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D E C I S I O N
of 13 May 1994

Case Number: G 0007/93
Application Number: 87116757.3
Publication Number: 0268222
IPC: A61K 47/00

Language of the proceedings: EN

Title of invention:

Penetration enhancers for transdermal delivery of systemic agents

Applicant:

Whitby Research, Inc.

Opponent:

-

Headword:

Late amendments/WHITBY II

Relevant legal norms:

EPC Art. 96(2), 113(2), 123(1), 167(2)
EPC R. 51(4), (6), 86(3)

Keyword:

"Amendments after a Rule 51(6) communication - discretion of
Examining Division"
"Reservations under Article 167(2) EPC"

Decisions cited:

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Headnote:

I. An approval of a notified text submitted by an applicant pursuant to Rule 51(4) EPC does not become binding once a communication in accordance with Rule 51(6) EPC has been issued. Following issue of such a communication under Rule 51(6) EPC and until issue of a decision to grant the patent, the Examining Division has a discretion under Rule 86(3) EPC, second sentence, whether or not to allow amendment of the application.

II. When exercising such discretion following issue of a communication under Rule 51(6) EPC, an Examining Division must consider all relevant factors. In particular it must consider and balance the applicant's interest in obtaining a patent which is legally valid in all of the designated States, and the EPO's interest in bringing the examination procedure to a close by the issue of a decision to grant the patent. Having regard to the object underlying the issue of a communication under Rule 51(6) EPC, which is to conclude the granting procedure on the basis of the previously approved text, the allowance of a request for amendment at that late stage in the granting procedure will be an exception rather than the rule.

III. Reservations under Article 167(2) EPC do not constitute requirements of the EPC which have to be met according to Article 96(2) EPC.



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Boards of Appeal

Chambres de recours

Case Number: G 0007/93

D E C I S I O N
of the Enlarged Board of Appeal
of 13 May 1994

Appellant: Whitby Research, Inc.
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Decision referring a point of law: **Decision of the Technical Board of Appeal 3.3.2 dated 25 May 1993 in case T 830/91.**

Composition of the Board:

Chairman: P. Gori
Members: G.D. Paterson
F. Antony
C. Payraudeau
E. Persson
R. Schulte
P. van den Berg

Summary of Facts and Submissions

- I. In case T 830/91 pending before Technical Board of Appeal 3.3.2, the Examining Division issued a communication under Rule 51(4) EPC, informing the applicant of the text in which it intended to grant a European patent, and requesting the applicant to indicate his approval of such notified text within a set period. The applicant approved the notified text in due time.

The Examining Division then issued a communication under Rule 51(6) EPC, inviting the applicant to pay the fees for grant and printing and to file translations of the claims within a further set period. Within such period, the applicant filed a letter which purported to withdraw his previously stated approval of the notified text, and purported to declare his approval of a text with amended claims as attached to such letter. The proposed amended claims included what was stated to be a correction of a clerical error in Claim 1, and three new sets of claims for three designated Contracting States who have made reservations under Article 167(2)(a) EPC allowing them to provide that European patents which confer protection on certain classes of subject-matter (in particular, chemical, pharmaceutical and food products) shall, in accordance with provisions applicable to national patents in such States, be ineffective or revocable.

The Examining Division issued a communication in reply, stating that correction of the clerical error in Claim 1 was possible under Rule 88 EPC, but that the other proposed amendments were not allowable because the applicant is bound by his previous approval of the notified text. Subsequently, the Examining Division issued a decision refusing the application pursuant to

Article 97(1) and (2) EPC because there was no agreed text as required by Article 113(2) EPC which could serve as the basis for grant of a patent.

II. Following the filing of an appeal by the applicant, Technical Board of Appeal 3.3.2 has referred the following questions to the Enlarged Board of Appeal under Article 112(1)(a) EPC:

1. In the light of Article 113(2) EPC, is Rule 51(6) EPC to be interpreted such that an approval submitted under Rule 51(4) EPC becomes binding once a communication in accordance with Rule 51(6) EPC has been issued?
2. Is the European Patent Office obliged to consider reservations under Article 167(2) EPC as constituting requirements of the EPC which have to be met according to Article 96(2) EPC?

III. In its decision of referral, Technical Board of Appeal 3.3.2 drew attention in particular to the following matters:

Question I

- (i) Previous relevant jurisprudence

In Decision T 1/92, OJ EPO 1993, 685, Technical Board of Appeal 3.3.2 held that approval of a proposed text in response to a Rule 51(4) EPC communication did not bind the applicant if such approval was withdrawn and amendments proposed, before expiry of the time limit set by the Rule 51(4) EPC communication for giving approval.

In Decision T 675/90, OJ EPO 1994, 58, Technical Board of Appeal 3.3.1 held that after the issue of a Rule 51(6) EPC communication, the Examining Division did not have any discretion under Rule 86(3) EPC to consider requested amendments to the text.

The facts of the case presently before Technical Board of Appeal 3.3.2 were parallel to those of Decision T 675/90.

(ii) Article 113(2) EPC

This provision was based on the "fundamental right of parties to civil law proceedings to decide the scope of their case", and in particular to control the content of the patent application at every stage of the proceedings. Rule 51(6) EPC did not necessarily limit such right, especially since according to Article 164(2) EPC, Article 113(2) EPC must prevail over any Implementing Regulation.

(iii) Rule 51 EPC

It seems that Rule 51(6) EPC should be interpreted merely as obliging the EPO (after having established that the applicant has approved the text) to invite payment of certain fees and filing of translations.

(iv) Balancing various interests

A speedy grant procedure is in the interest of the public, but the grant of invalid patents must be against the public interest.

It would be inconsistent to limit the procedural right of an applicant to request amendment by a provision (Rule 51(4) EPC) which was introduced in the interests of applicants. It does not seem consistent to allow amendments to be requested during self-opposition proceedings by the patentee after grant, but not to allow such amendments when requested by the applicant before grant (cf. Decision G 1/84 OJ EPO 1985, 299).

The interest of the EPO in having practicable working conditions should take third place after the interests of the applicant and the public.

Question 2

The basic responsibility of the EPO is to issue valid patents. While the validity of a patent in Contracting States that have made a reservation under Article 167(2) EPC is not an immediate condition under the EPC, nevertheless the Guidelines for Examination (C-VI, 4.10) suggest that requested amendments should be considered if the reason for the request is that otherwise unpatentable subject-matter would be claimed. It would therefore seem reasonable to conclude that amendments arising out of reservations under Article 167(2) EPC would qualify as fundamentally important in this respect.

IV. The President of the EPO submitted comments to the Enlarged Board, essentially, as follows:

Question 1

(i) The EPC imposes requirements on the EPO which must be met before a patent is granted, namely:

- obtaining the applicant's approval of the notified text (Articles 113(2) and 97(2)(a) EPC);
- obtaining translations of the claims (Article 97(5) and Rule 51(6) EPC);
- obtaining payment of fees for grant and printing, and, if applicable, claims fees (Article 97(2) and Rules 31(2) and 51(7) EPC);
- issuing a decision to grant (Article 97(2) EPC);
- printing the specification (Article 98 EPC), and publishing the mention of the grant of the patent in the European Patent Bulletin (Article 97(4) EPC): both of which require specific technical preparations.

These steps in turn require as a functional necessity that the final text of a patent must become fixed at a point in time before the grant proceedings are closed. This point in time must be before the Rule 51(6) EPC communication is issued, because some of the steps listed above, such as the payment of printing and claims fees (by the applicant) and the issue of the decision to grant and the publication of the patent (by the EPO) depend upon the content of the text.

- (ii) The practice of the EPO, as set out in the Guidelines for Examination (C-VI, 4.9-4.11; C-VI, 15.1) and in a Notice from the Vice-president of DG2 dated 20 September 1988 (OJ EPO 1989, 43), is that further amendments are not allowed after an applicant has approved the notified text. The proper legal basis for this practice is Rule 86(3) EPC.

- (iii) The nature of the "binding force" of an approval by an applicant under Rule 51(4) EPC was such that it was nevertheless mandatory for the EPO to react, even after receipt of such approval, if it is discovered that the text is deficient as to satisfying the requirements of the EPC.

- (iv) Contrary to Decision T 1/92, such "binding force" of an approval under Rule 51(4) EPC comes into existence upon the date of receipt of such approval by the EPO.

- (v) The discretionary power to allow amendments under Rule 86(3) EPC was limited by attributing binding effect to the approval under Rule 51(4) EPC, in the sense that no consent is given to further amendments proposed by the applicant which are not necessary to overcome substantial deficiencies in the application documents: this conformed with the EPC, in particular Articles 113(2) and 125 EPC.

Question 2

The Examining Divisions are not required under Article 96(2) EPC to consider requirements of national laws. The applicant's attention is drawn in every Rule 51(4) EPC communication to the possibility of obtaining separate sets of claims for designated States who have made reservations under Article 167(2) EPC, as voluntary practical assistance in this connection.

Reservations under Article 167(2) EPC are not considered as constituting requirements of the EPC under Article 96(2) EPC.

- V. The applicant submitted comments to the Enlarged Board in reply to the President's comments. In particular it was suggested that if the EPO was obliged to consider reservations under Article 167(2) EPC as requirements of the EPC which have to be met according to Article 96(2) EPC, any undesirable prolongation of the examination procedure would be avoided. In any event, if the EPO has not specifically advised the applicant of the necessity to file amended claims in respect of designated States which have made reservations under Article 167(2) EPC, the filing of such amended claims during proceedings before the Examining Division should be allowable.

Reasons for the Decision

1. *Background to referred question 1: summary of the relevant procedure*

Before deciding to grant a patent, in accordance with Rule 51(4) EPC an Examining Division "shall inform the applicant of the text in which it intends to grant it and shall request him to indicate ... his approval of the text notified". If no approval of the notified text is filed in due time, the application is refused under Rule 51(5) EPC.

After the applicant has approved the notified text, in accordance with Rule 51(6) EPC, an Examining Division "shall invite him to pay ... the fees for grant and printing and shall also invite him to file ... a translation of the claims in the two official languages of the EPO other than the language of the proceedings", within a set period of between two and three months. Any claims fees not yet paid must also be paid within this set period (Rule 51(7) EPC).

According to Article 97(2) EPC, if it is established that the applicant has approved the text in which the Examining Division intends to grant the patent, and if the fees for grant and printing have been paid within the set period, and if the renewal fees and any additional fees already due have been paid, the Examining Division shall decide to grant the European patent. The decision to grant the patent shall not take effect until the date on which the European Patent Bulletin mentions the grant (Article 97(4) EPC). The EPO must publish a specification containing the description claims and any drawings at the same time as it publishes the mention of the grant (Article 98 EPC).

2. *Question 1*

2.1 The referring Board of Appeal has indicated its view that Article 113(2) EPC is based on the fundamental right of parties to civil law proceedings to decide the scope of their case. In the Enlarged Board's view, this provision of the EPC does not give any right to an applicant in the sense that the EPO is in any way bound to consider a request for amendment put forward by the applicant. The effect of this provision is merely to forbid the EPO from considering and deciding upon any text of an application **other than** that "submitted to it, or agreed, by the applicant or proprietor ...".

The question whether an approval submitted under Rule 51(4) EPC becomes binding once a communication in accordance with Rule 51(c) EPC has been issued depends rather upon the proper interpretation of Article 123(1) EPC in conjunction with Rule 86(3) EPC. In particular the final sentence of such Rule reads as follows: "No further amendment may be made without the consent of the Examining Division".

This condition for amendment remains applicable so long as the Examining Division retains competence over the application, which is until it decides to grant the European patent under Article 97(2) EPC. In particular, this condition for amendment is applicable in the circumstances of the referred question, namely after issue of a communication under Rule 51(6) EPC. Thus as a matter of legal power, following receipt of the applicant's approval of the notified text under Rule 51(4) EPC and following issue of a Rule 51(6) EPC communication, the Examining Division still has a discretion to allow amendment of an application until a decision to grant a patent is issued.

Neither approval of the notified text by the applicant, nor issue of a Rule 51(6) EPC communication by the EPO, "binds" either the applicant or the EPO in the true meaning of that word, namely so as to bar subsequent amendment of the application. Contrary to the President's views as set out in his comments to the Enlarged Board, the Examining Division has a discretion to allow amendment prior to issue of a decision to grant a patent, either upon request by the applicant or on the Examining Division's own motion.

Thus the Enlarged Board does not accept the interpretation of these provisions of Rule 51 EPC as set out in Decision T 675/90 and subsequently confirmed and developed in Decision T 860/90 (not published in OJ EPO), according to which the amendments to Rule 51 EPC which came into effect on 1 June 1991 (OJ EPO 1991, 4) had the effect of curtailing the discretion to allow amendments as provided by Rule 86(3) EPC upon issue of a communication under Rule 51(6) EPC.

2.2 In general terms, the way in which the Examining Division should exercise its discretion to allow an amendment of an application must depend upon the circumstances of each individual case, and must also depend upon the stage of the pre-grant procedure which the application has reached.

It is clear from the wording of the provisions in Rule 51(4) to (6) EPC that the underlying object of the Rule 51(6) EPC communication is to conclude the granting procedure on the basis of the previously notified and approved text of the application. Thus although the Examining Division still has a discretion to allow amendments at this stage of the pre-grant procedure, such discretion must be exercised with the above underlying object in mind.

2.3 The wording in Rule 86(3) EPC "No further amendment may be made without the consent of the Examining Division" simply means that the Examining Division may or may not give its consent to a request for amendment by the applicant. However, as stated at the end of paragraph 2.2 above, since the underlying object of a Rule 51(6) EPC communication is to conclude the granting procedure on the basis of the approved text, a request for amendment which is received by an Examining Division after such a communication has been issued should be considered in a different way from a similar request for amendment received at a much earlier stage in the overall examination procedure, and in particular before approval by the applicant of a notified text. Such a request should be considered in the context of the very late stage in the pre-grant procedure at which it has been made, and against the background that the Examining Division has already completed its substantive examination of the application, and that the applicant has already had at least one opportunity to amend the

application. Against such background, the allowance of a requested amendment after issue of a Rule 51(6) EPC communication will be an exception rather than the rule. Nevertheless the question remains, in what kind of circumstances is it appropriate to make an exception to the normal rule?

2.4 In the Enlarged Board's view, when considering the possible circumstances when it may be appropriate for an Examining Division to exercise its discretion under Rule 86(3) EPC to allow an amendment after issue of a Rule 51(6) EPC communication, it should be borne in mind that a request for amendment at that stage may arise either as a result of a realisation by the applicant of a need for amendment, or as a result of a point raised by the Examining Division, or as a result of consideration of observations made by a third party pursuant to Article 115 EPC. In any of these circumstances, the discretion to allow amendment should be exercised according to the same principles. Of course, an objection should only be raised by an Examining Division at that stage of the proceedings if it is prepared to allow amendment to meet the objection.

2.5 When deciding whether or not to allow a request for amendment at that stage of the pre-grant procedure, in the exercise of its discretion under Rule 86(3) EPC, in the Enlarged Board's judgment an Examining Division is required to consider all relevant factors which arise in a case. In particular, it must consider both the applicant's interest in obtaining a patent which is legally valid in all of the designated States, and the EPO's interest in bringing the examination procedure to a close by the issue of a decision to grant the patent, and must balance these interests against one another.

As stated in paragraph 2.3 above, the allowance of a request for amendment at that stage will be an exceptional case. Nevertheless, in the Enlarged Board's view, a clear example of an exceptional case when it may be appropriate to allow amendment, is when the applicant requests separate sets of claims to be substituted in respect of designated States that have made reservations under Article 167(2) EPC. In such a case no further substantive examination of the case may be required, and any short delay caused by making the necessary amendments is then of little weight, compared to the importance to the applicant of obtaining a valid patent in such designated States.

Similarly, other minor amendments which do not require re-opening of substantive examination and which do not appreciably delay the issuing of a decision to grant the patent may be allowable after issue of a Rule 51(6) EPC communication.

- 2.6 It may be added that if an Examining Division has exercised its discretion under Rule 86(3) EPC against an applicant in a particular case and the applicant files an appeal against the way in which such discretion was exercised, it is not the function of a Board of Appeal to review all the facts and circumstances of the case as if it were in the place of the first instance department, in order to decide whether or not it would have exercised such discretion in the same way as the first instance department. If a first instance department is required under the EPC to exercise its discretion in certain circumstances, such a department should have a certain degree of freedom when exercising that discretion, without interference from the Boards of Appeal. In the circumstances of a case such as that before the referring Board, a Board of Appeal should only overrule the way in which a first instance

department has exercised its discretion if it comes to the conclusion either that the first instance department in its decision has not exercised its discretion in accordance with the right principles as set out in paragraph 2.5 above, or that it has exercised its discretion in an unreasonable way, and has thus exceeded the proper limits of its discretion.

3. *Question 2*

- 3.1 Under Article 96(2) EPC, an Examining Division is required to consider whether the application or the invention to which it relates meets the requirements of the EPC. When a Contracting State to the EPC makes a reservation under Article 167(2) EPC, it reserves the right to make provisions in its national law on the matters set out in Article 167(2) EPC. Such provisions of national law are clearly not "requirements of the EPC", within the meaning of Article 96(2) EPC. In the Enlarged Board's view, the present practice of the Examining Divisions in this respect, as summarised in paragraph IV above under the heading "Question 2", is correct.

Order

For these reasons, it is decided that:

The questions of law referred to the Enlarged Board of Appeal are to be answered as follows:

1. An approval of a notified text submitted by an applicant pursuant to Rule 51(4) EPC does not become binding once a communication in accordance with Rule 51(6) EPC has been issued. Following issue of such a communication

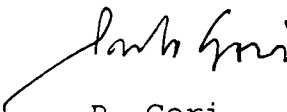
under Rule 51(6) EPC and until issue of a decision to grant the patent, the Examining Division has a discretion under Rule 86(3) EPC, second sentence, whether or not to allow amendment of the application.

2. The European Patent Office is not obliged to consider reservations under Article 167(2) EPC as constituting requirements of the EPC which have to be met according to Article 96(2) EPC.

The Registrar:

The Chairman:


J. Rückerl


P. Gori