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**D E C I S I O N**  
of 10 November 1999

**Case Number:** J 0022/97 - 3.1.1

**Application Number:** 90913952.9

**Publication Number:** 0493444

**IPC:** C12N 5/06

**Language of the proceedings:** EN

**Title of invention:**  
Blood-brain barrier model

**Applicant:**  
ELAN PHARMACEUTICALS, INC.

**Headword:**  
Due care/ELAN

**Relevant legal norms:**  
EPC Art. 86(2), 122

**Keyword:**  
"Article 122(2) EPC requirements (yes)"  
"All due care (no) - system not normally satisfactory"

**Decisions cited:**  
J 0002/86, J 0027/88, J 0027/90, T 0191/82, T 0287/84

**Catchword:**  
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Boards of Appeal

Chambres de recours

**Case Number:** J 0022/97 - 3.1.1

**D E C I S I O N**  
**of the Legal Board of Appeal 3.1.1**  
**of 10 November 1999**

**Appellant:**

ELAN PHARMACEUTICALS, INC.  
800 Gateway Boulevard  
South San Francisco, CA 94080 (US)

**Representative:**

Uexküll & Stolberg  
Patentanwälte  
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**Decision under appeal:**

Decision of the Receiving Section of the EPO dated 23 August 1996 refusing the request for re-establishment of rights into the period for further processing of application 90 913 952.9 under Article 121 EPC.

**Composition of the Board:**

**Chairman:** J.-C. Saisset  
**Members:** M. Vogel  
S. C. Perryman

## Summary of Facts and Submissions

- I. The international application PCT/US 90/05106 in the name of Athena Neurosciences, Inc. ("Athena") was filed on 13 September 1990 and entered into the regional phase under the Euro PCT No. 90 913 952.9 on 24 April 1992. The partial supplementary search report under Rule 45 EPC was sent to Athena's representative on 23 September 1994. It indicated that the claims of the application were considered to relate to six different inventions, individually listed by reference to the corresponding claims, and that the search related only to the first of these concerning an in vitro model of a blood-brain barrier.
  
- II. The EPO issued a communication pursuant to Article 96(1) and Rule 51(1) EPC (Form 1224) to the representative on 3 October 1994 inviting Athena to indicate whether it was desired to proceed further with the application, and setting a time limit for response of two months, thus ending on 13 December 1994. As no response was made a "Noting of loss of rights" communication pursuant to Rule 69(1) EPC was issued on 10 January 1995 setting a time limit for response of two months, thus ending on 20 March 1993. No response to this communication was filed within the time limit.
  
- III. By a letter of 10 August 1995 (received by the EPO on 11 August 1995) the representative requested restitutio in integrum under Article 122 EPC and further processing of the application under Article 121 EPC, paid the appropriate fees, completed the omitted act, i.e. indicated that Athena wished to process further with the application, stated the grounds for the application and provided supporting evidence including a declaration by a Patents Assistant employed by Athena.
  
- IV. In the grounds and evidence it was stated:

- The EPO communication of 3 October 1994 was duly reported by the European representative to her US instructing attorney, who in turn reported it to Athena. Whether to continue with the application was one of the matters considered at the quarterly meeting of Athena's patent committee on November 1, 1994.
  
- For this quarterly meeting numerous sets of claims were photocopied by the Patent Assistant, as part of her routine work in performing the clerical work needed to support Athena's intellectual property portfolio, which work included typing, photocopying and mailing. For the application in question she photocopied claims 1-100 of the international application as filed, but no copies of pending claims 101-152 were photocopied or given to the patent committee. The Patent Assistant had at the time been employed for five months by Athena's under the constant supervision of Athena's Director of Intellectual Property ("IP Director"), and had proved very reliable.
  
- On the basis of the incomplete set of claims 1-100 the committee decided that the US application and the International application corresponding to the European Application were no longer of interest to Athena, and that no further action should be taken with respect to these applications. The US attorney was informed of this who in turn informed the European representative that no action was to be taken, it being understood that the application would then be considered withdrawn and the examination fee reimbursed.

- Athena was informed of the EPO communication "Noting a loss of rights" issued on 10 January 1995, but in view of the committee decision this was expected and required no action to be taken.
  
- It was only on 20 June 1995 when the IP Director was preparing a schedule for an agreement on cell trafficking technology that she realized that subject-matter of the utmost interest to Athena was covered by claims 101-152 of the international application and the corresponding part of the European application, and that these claims had not been before the patent committee when taking its decision not to proceed. With a view to remedying the situation she immediately contacted Athena's US attorney, who immediately contacted the European representative.
  
- It was submitted that Athena was unable to comply with the time limit for indicating that the application should be proceeded with further, in spite of all due care in the circumstances being taken because of error as to the contents of the application induced as a result of the committee not having before it all the claims of the international application. This cause of non-compliance was not removed until the IP Director noted on 20 June 1995, that claims 101-152 of the international application had not been before the committee. The two month term under Article 122(2) EPC thus expired only on 20 August 1995.

V. The refusal of the request for re-establishment in the decision of the Receiving Section dated 23 August 1996 which is the decision under appeal was based on the ground that the date of removal of the cause of non-compliance was the 20 January 1995 and not - as submitted by Athena - the 20 June 1995. According to the established case law of the Boards of Appeal the date of removal of the cause

of non-compliance is the date on which the responsible person is made aware of the fact that a time limit has not been observed. In "the absence of circumstances to the contrary" a communication under Rule 69 EPC removes the cause of non-compliance. This happened on the 20 January 1995 when Athena's representative received the communication "Noting of loss of Rights" (Form 1099).

At the latest this was when Athena or its representative should have considered the claims carefully being aware of the non-extendable time limit pursuant to Rule 69 EPC.

VI. On 17 September 1996 Athena filed a notice of appeal against the said decision. The appeal fee was paid on the same date and a written statement of grounds was submitted on 27 December 1996. Athena requested that the decision under appeal be set aside and the application be maintained according to the request for restitutio in integrum of 8 August 1995; it also requested oral proceedings.

VII. In its grounds of appeal Athena argued that the cause of non-compliance was the decision, taken by the patent committee on the basis of an incomplete set of claims, not to proceed further with this application. Consequently the date of removal of the cause of non-compliance was the 20 June 1995, when Athena became aware that this decision was taken by reference to an incomplete set of claims. This view would be in line with the decision J 27/90 where it is stated that only "in the absence of circumstances to the contrary" would the communication under Rule 69(1) EPC remove the cause of non-compliance. In the present case there were circumstances to the contrary in the form of the committee's decision. Furthermore, all due care for the purpose of Article 122(1) EPC had been exercised by the person (the IP Director) responsible for the application by relying on a well trained and constantly supervised assistant to perform routine work such as

copying claims. In a written statement filed as exhibit 5 of the grounds the IP Director declared that she had worked as patent attorney since 1986, and for Athena and subsequently the appellant since April 1994.

- VIII. In the course of the appeal proceedings Elan Pharmaceuticals Inc. acted as the successor in title to Athena.
- IX. In a communication dated 21 July 1999 the appellant was invited to comment on the preliminary and non-binding view of the board that it would be unreasonable to leave to an assistant the task of identifying which of four different sets of claims filed during the application was the correct one and not to check that was done. Moreover, the set of claims only partly copied by the Patent Assistant would not have been the correct set on file at the EPO which, in amended form, comprised only 40 claims. In the communication it was also pointed out that the question whether Athena was unable to observe a time limit in the sense of Article 122(1) EPC or not was left open for discussion.
- X. During the oral proceedings the IP Director explained in further detail the procedure followed for preparing patent committee meetings, namely that:
- The IP Director herself identified the files of the applications on which the committee had to decide whether they should be continued or not, and personally marked in the respective file the relevant set of claims with a sticker and gave her assistant the order to copy those claims.
  - The patent committee decided during the meeting of 1 November 1994 on the further handling of some 20 to 40 cases in about 2 hours.

- The decision about this case was taken on the basis only of the incomplete set of claims 1-100 of the international application, and not on the basis of the reduced set of 40 claims actually on file at the EPO. This was because the committee members were most familiar with this set of claims based on US practice, and best enabled them to decide on the fate of the applications worldwide.
  
- No check lists or summaries of the claims were prepared for meetings.

## **Reasons for the Decision**

1. *Date of removal of cause of non-compliance*
  - 1.1 The board does not agree with the ground given in the appealed decision for refusing the appellant's request for re-establishment pursuant Article 122 EPC. The date of the removal of the cause of non-compliance in the sense of Article 122(2) EPC was not, as found by the Receiving Section, the date on which Athena received the communication under Rule 69 EPC but was rather the date when the IP Director noticed that Athena's patent committee had erroneously decided not to continue the application on the basis of an incomplete set of claims. This was 20 June 1995.
  
  - 1.2 According to the established case law of the Boards of Appeal, the cause of non-compliance normally can be considered to have been removed when the person responsible for the application is made aware of the fact that a time limit has not been observed (J 27/88; T 191/82, OJ EPO 1985, 189; T 287/84, OJ EPO 1985, 333; J 27/90, OJ EPO 1994, 422). This - as the Receiving Section pointed out correctly in



the contested decision - is usually the date on which the applicant or his representative received the "Noting of loss of Rights" communication under Rule 69(1) EPC (Form 1099), in this case 10 January 1995.

1.3 However, the Receiving Section overlooked that this principle is not always applicable. As the Board of Appeal held in the cited decision it only applies "in the absence of circumstances to the contrary" (see J 22/90, OJ EPO 1993, 422). Here Athena, in the form of the responsible body, the patents committee, was aware of the time limits associated with a particular European application number: what the committee was not aware of as a result of having only an incomplete set of claims before them, was the true identity of the application, so that they were not in a position to reach a proper decision.

1.4 While not every mistake as to the claims of an application would be sufficient to destroy the basis of a decision to allow an application to be deemed withdrawn, in this case the claims not seen by the committee do allow the conclusion to be drawn that their decision was vitiated by a fundamental mistake as to the subject-matter of the application. Claims 1 to 100 appearing on pages 70 to 84 of the international application and considered by the committee contained some eleven independent claims, whereas claims 101 to 152 appearing on pages 85 to 91 of the international application and not seen by the committee contained an additional fifteen independent claims, partly relating to considerably different subject-matter.

1.5 Thus contrary to the reasons in the appealed decision, the Board agrees with the appellant that in the circumstances of this case, it was the mistake as to the identity of the application that must be treated as the cause of non-compliance. While the instructions not to take any action were the immediate cause of non-compliance, the mediate cause of these instructions was the mistake as to identity and it is to this mediate cause to which one should look for the purpose of Article 122 EPC.

1.6 The communication under Rule 69 EPC did not dispel this mistake as to identity. Rather such a communication was only to be expected in view of the instructions sent, and cannot be treated as putting the applicant on notice that something needed checking. The cause of non-compliance was only removed on 20 June 1995 when the IP director noted that the decision had been taken on an incomplete set of claims.

1.7 The application for restitutio can thus be treated as made within the two month time limit from the removal of the cause of non-compliance laid down in Article 122(2) EPC. The other conditions of Article 122(2) and (3) EPC were complied with by Athena. It thus remains to consider whether the time limit was not observed despite all due care in the circumstances having been used.

2. *All due care in the circumstances*

2.1 The case law of the Boards of Appeal recognises that Article 122 EPC is intended to ensure that in appropriate cases the loss of substantive rights does not result from an isolated procedural mistake within a normally satisfactory system (cf J 2/86, OJ EPO 1987, 362 at point 4). In particular it has been accepted in the case law that secretaries and patent assistants, and even patent attorneys, are not perfect, and that human errors can occur.

However, as a counterbalance, the case law requires that the system used is one that is normally satisfactory, which means that the system used should also make some provision appropriate in the circumstances to allow for the occurrence of human errors and provide some checks for their detection. In decision J 27/88 of 5 July 1989 (not published in OJ EPO) relied on by the appellant, an error occurred in a letter drafted by a patents assistant. This letter was checked by the US attorney there involved but he too missed the error. But at least the system incorporated such a check. Further if a human error occurs just before a deadline, the error may be detected by the system too late to prevent the time limit being missed. But at least where a system detects the error for itself, even if one or more days too late, this is evidence that checks have been incorporated in the system by reason of which checks with a bit more luck any adverse consequences of the error would have been prevented. This can be taken into account when assessing whether the system can be considered as normally satisfactory.

- 2.2 Prior to the oral proceedings before it, the board had been under the, as it turns out mistaken, impression that the Patents Assistant had been left to select the correct claims for herself, which would have been a task beyond that which the board would have regarded as one which could reasonably be left to a patents assistant in a case with a complex application history such as the present one. The additional evidence of the IP director is however that she marked the claims which the Patent Assistant was to copy, so that provision of the incomplete copies can be regarded as an isolated error by an adequately instructed and supervised assistant in carrying out a task she could reasonably be expected to perform. The main question for decision is thus whether the system used, in which this error was not detected, can be regarded as satisfactory.

2.3 The error of the patents assistant in providing an incomplete set of claims was not the last opportunity to correct this error. Athena's patents committee considered the incomplete set of claims without the error being noticed, and subsequently instructions were sent to the attorneys without the error being noticed. The error of the patents assistant in providing the incomplete set would not have been decisive if any person at the meeting had relied on the documents in Athena's complete file instead of on the (incomplete) copy. It was not submitted to the board that anybody checked the copy claims against the original file before supplying the copies to the committee members, or checked them at the meeting, and the board must thus assume that this was not part of the system.

2.4 In answer to a question from the board the IP director stated that no check lists had been prepared or used identifying the number of claims in the international application, or identifying the independent claims. It was not submitted to the board that the search report from the European Office identifying the different inventions in the 40 claims then before the EPO was considered by the committee, and this would indeed have been difficult to consider given that the committee had before it only the differently numbered and more numerous claims of the international application. Nor was it submitted to the board that there was any cross-reference on the file to alert those responsible for patents as to what ongoing research was covered by the application.

2.5 Further the decision of the committee was apparently noted in the form of a decision that the US and the international applications were to be abandoned, without any comment as to what claims were considered by the committee. It was not submitted to the board that any check of the copied claims that the committee had decided on against the content of the file was made when giving the instructions to abandon,

and again the board must assume that this was no part of the system.

2.6 It was explained to the board that at such a patent committee meeting some 20 to 40 cases would be considered in two hours. Given that on the evidence the Patents Assistant was preparing copies of claims for all cases to be considered, the need for some form of check that the copies for each case were indeed accurate seems pressing. While it might be natural to assume that a patents assistant can correctly copy a single set of claims, if she is copying some twenty or more, the chances of at least one mistake seem great enough for a check on accuracy to be called for, however reliable and conscientious the patents assistant had proved to be. One person of the committee looking at the actual claims in the original file would serve as such a check, so no great effort was needed.

2.7 Further this time schedule would appear to leave an average of 3 to 6 minutes consideration per case. Given that even the incomplete set of claims was fifteen pages long with eleven independent claims, even if more than an average amount of time was spent on this application, it was still dealt with very quickly. This helps to explain why the error in the copies was not noticed, but cannot be regarded as providing any form of check that the copies being considered were correct, or even enough time for anyone to be likely to question the completeness of the copied claims on the basis of a vague recollection from previous consideration of the international application.

2.8 It is not for the board to prescribe what system an applicant should use when looking after its patent portfolio. None of the matters above mentioned as not being part of Athena's system would seem in itself to be absolutely essential. Nevertheless the total absence of these, or any equivalent checks, precludes a finding that the system used was normally satisfactory, and thus that all due care in the circumstances had been used as required for re-establishment under Article 122 EPC. A system in which a decision whether to proceed or not is based only on copies of claims seems to be introducing a hazard, which would need to be counterbalanced by adequate checks to ensure that the copies are accurate. Here the system as described to the board incorporated no checks on the copies of the claims prior to submission to the committee, no checks when considering the copies of the claims in the committee, and no checks later when executing this decision, nor any cross-reference to ongoing research programmes covered by the application. The system cannot be regarded as meeting the requirements of Article 122 EPC.

2.9 The IP Director has assured the Board that apart from this instance, the system of making decisions relying on copies of the claims had otherwise worked without fail. However, with such an intrinsically hazardous system the board cannot accept this as decisive evidence that the system was satisfactory, but merely as evidence that those operating the system have been extremely conscientious. Here the communications between Athena, its US patent attorney and its European representative worked perfectly. Normally it is in these, and not internally in an appellant that some break-down occurs. That an error occurred internally which was not brought to light by the system, but only because the IP director was preparing a schedule for a licence agreement concerning an invention covered only by the claims not considered by the committee, only highlights the unfortunate defect in the system using only

unchecked copies of claims for bringing to the attention of the committee the question of whether or not to proceed with the application and for executing the committee's decision. The practice, operated by Athena in the instant case, involved a foreseeable risk, which could have been avoided or reduced if Athena had taken appropriate precautions. The absence of any such precautions precludes re-establishment pursuant to Article 122 EPC as it has not been shown that the time limit was missed despite all due care in the circumstances being used.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

M. Beer

J.-C. Saisset