17 and D23, the latter concerning the meaning of IU/L in the patent, as part of the discussion on sufficiency (cf. point III. 1. above).

Objection 5: In contrast to the non-admitted arguments of the patentee, even the Board brought forward new arguments (see point 2.2.4 of the petition). The Board's new argument also concerned the meaning of IU/L in the patent in the discussion on sufficiency (cf. point III. 2. above).

VIII. The Enlarged Board issued a communication under Articles 13 and 14(2) of the Rules of Procedure of the Enlarged Board of Appeal (RPEBA) and summoned the petitioner to oral proceedings. The Enlarged Board stated that the petition appeared as clearly inadmissible under Rule 106 EPC and also clearly unallowable in respect of all objections. The petitioner did not submit further observations in writing.

IX. The oral proceedings before the Enlarged Board were held on 30 May 2022.

The petitioner requested

that the contested decision be set aside and
the proceedings re-opened, and
that the fee for the petition for review be

reimbursed.

The Enlarged Board issued the decision at the end of the oral proceedings.

Reasons for the decision

Admissibility

1. The petition is reasoned, it was timely filed and the fee was paid (Rule 107(1) and (2) EPC). The petitioner is adversely affected by the decision.

Requirements of Rule 106 EPC

2. Pursuant to Rule 106 EPC, a petition for review based on a petition ground under Article 112a(2) (a) to (d) EPC is only admissible where an objection in respect of the procedural defect was raised during the appeal proceedings and dismissed by the Board of Appeal, except where such objection could not be raised during the appeal proceedings.
3. The file and the submissions of the petitioner do not permit any statement of the petitioner to be recognised as an objection under Rule 106 EPC. This holds true for all five objections. From the minutes, the Board's decision and from the totality of the file it is clear that all those perceived procedural irregularities which now constitute the petitioner's case were known to the petitioner already during the oral proceedings. At no point does the petitioner argue that any of the irregularities only became apparent to it from the written decision. It is also apparent from the minutes that the petitioner had multiple opportunities to formulate a proper objection under Rule 106 EPC already during the oral proceedings.

Objection 1

4. The Enlarged Board indicated in its preliminary opinion that the objections of the petitioner set out in points 2.1.2-4 of the petition are considered to constitute a single objection, based on the statements of the petitioner in point 2.1.5 of the petition. During the oral proceedings before the Enlarged Board this was not contested by the petitioner, who stated that that the core of objection 1 was the rejection of the postponement of the oral proceedings before the Board.

5. As to the requirements of Rule 106 EPC, the petitioner argued in the oral proceedings before the Enlarged Board that it must have been clear to the Board that the proprietor intended to file a petition for review. The petitioner's request for recording its complaint in the minutes could not have meant anything else under the circumstances. An explicit mention of Rule 106 EPC was not required by this rule or any other provision of the EPC.

6. The Enlarged Board acknowledges that the recorded statement in the minutes (see point V. iii. above) is clearly a complaint which expresses the dissatisfaction of the proprietor with the rejection of its request for postponement. However, the Enlarged Board does not accept that the request for recording the complaint or the recorded statement itself is to be considered a formal objection under Rule 106 EPC. The Enlarged Board points to the settled case law of the Enlarged Board of Appeal, namely that an objection under Rule 106 EPC must be expressed by the party in such a form that the Board is able to recognise immediately and without doubt that an

objection under Rule 106 EPC is intended. An objection under Rule 106 EPC is additional to and distinct from other statements, such as arguing or even protesting against the conduct of the proceedings or against an individual procedural finding. Reference is made to the Case Law of the Boards of Appeal (CLBA), 9th edition 2019, chapter V.B.3.6.2.a).

7. The Enlarged Board recognises that an objection under Rule 106 EPC does not have to make a direct and explicit reference to this rule. As stated in decision R 08/12, Reasons 19, when it comes to determining whether the petitioner has observed Rule 106 EPC, what matters is not the formal wording of the objection but its substance as it could be understood by the Board. On the face of it, the minutes record that there was a request from the proprietor. This request was explicitly directed at the recording of the following statement: "*The respondent had requested that the oral proceedings be postponed, which had however been rejected. The rejection had been detrimental to [the respondent's] case.*" The recording request was apparently granted and the statement was recorded in the minutes, even twice. The recorded statement itself contained nothing that could have demonstrated to the Board that the petitioner in fact meant it as an objection under Rule 106 EPC.
8. The Enlarged Board observes, following the case law, that the purpose of Rule 106 EPC is to give the Board a chance to react immediately and appropriately by either removing the cause of the objection or by dismissing it (R 04/08, Reasons 2.1). By ensuring that errors can be corrected by a Board before a final decision is taken, Rule 106 EPC also ensures that unnecessary petitions for review are

avoided (R 18/12, Reasons 19). See also CLBA, *supra*, chapter V.B.3.6.1.

9. However, from the minutes it transpires that no other requests were formulated at that point from which the Board might have recognised that it was expected either to dismiss an objection or to eliminate the cause of the objection pursuant to Rule 106 EPC.
10. This is also confirmed by the statements of the petitioner made during the oral proceedings before the Enlarged Board. There the petitioner stated in response to a question from the Enlarged Board that at that point in time when the petitioner made its recording request in the oral proceedings before the Board, it would have been too late to request the postponement, as the oral proceedings had effectively finished and the request for postponement and the substantive issues were already discussed and decided on. This demonstrates that at the end of the oral proceedings before the Board the petitioner itself did no longer expect the Board to take any decision that could have corrected the perceived procedural defect. Thus, the Board had no reason to believe that, beyond the recording of the statement, it was also expected to take some corrective action in order to prevent a possible petition for review by the proprietor.
11. It is also clear that the petitioner made no further request for the postponement of the oral proceedings, nor any objection under Rule 106 EPC, when it would still have been possible from the perspective of the petitioner to correct the alleged procedural error, namely at the start of the oral proceedings.

12. The Enlarged Board can even accept that the Board might have suspected under the circumstances that the recording request was made by the proprietor with some purpose, possibly a petition for review of the Board's decision. However, the petitioner could not have expected the Board to enquire about an underlying additional purpose of the request. It is up to a party to formulate its requests, and the explicit request - the recording of a statement - was unambiguous. Even less could the petitioner have expected that the Board would call its attention to the fact that the statement and the request to have it recorded might not be suitable as an objection under Rule 106 EPC. Doing so would have gone against the Board's obligation to remain impartial, and to avoid assisting any party against the other (see also CLBA, *supra*, chapter V.B.4.3.6).

13. In summary, there was no apparent circumstance that must have led the Board to conclude that the statement of the petitioner and the request to have it recorded in the minutes is nothing else but an objection under Rule 106 EPC, possibly indicating a violation of Article 116 EPC within the meaning of Rule 104 EPC or indicative of a procedural defect under Article 112a(2) EPC in some other way. Even less could it be understood by the Board as an objection relating to Article 113 EPC.

Objections 2-5

14. During the oral proceedings before the Enlarged Board the petitioner maintained these objections, but refrained from providing further comments or arguments on them.

15. In the communication of the Enlarged Board (see point VIII.) it was already pointed out that the

petitioner only argued that the admission issues underlying the objections had been timely presented by the petitioner (point 2.2.6 of the petition) but had been incorrectly decided by the Board. There is no statement of the petitioner, either in the file or mentioned in the petition, which the Enlarged Board might possibly identify as an explicit objection under Rule 106 EPC in respect of any of the Objections 2 to 5.

16. Furthermore, the petitioner did not argue that any of the alleged irregularities only became apparent to it from the written decision, as mentioned above in point 3. Indeed, the facts underlying Objections 2, 4 and 5 play no role in the Board's decision, as the corresponding issues did not have to be decided. The non-admission of the argument in respect of the auxiliary request 2 underlying Objection 3 was discussed and decided in the oral proceedings before the Board, and the petitioner had multiple opportunities to make observations after this issue was decided and announced.

17. In conclusion, the Enlarged Board holds that the petition is clearly inadmissible pursuant to Rule 106 EPC in respect of all petition grounds and as such it is clearly inadmissible within the meaning of Rule 109(2)(a) EPC.

Order

For these reasons it is decided that:

The petition for review is unanimously rejected as being clearly inadmissible.

The Registrar:

The Chairman:



N. Michaleczek

I. Beckedorf

Decision electronically authenticated