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File Number: T 0830/91 - 3.3.2
Application No.: 87 116 757.3
Publication No.: 0 268 222
Title of invention: Penetration enhancers for transdermal delivery of
systemic agents

Classification: A61K 47/00

I N T E R L O C U T O R Y D E C I S I O N
of 25 May 1993

Applicant: WHITBY RESEARCH, Inc.

Headword: Late amendments/WHITBY

EPC Art. 96(2), 112, 113(2), 164(2), 167(2)
R. 51, 86(3)

Keyword: "Admissibility of amendments after a Rule 51(6) communication" -
"Reservations under Article 157(2) EPC" - "Important points of
law"

Headnote

follows



Case Number : T 0230/91 - 3.3.2

I N T E R L O C U T O R Y D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 25. May 1993

Appellant : WHITBY RESEARCH, Inc.
2801 Reserve Street
US - Richmond, VA 23261-7426 (US)

Representative : KOHLER SCHMID + PARTNER
Patentanwälte
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Decision under appeal : Decision of the Examining Division of the European Patent Office dated 5 June 1991 refusing European patent application No. 87 116 757.3 pursuant to Article 97(1) EPC.

Composition of the Board :

Chairman : A. Nuss
Members : C. Holtz
U. Kinkeldey

Summary of Facts and Submissions

- I. The Appellants filed European patent application No. 87 116 757.3 on 13 November 1987. Among the States designated were Austria, Greece and Spain. No separate sets of claims were filed for these States.
- II. On 14 December 1989, a communication under Rule 51(4) EPC was issued, in which the Examining Division of the EPO declared its intention to grant the patent on the basis of a specified text.

In response to this communication, the Appellants in a letter received by the EPO on 9 April 1990 agreed to the amendments made in the application and stated that they were now waiting for the communication under Rule 51(6) EPC.

- III. On 19 April 1990, a communication under Rule 51(6) EPC was issued, stating that the Appellants' approval of the text as the basis for grant had been duly received. The Appellants were further requested to pay the granting and printing fees within a non-extendable period of three months from notification of the communication.
- IV. In a letter received by the EPO on 9 July 1990, the Appellants withdrew their approval of the text proposed for grant. They further declared their approval of the description and the claims, on condition that a clerical error in Claim 1 could be corrected, three new sets of claims for the States mentioned above in point I be added and the claims already on file be allotted to the remaining designated States. The reason given for the latter requests was that product claims were not allowable in the three States concerned. This had been overlooked, partly due to the fact that no communication

under Rule 51(2) EPC had preceded the communication under Rule 51(4) EPC. The Appellants also gave their reasons why these amendments were allowable. On 20 August 1990, the Appellants submitted further arguments as to why their requests for amendments should be allowed.

- V. The Examining Division on 10 October 1990 issued a communication under Article 96(2) and Rule 51(2) EPC, giving the Appellants the opportunity to reinstate the claims in the form on the basis of which the communication under Rule 51(6) EPC had been sent, possibly with a correction of the clerical error in Claim 1, as they were bound by their approval. The Appellants were further informed that failure to do so would result in the application being rejected, as for the time being there was no text on which the patent could be granted (Article 97(1) EPC).

On 7 March 1991, the Formalities Officer of the Examining Division issued a communication (Form EPO 2093) to replace the one of 10 October 1990. In the new communication, the Appellants were again reminded that they were bound by their approval of the text, and that therefore the requested amendments no longer could be taken into account. The Appellants were asked to notify the EPO within two months, whether they requested grant on the basis of the previously notified acceptable version of the documents or not, and were further informed that, if the request to amend the application was maintained, the patent application would be refused pursuant to Article 97(1) EPC.

- VI. On 16 May 1991, the Appellants filed their response to the communication of 7 March, again asking that the separate sets of claims be allowed.

VII. On 5 June 1991, the Examining Division took a decision to refuse the patent application, pursuant to Article 97(1) in conjunction with Article 97(2) EPC, on the ground that there was no text agreed by the applicant.

VIII. On appeal, the Appellants request that the decision under appeal be set aside, and that the patent be granted on the basis of four separate sets of claims (one set for BE, CH+LI, DE, FR, GB, IT, LU, NL, and SE, and one each for Austria, Greece and Spain) as the main request, or on the basis of four corresponding sets of five auxiliary requests to be considered in descending order. Further, the Appellants request a correction in Claim 1. Finally, the Appellants request oral proceedings.

IX. In support of their appeal the Appellants have mainly argued as follows:

Decisions T 166/86 and T 182/88 both indicate that the amendments are allowable. These amendments would not cause any considerable delay in the proceedings, consisting mainly of a simple change of category of claims. The translations and fees for grant had all been promptly submitted. Compared to the possibility of having further processing in accordance with Article 121 EPC accepted in case the formalities had not been complied with within the three month period under Rule 51(6) EPC, a consideration of the requests for separate claims would not have meant any delay whatsoever. The interest of the public is protected through the already published publication, beyond which no amendments extending its content are allowable.

Reasons for the Decision

1. *Background*

The object of the present appeal is to have mistakes rectified which could otherwise possibly lead to an invalid patent being issued for three designated States as a result of reservations made by these States in accordance with Article 167(2) EPC.

This interlocutory decision concerns the proper interpretation of Rule 51 EPC, specifically its paragraphs 4 and 6, in the version in force as from 1 September 1987. It is limited to the question whether amendments requested after the Rule 51(6) communication has been issued may be admitted at all for consideration.

2. *The EPO jurisprudence on Rule 51 EPC*

The decisions referred to by the Appellants, T 166/86, OJ EPO 1987, 372, and T 182/88, OJ EPO 1990, 287, both applied Rule 51 EPC in its version **prior** to 1 September 1987, under which express approvals were not foreseen. The conclusions drawn in these cases are thus not automatically valid for the present situation to which the new version of Rule 51 EPC applies.

In T 1/92 of 27 April 1992, to be published in the OJ EPO, this Board concluded that neither the Convention, nor the Implementing Regulations, expressly prescribes any binding effect of the approval under Rule 51(4) EPC in its new version. This finding of T 1/92 was recently confirmed in decisions J 11/91 and J 16/91 of 5 August 1992, to be published in the OJ EPO, points 2.3.3 and 2.3.5.

It was established in T 1/92 that an approval under the new Rule 51 procedure would not be binding, if the applicant had requested amendments within the time period given for a response to the Rule 51(4) EPC communication, the reason being that the EPO then could not establish beyond doubt - in accordance with Rule 51(6) EPC - that there was an unambiguous approval. An approval would only enable the Office to start **preparations** for grant before expiry of the Rule 51(4) time period. As the amendments sought in that case had been submitted **within** the time limit prescribed by Rule 51(4) EPC, the decision stopped short of resolving the present issue of whether or not amendments introduced at any **later** stage may be considered.

A recent decision, T 675/90 of 24 June 1992, to be published in the OJ EPO, held that amendments requested after a Rule 51(6) communication (in its new version from 1.9.1987) must be rejected, the main reasons being a) the need for a proper balance between the obligation to ensure that invalid patents are not granted and a speedy grant, and b) the function of Rule 51(6) EPC to draw the amendment procedure to a firm and final conclusion. The Board thus concluded that the discretion under Rule 86(3) EPC did not extend to the Rule 51(6) stage of the proceedings.

According to the jurisprudence available on the new version of Rule 51 EPC, amendments would seem admissible during the Rule 51(4) period and possibly until the Rule 51(6) communication is issued.

T 675/90 assumed that, because of its purpose of bringing the procedure to a firm conclusion, Rule 51(6) EPC necessarily implies a limitation in time of the applicant's right to request amendments and that Rule 86(3) EPC ceases to apply at that stage. However,

this decision failed to address a number of questions arising out of such an assumption. The question therefore remains whether the EPC still allows for such requests to be admitted at a later stage of the Rule 51 procedure.

The facts of the present case are parallel to those of T 675/90.

3. *The 1987 amendments to Rule 51 EPC*

The *travaux préparatoires* to the 1987 amendments explain that a need existed to separate the substantial issue of the text for grant from that of other formalities to be carried out in order for the application to proceed to grant, i.e. the filing of translations and payment of fees. In the past, in order to protect applicants against loss of rights as a result of the rather complicated procedure a practice making use of *restitutio in integrum* under Article 122 EPC had evolved, which however was called to a halt by decision J 22/86 (OJ EPO 1987, 280). The proposed separation of procedures was intended to safeguard the interest of the applicants. There is no indication in these documents that the implication of Rule 51(6) EPC assumed by T 675/90 was intended.

Neither is such an interpretation or legal effect mentioned in the publication of the amended Rule 51 EPC in OJ EPO 1987, 272. There the amendments to Rule 51 EPC are described as serving the purpose of enabling loss of rights to be remedied through further processing rather than the time-consuming and burdensome procedure under Article 122 EPC of *restitutio in integrum*.

According to the Guidelines for Examination in the Patent Office, C-VI, 4.10, as a result of the 1987 amendments the applicant is bound by an approval given to the text communicated to him under Rule 51(4) EPC. The Guidelines

only foresee substantive amendments at this stage if the Examining Division becomes aware of circumstances causing it of its own motion to resume the proceedings, i.e. if it discovers that non-patentable subject-matter is claimed. Such circumstances can also be brought to the attention of the Examining Division by the applicant. As the Guidelines, Part C-VI, 15.1.2, are silent with regard to the stage after the Rule 51(6) communication, they seem to presuppose that any request for amendments from the applicant should be filed within the time period stipulated under Rule 51(4) EPC. It must be kept in mind, however, that the Guidelines are not binding on the Boards of Appeal.

4. *Article 113(2) EPC*

This Article obliges the Office not to issue patents to which the applicant or patentee has not agreed. This provision is based on the fundamental right of parties to civil law proceedings to decide the scope of their case, and the procedural principle that the parties may at any time file a request, indicating their intention to change this scope, as long as their case is still pending.

Although the present Board agrees with T 675/90 in saying that the **object** of Rule 51(6) EPC is to ensure a speedy conclusion of proceedings, this does not necessarily mean that the applicant's right to control the content of the patent application at every stage of the proceedings, as guaranteed by Article 113 EPC, is limited to the "pre-51(6)" stage. In accordance with Article 164(2) EPC, the provision of Article 113(2) EPC must prevail over any practical arrangements provided for in the Implementing Regulations (cf. also the EPO practice in cases of late filed amendments, e.g. T 375/90 of 21 May 1992, not published in the OJ EPO).

5. *Rule 51 EPC*

5.1 Rule 51 EPC serves to terminate the examination stage and to process the application to grant. The applicant is requested through the Rule 51(4) communication to submit an express approval of the text intended for grant. A time limit of four months, extendable to six months, is provided. When it has been received, the approval is acknowledged through a Rule 51(6) communication. Should the applicant request amendments within the 51(4) period, the Examining Division may allow them under Rule 86(3) EPC, but if it does not, the Division must issue a reasoned opinion, requesting the applicant to submit his observations (Rule 51(5) EPC). If the amendments are accepted, there will as a rule be no further 51(4) communication and the Rule 51(6) communication will be issued without delay. Should the applicant choose not to submit any approval in writing under Rule 51(4) EPC, the application will be refused by way of a decision which is appealable.

5.2 Rule 51(6) EPC requires the Office to establish whether or not there is a valid approval. A communication pursuant to this paragraph only invites the applicant to pay certain fees and file the translations due. It may therefore be seen as a last check-point before grant to establish that there is a valid approval, but not as a further opportunity to amend.

Seen from the above narrow perspective, a consideration of amendments filed after the Rule 51(6) communication does not seem justified. On the other hand, the fact that Rule 51(6) EPC is addressed primarily to the Office could be seen as an indication that it should not be interpreted as normative in any other sense than what its express wording allows, i.e. to put a specific obligation on the Office.

In fact, it can be questioned whether Rule 51(6) EPC governs the present situation at all. Firstly, a request for amendments from the applicant **after** the Rule 51(6) procedure has already occurred is not covered by the wording of this rule. Secondly, an interpretation that would limit the rights under a higher-ranking Article of the Convention cannot be acceptable, as such a limitation otherwise would call for a diplomatic conference to amend that very Article.

The interpretation of provisions in an international legal instrument such as the EPC must follow generally accepted methods of interpretation. As expressed in the Vienna Treaty on the Law of Treaties, Articles 31 and 32, the interpretation of a provision should be made in good faith, according to the normal meaning of its words as seen in their context and in the light of the object and purposes of the instrument. In the present case, this context would cover not only the immediate provisions in Rule 51 EPC governing the procedure to grant, but also the relationship between this Rule and other provisions.

Against this background and in the light of Articles 113(2) and 164(2) EPC, Rule 51(6) EPC seems to have to be interpreted more narrowly than was done in T 675/90, i.e. such that it covers only the situation expressly mentioned therein.

- 5.3 Another effect is the procedural situation resulting from a broader interpretation of Rule 51(6) EPC. In T 675/90 as well as in the present case, while insisting that the approval under Rule 51(4) EPC was binding, the Examining Divisions were forced under Article 113(2) EPC to conclude the exact opposite, i.e. that the patent had to be refused since there was no approved text. The result of such an interpretation of Rule 51(6) EPC leads to an

unacceptable inconsistency, whereas the solution of T 675/90 to remit the case for grant disregards Article 113(2) EPC.

6. *Articles 96(2) and 167(2) EPC*

The basic responsibility of the EPO is to issue valid patents. This obligation derives from the substantive provisions of the European Patent Convention, viz. the central Articles on the conditions for patentability (Articles 52-57 EPC): Other provisions in the Convention as well as in the Implementing Regulations serve to define the details and extent of this responsibility. There could be no argument that the EPO in examining applications has to abide by these provisions and that errors should be redressed, at any stage of the proceedings.

Decision T 20/83, OJ EPO 1983, 419, noted that Article 96(2) EPC prescribes that the Examining Division must draw all obstacles to patentability to the applicant's attention (point 8 of the decision). This conclusion related to the requirements for patentability as laid down in the Convention itself. The validity of a patent in various Contracting States is however not an **immediate** condition under the Convention.

The reference in the Guidelines to the possibility of considering amendments for the reason that otherwise unpatentable subject-matter would be claimed (C-VI, 4.10) corresponds exactly to the situation at hand. It would therefore seem reasonable to conclude that amendments arising out of reservations to the EPC would qualify as fundamentally important in this respect.

The question to be answered is this: Should an examiner have reservations under Article 167(2) EPC in mind as part of the requirements of the EPC to be considered under Article 96(2) EPC? If so, there would be an obligation under Article 96(2) EPC to point out deficiencies in this respect and invite the applicant to comment. Having regard to what is said above in point 6 as to the appropriate interpretation of international treaties, as a consequence, there would be a reason for resumption of the proceedings, even if the deficiencies were pointed out by the applicant himself at a late stage of the proceedings.

7. *Balancing various interests*

It was held in T 182/88 (point 7) that a speedy grant is **in the interest of the public**. From the point of view that this would establish the extent of the applicant's rights vis-à-vis the public without undue delay, this is a correct observation.

Because of the EPO system of post-grant opposition, however, the public cannot rely on the granted patent until the period for opposition has expired, or, where oppositions have been lodged, until a final decision has been taken. In the end, oppositions may lead to a restricted patent. If the competition had prepared beforehand for a wider patent, they would find themselves in a worse position than if they had waited for the final decision.

On the other hand, a "reopening" of the examining procedure just before grant to consider amendments could lead to a wider scope of the patent than was contained in the text already approved under Rule 51(4) EPC. The check on the scope of the claims is laid down in Article 123(2) EPC. As the Appellants correctly pointed out, the public

is protected through the published patent application as no claims can be accepted which are wider than the text of the application would allow.

Finally, non-valid patents, which have to be challenged through costly and time-consuming litigation, either through opposition or before national courts, must be considered to be against the interest of the public.

- 7.2 Turning now to **the interest of applicants**, it would be inconsistent to **limit** procedural rights as a direct result of a provision that was introduced in this very same interest.

It would therefore seem unjustified to limit the **possibility** of having an amendment admitted for consideration, unless the amendment sought is not *bona fide*, for example only seeking to delay the proceedings or not trying to overcome a true problem of patentability or constituting an outright abuse of proceedings.

In determining the rights of an applicant to have late amendments considered, the patentee's right to have a patent amended or revoked through an opposition instigated by himself may be of significance (cf. G 1/84, OJ EPO 1985, 299). It does not seem consistent to admit amendments requested in a centralised procedure **after** grant, but not amendments requested **before** grant.

Not only would this discrepancy be inconsistent from a legal point of view and opposed to the purposes noted in G 1/84, but substantially the prohibiting of amendments before grant would mean more costs and further delays before the extent of the patentee's proprietary rights is finally established. This state of affairs is unsatisfactory.

7.3 **The interest of the EPO** to have practicable working conditions, if this did play any part in the proposals for the 1987 amendments to Rule 51 EPC, must take third place to the interests of the applicant and/or the public.

7.4 On balance, it does not seem self-evident that the interest in a speedy conclusion of the procedure must always take precedent over the interest of having only valid patents issued. The last interest is shared by applicants and the public alike.

8. *Conclusions*

The above gives rise to an important point of law concerning the proper interpretation of an Implementing Rule (here: Rule 51(6) EPC) vs. an Article of the Convention (here: Article 113(2) EPC), which would justify referral of a question to the Enlarged Board of Appeal under Article 112(1) EPC.

Another point of law raised is how reservations under Article 167(2) EPC should be considered in the course of the examination of European patent applications.

Order

For these reasons, it is decided that:

The following questions are referred to the Enlarged Board:

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?

The Registrar:

The Chairman:

E. Görgmaier

A. Nuss