

Internal distribution code:

(A) Publication in CJ
(B) To Chairmen and Members
(C) To Chairmen

D E C I S I O N
of 6 August 1999

Case Number: T 0755/96 - 3.3.1

Application Number: 90310085.7

Publication Number: 0418099

IPC: C07D 491/22

Language of the proceedings: EN

Title of invention:

10, 11-Methylenedioxy-20 (RS) camptothecin and 10, 11-
methylenedioxy-20 (S) - camptothecin analog

Applicant:

RESEARCH TRIANGLE INSTITUTE

Opponent:

-

Headword:

Camptothecin derivatives/RESEARCH TRIANGLE INSTITUTE

Relevant legal provisions:

EPC Art. 123
EPC R. 71a and 86(3)

Keyword:

"Discretion to admit or refuse amended claims under
Rule 71a EPC (yes)"
"Adequate reasons for not admitting amended claims (no)"
"Substantial procedure violation (yes)"
"Reimbursement of the appeal fee (yes)"
"Remittal to the first instance for further prosecution"

Decisions cited:

G 0007/93, T 0182/88, T 0183/89, T 0872/90, T 0951/97

Headnote follows:

Headnote:

In ex parte proceedings, Rule 71a EPC gives the Examining Division a discretion to admit or refuse amended claims until a decision is issued under Article 97 EPC. This discretion must be exercised by considering all relevant factors which arise in a particular case and by balancing the Applicant's interest in obtaining a proper patent protection for his claimed invention and the EPO's interest in bringing the examination procedure to a speedy close by the issue of a decision. If in exercising said discretion amended claims are not admitted, the reasons therefore must be given. The assessment that they were filed too late under Rule 71a EPC does not represent an adequate reasoning in conformity with Rule 68(2) EPC.



Europäisches
Patentamt

European
Patent Office

Office européen
des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 0755/96 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 6 August 1999

Appellant:

RESEARCH TRIANGLE INSTITUTE
P.O. Box 12194
Research Triangle Park, NC 27709-2194 (US)

Representative:

Beresford, Keith Denis Lewis
BERESFORD & Co.
2-5 Warwick Court
High Holborn
London WC1R 5DJ (GB)

Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 22 April 1996
refusing European patent application
No. 90 310 085.7 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: A. J. Nuss
Members: J. M. Jonk
S. C. Perryman

Summary of Facts and Submissions

- I. The Appellant lodged an appeal against the decision of the Examining Division on the refusal of the application No. 90 310 085.7 (publication number 0 418 099).
- II. The decision was based on the originally filed Claims 1 to 39.

Independent Claim 1 concerned 10,11-methylenedioxy-20(S) or 20(RS)-camptothecin compounds substituted in the 9- and/or 7-position.

Independent Claim 19 concerned 10,11-methylenedioxy-20(S) or 20(RS)-camptothecin compounds having the open lactone form.

Independent Claim 26 related to a method for preparing 9-nitro-10,11-methylenedioxy-20(S) or 20(RS)-camptothecin by reacting 10,11-methylenedioxy-20(S) or 20(RS)-camptothecin with a mixture of concentrated sulphuric acid and concentrated nitric acid.

Independent Claim 27 related to a method for preparing 9-amino-10,11-methylenedioxy-20(S) or 20(RS)-camptothecin by reducing the 9-nitro group of the corresponding 9-nitro compound obtained in accordance with Claim 26.

Dependent Claim 28, related to the method of Claim 27, wherein the reducing step was conducted by catalytic hydrogenation.

Independent Claim 29 related to a method for preparing a group of compounds falling under the scope of Claim 1 by reacting 9-amino or 9-amino-7-C₁₋₈-alkyl substituted

10,11-methylenedioxy-20(S) or 20(RS)-camptothecin with an amino group-protected amino acid or peptide containing 1-4 amino acid units, a C₄₋₁₀ saturated or unsaturated carboxylic acid anhydride or with phosgene followed by the reaction with a primary or secondary straight chain, branched or cyclic diamine or a tertiary-amino alcohol.

Independent Claim 30 concerned a method for preparing camptothecin compounds having the open lactone form by hydrolysing the lactone ring of a camptothecin as defined in Claim 1 with an aqueous solution of a monovalent metal hydroxide.

III. The Examining Division considered that, in the light of documents

(B) EP-A-0 325 247, and

(C) J. Med. Chem., 29(11), 1986, 2358-63,

the subject-matter of Claim 1 as originally filed did not involve an inventive step in the sense of Article 56 EPC.

Furthermore, the Examining Division **refused to consider a first auxiliary request and a second one both submitted on 26 March 1996, i.e. one day before oral proceedings, on the ground that these requests were filed too late in view of Rule 71(a) EPC.**

Claims 1 to 6 of the **first auxiliary request** related to the preparation of the compounds as defined in the originally filed Claims 1 and 19 involving the nitration of 10,11-methylenedioxy-20(S) or 20(RS)-camptothecin and the reduction of the formed 9-nitro-derivatives as claimed in the originally filed Claims 26 and 27 respectively. Claim 7 related to a restricted

group of compounds falling under the scope of the originally filed Claim 1. Claims 8 and 9 concerned preferred compounds as claimed in the originally filed Claims 16 (R is NH₂) and 15 respectively.

The **second auxiliary request** corresponded to said main request, except that the compound Claims 7 to 9 were omitted.

Moreover, the Examining Division also **refused to consider an auxiliary request submitted during oral proceedings** to grant a patent on the basis of the originally filed Claims 26 to 30 relating to a method for preparing the compounds as defined in the originally filed Claims 1 and 19. In this context they only stated in the minutes of the oral proceedings that this auxiliary request could not immediately be assessed.

- IV. Together with the statement setting out the grounds of appeal, the Appellant filed on 8 August 1996 Claims 1 to 9 as main request and Claims 1 to 6 as auxiliary request 1. These requests corresponded to the first and second auxiliary requests which were submitted on 26 March 1996 and were not taken into consideration by the Examining Division.
- V. The Appellant argued that the refusal of the Examining Division either to admit the two requests as submitted on 26 March 1996 or to decide on the patentability of originally filed process Claims 26 to 30 amounted to a substantial procedural violation. In this context, he referred to the description of the present patent application, which clearly emphasised the surprising result of the nitration reaction as claimed in original Claim 26.

Moreover, he defended that the claimed subject-matter involved an inventive step by submitting that the cited documents did not disclose the direct nitration of 10,11-methylenedioxy-20(S) or 20(RS)-camptothecin and therefore could not give any incentive to the skilled person that according to this reaction selectively the corresponding 9-nitro compound could be prepared. With respect to the Claims 7 to 9 he argued that the compounds as claimed therein surprisingly showed an increased biological activity.

- VI. The Appellant requested that the decision under appeal be set aside, and that the case be remitted to the Examining Division with the order to grant a patent on the basis of the main or auxiliary request as submitted on 8 August 1996.

Moreover, he requested the reimbursement of the appeal fee.

Reasons for the decision

1. The appeal is admissible.
2. *Background to Rule 71a EPC*
 - 2.1 New Rule 71a EPC came into force on 1 June 1995 pursuant to the Decision of the Administrative Council of 13 December 1994 (OJ EPO 1995, 009). It reads:

"Preparation of oral proceedings

(1) When issuing the summons, the European Patent Office shall draw attention to the points which, in its opinion, need to be discussed for the purposes of the decision to be taken. At the same time a final date for making written submissions

in preparation for the oral proceedings shall be fixed. Rule 84 shall not apply. New facts and evidence presented after that date need not be considered, unless admitted on the grounds that the subject of the proceedings has changed.

(2) If the applicant or patent proprietor has been notified of the grounds prejudicing the grant or maintenance of the patent, he may be invited to submit, by the date specified in paragraph 1, second sentence, documents which meet the requirements of the Convention. Paragraph 1, third and fourth sentences, shall apply mutatis mutandis."

2.2 The reasons which persuaded the Administrative Council to introduce this rule are set out in the Explanatory Memorandum CA/012/94- Rev. 1 dated 17 October 1994 from the President of the European Patent Office (published in OJ EPO 1995, pages 418 and 419), and read:

"7.1 The aim of oral proceedings is to reach a decision closing the case. This presupposes that the earlier written proceedings have prepared the ground properly (airing of facts, narrowing down the matters to be discussed). The way the EPO normally does this, at least in examination and opposition proceedings, is by setting out in the summons the questions it considers relevant.

7.2 The parties, for their part, normally prepare for oral proceedings by setting out their arguments in written submissions. If these are to help expedite matters, they need to reach the Office and any other parties in time for them to be able to comment on their substance at the oral proceedings. Documents handed in during or just before those proceedings do not fulfil this

requirement, and often lead instead to complaints from the other party that he has been taken off guard and is not prepared to discuss the new points raised.

7.3 Proposed new Rule 71a(1) would therefore introduce into the law the existing practice of issuing a summons and require a deadline to be set for any written submissions. It also makes it clear that new facts and evidence put forward after that date need only be taken into account if based on a change in the subject of the proceedings, for example because the other party has raised new material in his own preparatory papers.

7.4 Rule 71a(1) also firms up the Office's discretionary powers enshrined in Article 114(2) by describing one situation in which late submission may be allowed. It makes clear to applicants the procedural consequences of a late submission, and relieves the Office of some of the burdens of substantiating a refusal to consider it. Rule 71a does not restrict EPO discretion under Article 114, but would give it more flexibility in such cases. It thus supplements the line already developed by the boards of appeal to deal with abuse of procedure - i.e. to refuse to consider facts or evidence put forward late for no-good reason.

7.5 The amendment proposed in Rule 71a(2) is also designed to speed up the procedure, and to prevent parties being unfairly confronted with new documents and/or facts in oral proceedings. If the applicant or patent proprietor has been told beforehand that refusal or revocation is on the

cards (and why), then he can reasonably be expected to react if given time enough to do so."

3. *Purpose of Rule 71a EPC*

3.1 As follows from the wording of Rule 71a EPC and the Explanatory Memorandum (see point 2.2 above), the purpose of this Rule is, in particular, to avoid that departments of the EPO entrusted with substantive examination and other parties in opposition proceedings, being surprised by **new facts or evidence** (Rule 71a(1) EPC), or by **new requests** in the form of amendments (Rule 71a(2) EPC), so that at the end of the oral proceedings a decision closing the case can be reached.

3.2 Moreover, this Rule gives the EPO a discretionary power to admit or refuse such late filed new facts, evidence and/or amended claims. This discretionary power follows in particular from the fourth sentence of the first paragraph of this Rule indicating that new facts and evidence **need not** be considered, which, in accordance with Rule 71a(2), applies *mutatis mutandis* to new requests in the form of amended documents (see also T 951/97, OJ EPO 1998, 440, point 5.1).

3.3 In this context, the Board notes that the power of the EPO to accept or refuse late filed **new facts or evidence** is in fact governed by **Article 114(2) EPC**, and that the discretionary power to refuse **new requests for amendments** is actually governed by **Article 123 EPC** and the corresponding Implementing Regulations, i.e. Rule 86(3) EPC in cases before an Examining Division and Rule 57a EPC which is however limited to proceedings before an Opposition Division.

Said Rule 86(3) stipulates that **no further amendment may be made without the consent of the Examining Division**, if the applicant, after receipt of the first communication from the Examining Division, has amended, in reply to said communication, the description, claims and drawings of his own volition.

4. *Exercise of Rule 71a discretion regarding amendments*

4.1 The task of the European Patent Office is to grant European patents which comply with the European Patent Convention. On the other hand, it is also desirable that the procedure before the EPO be as efficient as possible. It would not be conducive to this end if the discretionary power conferred by Rule 71(a) EPC was exercised in a purely formalistic way so that the European Patent Office refused to consider new claims on the sole ground that they had not been filed by a final date stated in a summons to oral proceedings, even though the request in fact complied with all requirements of the EPC and raised no new issues. The result would be that an appeal would be necessary, in which the request would then be allowed into the proceedings and the matter would be referred back to the first instance, causing expense and delay.

4.2 In this context, the **Enlarged Board** considered in a situation where an applicant had already consented to the text to be granted and the invitation pursuant to Rule 51(6) EPC had been issued, i.e. in a very late stage of the examining proceedings, that in exercising the discretion under Article 123 and Rule 86(3) EPC of whether or not to allow a request of further amendment **an Examining Division must consider both the applicant's interest in obtaining a patent and the EPO'S interest in bringing the examination procedure to a close by the issue of a decision, and must balance**

these interests against one another taking into account all relevant factors which arise in a case (see G 7/93, OJ EPO 1994, 775, in particular point 2.2, first paragraph, and point 2.5).

4.3 Here it is important to make a distinction between the application stage and the opposition stage. The reasons given for introducing Rule 71a EPC (see point 2.2 above) make clear that a particular concern was that in oppositions other parties are not taken by surprise. As parties may be represented only by professional representatives, who would need to consult their clients and the latter's technical experts for further instructions to deal with new requests or evidence, there could be good reasons to refuse material filed after the final date stated in the summons for directions, or to postpone oral proceedings, with the party at fault being made responsible for the costs of this.

4.4 However, the same considerations do not apply to a department of the EPO entrusted with substantive examination, because it has its own technical expertise and does not have to obtain instructions from third parties. If prepared for oral proceedings, it should normally, even in relation to requests filed at the oral proceedings, be in a position, if necessary after an appropriate break of the oral proceedings, to assess whether a new request is **clearly not allowable** under the EPC, e.g. under Article 123(2) EPC, Article 84 EPC, Article 82 EPC or Rule 86(4) EPC, and to decide on the basis of this finding not to admit such a new request into the proceedings.

4.5 Thus, having regard to the considerations above, in the Board's judgment, the discretion under Rule 71a EPC to refuse new requests should not be exercised by an

Examining Division in a purely formalistic manner, in particular for the following reasons:

(a) the importance of keeping oral proceedings before the Examining Division as a useful institution serving to allow the Examining Division to get a final picture of that which the applicant regards as being his invention in the light of the prior art, and to give the applicant the opportunity fairly to deal with the EPO's objections, which may render amendment of his request(s) necessary even at a late stage, as well as a consequent submission of claims which the applicant believes best meet the requirements of the Convention and his own needs;

(b) the importance of not upsetting the balance of the interest of an applicant in obtaining a patent and the EPO's interest in efficient proceedings to the detriment of the applicant;

(c) the lack of procedural efficiency which a high risk of refusal of new requests filed after the final date set under Rule 71a EPC would cause, because applicants would be driven to an earlier submission of numerous premature auxiliary requests purely as a precautionary measure, resulting in much unnecessary work for both the EPO and the applicant; and

(d) the lack of procedural efficiency which the formalistic refusal without examination of late filed requests by an Examining Division under Rule 71a EPC would cause, if the same request would then have to be admitted on appeal in accordance with the established jurisprudence of the Boards of Appeal and remitted to the Examination Division for consideration of undecided issues, a way of proceeding counterproductive from the point of view of both speed and efficiency of the application procedure as a whole.

4.6 In this context, the Board emphasises that it would in no way suggest that applicants should not do their utmost to meet the final date set in the summons to oral proceedings, because requests filed in time could indeed help expedite matters and sometimes could even render oral proceedings superfluous. Moreover, if applicants fail to meet the deadline, they would put themselves at a disadvantage, as the Examining Division would then be less well prepared to make helpful suggestions as to how to remove remaining objections, and all concerned would suffer from increased time pressure.

4.7 Further, it is established jurisprudence of the Boards of Appeal that a department of the EPO for substantive examination must indicate in its decision the reasons for not accepting amended claims when exercising its discretion under Rule 86(3) EPC (see e.g. T 182/88, OJ EPO 1990, 287; T 183/89 (not published in the OJ EPO), points 2.5 and 2.7; and T 872/90 (not published in the OJ EPO), point 2.1, paragraphs 3 and 4). Since the considerations when applying Rule 71a EPC are comparable to those when considering requests under Rule 86(3) EPC, in the Board's judgment, the need for giving the reasons for the exercise of this discretion must also apply to the new Rule 71a EPC. It is therefore not sufficient merely to refer to the power given by Rule 71a EPC to justify a refusal.

5. *Requests refused by the Examining Division as belated*

5.1 In the present case, the Examining Division decided not to consider the two sets of claims as filed one day before the oral proceedings as main request and first auxiliary request respectively, as well as the request submitted during the oral proceedings to examine and

decide on the basis of the originally filed process claims, i.e. Claims 26 to 30.

- 5.2 The decision of the Examining Division by which the two requests as filed one day before the oral proceedings were not considered was only based on the ground that they were filed too late according to Rule 71a EPC. However, in the Board's judgment, this ground given by the Examining Division for not accepting these two requests cannot be considered as an adequate reason in support of the exercise of their discretion, but rather constitutes a mere reference to the power given to the Examining Division by said Rule 71a EPC.
- 5.3 With respect to the refusal to consider the request as submitted during the oral proceedings, the Examining Division only stated in the minutes of the oral proceedings that this request could not immediately be assessed (see the last paragraph). However, this statement only represents a bald assertion, unsupported by any legal or factual reasons for its justification.
- 5.4 Therefore, in the Board's judgment, the arguments given by the Examining Division for not admitting the Appellant's requests into the proceedings, which do not comprise any balancing of the EPO's interest in a speedy completion of the proceedings against the Appellant's interest in obtaining a proper patent protection for his invention, cannot provide an adequate basis for deciding upon the exercise of discretion under Rule 71a EPC.
- 5.5 Thus, in view of these considerations, the Board concludes that the decision under appeal was not reasoned in conformity with Rule 68(2) EPC, which amounts to a substantial procedural violation.

6. *Requests on appeal*

6.1 The main request and first auxiliary request on appeal are identical to the first and second auxiliary requests before the Examining Division at the oral proceedings, which auxiliary requests the Examining Division refused to allow into the proceedings merely by reference to Rule 71a EPC. The Appellants are not on appeal maintaining the main request before the Examining Division which was refused on substantive grounds in the decision under appeal.

6.2 The general principle in appeals in application proceedings, is that requests with new claims filed with the Statement of Grounds are admitted into the proceedings unless they are clearly not allowable under the EPC. The present main and auxiliary request do not appear clearly objectionable, and accordingly are admitted into the proceedings pursuant to the exercise by the Board of its powers under Article 111(1) and Rule 86(3) EPC.

6.3 The general rule is that an applicant is entitled to consideration of his requests by two instances. The requests now before the Board have not been considered by the Examining Division, and neither the appellant nor the Board could be expected to deduce what the Examining Division's views on the present requests would be, merely on the basis of the view it expressed on the different main request before it at the oral proceedings on 27 March 1996. Accordingly the Board exercises its powers under Article 111(2) to remit the application for further prosecution before the examination division.

7. *Reimbursement of appeal fee*

The appellant has been successful on appeal to the extent requested. In view of the substantial procedural violations that have occurred, and the fact that if they had not occurred, an appeal would probably have been unnecessary, in the Board's judgement it is equitable to reimburse the appeal fee pursuant to Rule 67 EPC.

Order

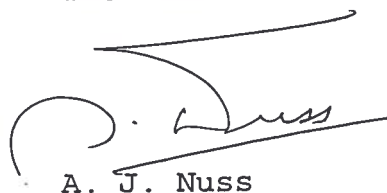
For these reasons, it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division for further prosecution.
3. The request for reimbursement of the appeal fee is allowed.

The Registrar:


E. Gorgmaier

The Chairman:


A. J. Nuss