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**Datasheet for the decision
of 16 May 2018**

Case Number: J 0005/17 - 3.1.01

Application Number: 11000464.5

Publication Number: 2322194

IPC: A61K38/11, A61P13/00

Language of the proceedings: EN

Title of invention:

Pharmaceutical compositions including low dosages of
Desmopressin

Applicant (Respondent):

Reprise Biopharmaceutics, LLC

Third party (Appellant):

Ferring B.V.

Headword:

Resumption of proceedings for grant

Relevant legal provisions:

EPC Art. 61(1)

EPC R. 14(1), 14(3)

Keyword:

Stay of proceedings for grant
Resumption of proceedings for grant

Decisions cited:

G 0003/92, J 0007/93, J 0010/02, J 0033/03, J 0006/10,
J 0007/10, J 0017/12, J 0013/12, J 0015/13

Catchword:

Rule 14(3) EPC is silent on the reasons for setting a date for resumption of the proceedings for grant. It is thus to be concluded that the legislator let it to practice and jurisprudence to define the circumstances that justify setting a date for resumption on a discretionary basis.

Resumption of the proceedings is not limited to cases involving misuse or delaying tactics. The possibility that the EPO sets a date for resumption upon staying the proceedings for grant hints towards a broader construction.

However an applicant cannot justify its request for resumption based on the length of the entitlement proceedings where this duration has been significantly caused by the applicant's procedural conduct.



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Case Number: J 0005/17 - 3.1.01

D E C I S I O N
of the Legal Board of Appeal 3.1.01
of 16 May 2018

Appellant: Ferring B.V.
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2132 JX
Hoofddorp (NL)

Representative: Kuipers, Gertjan et al.
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Respondent: Reprise Biopharmaceutics, LLC
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Representative: Kupecz, András Ferenc
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Decision under appeal: **Decision of the Legal Division dated 28 March
2017**

Composition of the Board:

Chairwoman C. Vallet
Members: J. Geschwind
P. Guntz

Summary of Facts and Submissions

I. The appeal lies against the decision of the Legal Division dated 28 March 2017 with regard to patent applications EP 03781836.6, EP 11000464.5, EP 11000465.2, EP 11000466.0, EP11000467.8 and EP 11000468.6, by which it ordered that the grant proceedings related to them be resumed under Rule 14(3) EPC on 1 June 2017.

II. The essential facts of the case are as follows:

The parent application was filed as an international application (PCT/US2003/35662) on 10 November 2003 and the time period for entry into the European phase expired on 10 June 2006.

The transfer of this application to Reprise Biopharmaceutics LLC (hereafter: Reprise or: the respondent) was registered in the European Patent Register with legal effect from 3 September 2008.

Five divisional European patent applications were filed on 21 January 2011 and published on 18 May 2011.

On 7 February 2011, the EPO sent out a communication under Rule 71(3) EPC of its intention to grant the parent application.

On 28 March 2011, Ferring B.V. (hereafter: Ferring or: the appellant), a third party, instituted entitlement proceedings against Reprise before the District Court of The Hague with regard to all the above-mentioned patent applications.

Patent grant proceedings before the EPO were stayed pursuant to Rule 14(1) EPC, for the parent application as of **28 March 2011** and for the divisional applications as from their date of publication, **18 May 2011**.

The further transfer of the above-mentioned patent applications to a contractual transferee, Allergan Inc., was registered in the European Patent Register pursuant to Rule 22 EPC with legal effect from 20 April 2011.

By letter of 2 August 2011, Allergan Inc. requested resumption of the grant proceedings for the parent application with immediate effect.

By a decision of 25 May 2012, the Legal Division refused to resume the proceedings pursuant to Rule 14(3) EPC.

In its decision J 17/12 of 13 November 2013, the Legal Board of Appeal reversed the registration of Allergan Inc. as applicant, considering it to be merely an "interested party" with no right to request resumption of the grant proceedings.

On 12 March 2014, the District Court of The Hague decided in favour of the defendants (i.e. Reprise, Allergan Inc. and one other party) and rejected the entitlement claims of the plaintiff (i.e. Ferring). Ferring filed an appeal against this decision. The appeal proceedings are still pending before the Court of Appeal in The Hague.

By letters of 23 April 2014 and 31 October 2014, Reprise and Allergan Inc. filed new requests for resumption under Rule 14(3) EPC of the grant proceedings for the parent and divisional applications.

On 28 March 2017, the Legal Division decided that the grant proceedings for the European patent applications were to be resumed under Rule 14(3) EPC on **1 June 2017**. This decision was appealed by Ferring and is the subject of the present proceedings.

III. On 12 February 2018, the Board sent out a communication summarising the issues to be discussed and informing the parties of its preliminary opinion and its intention to dismiss the appeal.

Both parties filed submissions in response.

Meanwhile, concerning the Dutch entitlement proceedings, the Court has set Reprise a deadline of 22 May 2018 for filing a reply brief, and oral proceedings have been scheduled for 13 September 2018.

Oral proceedings before the Board took place on 16 May 2018.

IV. The parties' arguments both in writing and at the oral proceedings can be summarised as follows:

(a) The appellant's arguments:

- Grant proceedings can only be resumed if the third party gives its consent or upon a final decision within the meaning of Article 61(1) EPC.

- The discretionary power of the EPO under Rule 14(3) EPC should only take into account possible misuse of proceedings or delaying tactics. When instituting entitlement proceedings there was neither misuse of procedure nor delaying tactics on the appellant's part.

- The Legal Division's decision is based on a wrong interpretation of Rule 14(1) and (3) EPC. The approach taken - engaging in an act of balancing the interests of the parties - is fundamentally wrong and only adds to the prejudice of the third party. Furthermore the case law of the boards of appeal with regard to Rule 14 EPC and balancing the parties' interests is unclear.

- If the Board decided that it could engage in a balancing act, a referral to the Enlarged Board of Appeal would be necessary because of the absence of clarity in the case law of the boards of appeal with regard to this issue.

- It may only be decided in exceptional circumstances to resume proceedings based on a balancing act. A decision to resume the proceedings leads to the third party irretrievably losing its rights under Article 61 EPC once the patent is granted to the allegedly unlawful initial applicant, whereas the initial applicant only suffers a delay but no final loss where the proceedings keep stayed.

- The EPO is prohibited from taking into account the merits and material strength of entitlement claims.

- A non-final, first-instance decision in entitlement proceedings in favour of the applicant cannot be taken

into account and can by no means be a circumstance to base a resumption on.

Appeal proceedings in the Netherlands are de novo and a final decision should be awaited.

- There is no reason to hold the normal duration of national entitlement proceedings against the third party.

- The fact that the patent will reach the end of its life in 2023 cannot by any means be used against the third party.

- The respondent has no particular interest in a resumption and is not caused any irreparable harm by a stay of the grant proceedings; it has also used delaying tactics.

- The appellant has huge interest in a stay of the grant proceedings and would suffer irreparable harm in the event of a resumption.

(b) The respondent's arguments:

- The appellant has effectively managed to stop the parent application proceeding to grant for more than six and a half years.

For its part, the respondent denies using delaying tactics.

- The appellant as a third party brought proceedings at the latest possible point in time, just before grant of the patent.

- It is outside the scope of the appeal procedure to retake the Legal Division's decision, and the appeal is limited to a review of whether or not the Legal Division exercised its discretion correctly.

- The Legal Division exercised its discretion in the appropriate way. Exercising discretionary power requires balancing the interests of the applicant and the third party, which does not create an unbalanced situation to the detriment of the third party.

- Procedural abuse is only one of the factors to be considered, and it is not a precondition for resumption of the proceedings.

- The Legal Division balanced the interests of the parties by taking the circumstances in combination, and not in isolation.

- Resumption can be decided on regardless of the stage reached in the national entitlement proceedings.

- The fact that appeal proceedings in the Netherlands are de novo does not render the first-instance decision meaningless. The importance of a first-instance decision is recognised in the case law of the boards of appeal.

- The Court of Appeal's decision will not necessarily be the final ruling in the entitlement proceedings, and the appellant is likely to file a further appeal with the Supreme Court, meaning a further delay and an expected three to four more years of proceedings.

- The appellant has failed to explain what its real interests are in maintaining the stay of the grant proceedings.

- The patent applications that are stayed are of significant value to the applicant, and that value is dependent on the grant proceedings.

V. At the end of the oral proceedings before the Board, the final requests of the parties were as follows:

The appellant (third party), Ferring, requested that the decision under appeal be set aside and that the stay be kept in place until a final decision in the entitlement proceedings. By way of a first auxiliary request, it requested that the question, in substance, "whether misuse is a prerequisite for resumption of proceedings" be referred to the Enlarged Board of Appeal. By way of a second auxiliary request, it requested that a date be set for resumption of the grant proceedings that was one month after the date of the decision of the Dutch Court of Appeal if the ruling was in favour of Reprise, or if the decision by the Court of Appeal was favourable to Ferring that the grant proceedings before the EPO continue to be stayed.

The respondent (applicant), Reprise, requested that the third party's appeal be rejected and that the proceedings for grant be resumed. As a first auxiliary request, it requested a sufficient interruption of the oral proceedings to be able to deal with the requested referral to the Enlarged Board without postponement of the proceedings. As a second auxiliary request, it requested that the grant proceedings be resumed in accordance with Rule 14(3) EPC and the grant

proceedings be allowed only in respect of the suspended parent application to continue immediately.

Reasons for the Decision

1. *Admissibility of the appeal*

The appeal fulfils the requirements of Article 108 EPC and Rule 99(1) and (2) EPC. Thus the appeal is admissible.

2. *Allowability of the appeal*

2.1 The legal provisions

Article 61 EPC and Rule 14 EPC form part of a legal process for determining who is entitled to a European patent application which is disputed, and for implementing that party's entitlement.

Article 61(1) EPC provides that: "*If by a final decision it is adjudged that a person other than the applicant is entitled to the grant of the European patent, that person may, in accordance with the Implementing Regulations:*

- (a) prosecute the European patent application as his own application in place of the applicant;*
- (b) file a new European patent application in respect of the same invention; or*
- (c) request that the European patent application be refused."*

Under Rule 14(1) EPC, the European Patent Office must stay the grant proceedings if a third party provides evidence that it has instituted national proceedings for entitlement against the applicant. However, Rule 14(3) EPC provides that the European Patent Office may set a date on which it intends to resume the proceedings for grant of the patent stayed pursuant to Rule 14(1) EPC, regardless of the stage reached in the national proceedings.

2.2 Interpretation of Rule 14(3) EPC

2.2.1 The appellant took the view that, unless there is a final decision in the entitlement proceedings or the third party gives its consent to resumption according to Rule 14(1) or (2) EPC, a decision to resume the proceedings for grant can only be issued under Rule 14(3) EPC when there is evidence of abuse of proceedings such as delaying tactics on the part of the third party, in other words when the third party maliciously diverts the entitlement proceedings in order to stop or to delay the grant of a patent to the detriment of the legitimate applicant.

2.2.2 This interpretation cannot be derived from the wording of the rule itself, which says nothing about the possible reasons for setting a date for resumption of the proceedings. Thus the legislator has left it to practice and the case law to define the situations that justify setting a date for resumption.

2.2.3 The mere fact, as submitted by the appellant, that the *Travaux Préparatoires* mention twice that suspending proceedings could be abused as a way to delay the grant of a patent does not mean, as contended, that a decision to resume proceedings can only be taken in

cases of abuse. If this had been the legislator's intention, it would have indicated it expressly.

- 2.2.4 Moreover, the circumstance that a date for resumption can be fixed upon staying the proceedings for grant does not support the proposed restrictive interpretation. At that point in time, the EPO is typically not in a position to assess and not even to presume that the third party has or could have malicious intentions against the applicant.
- 2.2.5 As a consequence, the Legal Board considers that there is no need to further question the established case law, according to which Rule 14(3) EPC is to be understood as giving the deciding bodies of the EPO discretion to decide upon a date for resumption of the proceedings for grant taking into account all the considerations that have been developed by said case law.

3. *The request for referral to the Enlarged Board of Appeal*

Since the conditions laid down in Article 112 EPC are not fulfilled in the sense that no discrepancy exists in the case law and no new point of law of fundamental importance arises from the present case, the request for referral to the Enlarged Board of Appeal must be dismissed.

4. *The exercise of discretion by the Legal Division*

- 4.1 It is established case law that, in appeal proceedings where the board has to decide on a case where the

department of first instance had to exercise its discretion, it is not the function of the board to review all the facts and circumstances of the case as if it were the first-instance department in order to decide whether or not it would have exercised that discretion in the same way.

As a consequence, a board of appeal should only overturn the decision of the first-instance department if it comes to the conclusion that that department did not exercise its discretion according to the correct criteria or exercised it in an inappropriate way (J 7/93, OJ EPO 1994, 775, point 2.6 of the reasons; J 15/13, point 2.2 of the reasons), or if changes have occurred in the facts of the situation between the decision of the first-instance department and the decision of the board of appeal.

- 4.2 The Board is of the opinion that, in the present case, the Legal Division exercised its discretion under Rule 14(3) EPC based on the correct principles and in an appropriate way with regard to the facts of the case and the context of the entitlement proceedings at the time when it took its decision.
- 4.3 The Legal Division, in reaching its decision, balanced the interests of the appellant and the respondent. In this respect the Legal Board of Appeal has previously ruled that the department initially responsible for a decision pursuant to Rule 14(3) EPC has to take into account all valid interests of the parties. Aspects that should be considered are, in particular, how long the proceedings before the national courts or authorities have been pending, the duration of the suspension and whether the request for suspension of the grant proceedings was filed at a late stage

(J 6/10, point 4.2 of the reasons; J 7/10, point 4.1 of the reasons; J 15/13, point 2.5 of the reasons; J 33/03, point 2.2 of the reasons).

These criteria have not to be fulfilled cumulatively, and they may be assessed in combination with each other or in relation to other relevant aspects having an effect on the parties' interests (J 6/10, point 4.3 of the reasons; J 7/10, point 4.3 of the reasons). Abuse of proceedings is only one potential additional criterion; it is not a prerequisite for a resumption of the proceedings.

4.4 Stage reached in the national proceedings - non-final decision of the national court

Contrary to the appellant's argument, a final decision in entitlement proceedings within the meaning of the respective national procedural rules is not a precondition for resumption of the proceedings for grant.

It is undisputed that the European Patent Office has no power to determine the merits of the parties' cases in national entitlement proceedings, nor to evaluate the possible outcome of such proceedings after the parties have used all their available procedural rights (G 3/92, OJ EPO 1994, 607, point 3 of the reasons).

However, this does not mean that the Legal Division cannot take into consideration the fact that the appellant did not succeed in the first-instance proceedings before the District Court of the Hague (J 13/12, point 3.1.16 of the reasons), at least in order to assess the further procedural steps in which the parties may engage in the national proceedings, and the impact on those proceedings' expected duration. The

fact that appeal proceedings in the Netherlands are *de novo* is therefore to be considered in that the first-instance decision might well be reversed on appeal, based on a different factual background. The Legal Division also mentioned that it did not consider this aspect in isolation, but in combination with further aspects.

4.5 Duration of the stay of grant proceedings

Although it is undisputed that grant proceedings for a patent can be stayed by the European Patent Office for the entire duration of the national entitlement proceedings, as Rule 14(2) EPC suggests, the overall duration of a suspension and its impact on the legitimate interests of the applicant should be taken into consideration when it comes to deciding on a request for resumption (J 15/13, point 2.8 of the reasons).

According to the case law of the boards of appeal, a stay that has lasted longer than three and a half years could, under certain circumstances, damage the legitimate interests of the applicant (J 13/12, point 3.1.18 of the reasons; J 10/02 point 4.1. of the reasons). In further cases the boards of appeal have decided that a stay of four years is not in itself a decisive factor for a resumption and considered this aspect in combination with further elements, such as the procedural behaviour of a party in the national entitlement proceedings (J 6/10, point 4.3 of the reasons; J 7/10, point 4.3 of the reasons).

In the present case, the Legal Division considered the fact that the stay of the grant proceedings had been long, i. e. **six and a half years**, in combination with

the point in time when the entitlement proceedings had been initiated and the lifetime of the parent application, which will end in 2023.

Furthermore the Legal Division also combined the above-mentioned aspects with the consideration that, with regard to the still pending entitlement proceedings and the expected remaining time before a final decision, it would be unreasonable to expect the applicant to wait for a final ruling in the entitlement proceedings before the grant proceedings were continued (see J 33/03, point 3 of the reasons).

As already underlined before (see point 4.3. penultimate sentence) the Board agrees that it is not required that all the criteria cited in the case law or in the Guidelines for Examination be fulfilled, and that they may be considered in combination with each other.

The Legal Division decided to leave out further criteria with regard to the parties' procedural behaviour, either in the national entitlement proceedings or before the EPO, and the provision of evidence of possible economic losses for the applicant, since the EPO would not be in a position to assess or verify economic allegations made in this context.

In exercising its discretion, the first-instance department should have a certain degree of freedom (J 7/93, OJ EPO 1994, 775, point 2.6 of the Reasons).

It is the essence of a discretionary power to weigh up the specific facts and aspects of a case which the deciding body considers the most relevant and valid to reach a correct and appropriate balancing of the interests of the parties.

Thus the Board considers that the Legal Division exercised its discretion correctly and appropriately in consideration of the facts of the case and the context of the entitlement proceedings at the time that the impugned decision was taken.

5. *New facts and circumstances*

New facts and circumstances now prevail, distinguishing the current situation from the situation when the impugned decision was taken.

Firstly, both parties informed the Board for the first time during the oral proceedings of their **bipartisan** request that the results of the US discovery proceedings, which ended in April 2016, be included in the Dutch entitlement proceedings.

The Legal Division did not know of that request when it took its decision, in particular when it assessed the duration of the stay (see point 4.5 above). Yet a significant part of the length of the national proceedings is due to this agreement between the parties.

Secondly, although another year has elapsed, Reprise has not replied so far to the statement of grounds of appeal of the third party in the entitlement proceedings. As a consequence, the Dutch court set a first deadline for such a reply, which was subsequently extended to 22 May 2018.

A hearing has also been scheduled for 13 September 2018.

Reprise justified the delay in particular by the transfer of the parent and divisional applications or licences therefor to further companies (i.e. Allergan Inc., Serenity Pharmaceuticals), such that many parties represented by different counsels were involved, rendering it more difficult to get instructions from the parties in the US.

Since the entitlement proceedings take place within the framework of the national procedural law applicable in the competent national jurisdiction, the parties' procedural conduct must be in accordance with those specific regulations and the judicial practice of the court concerned.

The Board is however satisfied that Reprise, the defendant in the entitlement proceedings, has not shown any urgency in making its case, which has contributed to the duration of the proceedings before the Court of Appeal of The Hague. During the oral proceedings before the Board, Reprise even declared that it would file a rejoinder to the statement of grounds for appeal, but on 22 May 2018, i.e. at the very latest opportunity in the time frame for doing so set by the Court.

Although the procedural conduct of Reprise is compliant with the procedural law and judicial practice at national level, and thus cannot qualify as an abuse, this attitude is fundamentally in contradiction with the reasons it has given in favour of a resumption of the grant proceedings.

Moreover, questioned at the oral proceedings before the Board about commercial activities undertaken with the aim of launching the product "Noctiva" on the market, Reprise was not in a position to supply any precise answer.

6. *Consequences for the resumption of the proceedings*

When weighing up the interests of the parties, it has to be kept in mind that a decision to resume the proceedings leads to an actually entitled third party irretrievably losing its right to influence the grant proceedings under Article 61(1)(a) to (c) EPC once the patent is granted to an unlawful initial applicant, whereas an actually entitled initial applicant normally suffers a delay but no final loss where the proceedings remain stayed until its rights have been finally established in national proceedings. Therefore, Rule 14(1) and (2) EPC, in order to keep open the three options under Article 61(1) EPC, envisages a staying of the proceedings until a final decision has been taken in the national proceedings. Rule 14(3) EPC is an exception to that principle that allows for resumption of the proceedings when the harm caused by the delay is about to outweigh a loss of the options under Article 61 EPC. The fact that a date for future resumption under Rule 14(3) EPC can be ordered at the outset shows that the EPC accepts a potential loss of the options under certain circumstances. As set out above, according to the case law of the boards of appeal, not only an abuse of the proceedings, but also a long stay of the proceedings can tip the balance towards a resumption under Rule 14(3) EPC.

However, long entitlement proceedings can only be seen as an unbearable burden if the applicant has not itself either caused the delay or significantly contributed to it. That does not need to amount to an abuse of proceedings. Even though it may be reasonable conduct to await the outcome of the US discovery proceedings, and even though it is not abusive to extend periods and to make full use of them, any delay willingly taken

into account cannot at the same time be used as proof of unbearable harm caused by the duration of the stay of proceedings.

Taking into account the new facts brought forward by the parties and the situation prevailing at the date of the oral proceedings, the Board considers that balancing the interests of the parties at this point in time leads to a further stay of the proceedings. The fact that the lifetime of the parent application will end in 2023 is not decisive any more in the context described above. The mere fact that the first-instance decision in the entitlement proceedings was in favour of the applicant is not sufficient to resume the proceedings for grant. As a consequence, the Board considers that the stay of the proceedings for grant must be maintained.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The stay of the proceedings is maintained.

The Registrar:

The Chairwoman:



P. Cremona

C. Vallet

Decision electronically authenticated