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Anmeldenummer / Filing No / N^o de la demande : 78 300 831.1
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Bezeichnung der Erfindung: 13-Halo and 13-deoxy derivatives of modified
Title of invention: milbemycin compounds and their preparation
Titre de l'invention :

Klassifikation / Classification / Classement : C07D 493/22

ENTSCHEIDUNG / DECISION

vom / of / du 8 December 1988

Anmelder / Applicant / Demandeur :

Patentinhaber / Proprietor of the patent /
Titulaire du brevet :

Merck & Co. Inc.

Einsprechender / Opponent / Opposant :

Sankyo Company Ltd.

Stichwort / Headword / Référence : Starting compounds/MERCK

EPU / EPC / CBE Articles 83 and 123(2); Rule 27(1)(c) EPC

Schlagwort / Keyword / Mot clé : "Relevant background art - inclusion in the description".

Leitsatz / Headnote / Sommaire

I. If a document necessary for carrying out the invention is not mentioned in the application as originally filed, the invention may nevertheless sufficiently be disclosed (Art. 83 EPC) if the document is part of the common general knowledge (following decision T 11/82, "Control circuit/LANSING BAGNALL", OJ 1983, 479-522, at point 22).

II. Where the starting compounds are highly elaborated microbial metabolites, opening a field of research which is so new that technical knowledge is not yet available from textbooks, special considerations prevail on whether or not the common general knowledge of the man skilled in the art may include a patent specification (in contrast to the situation in classical field as in T 171/84, "Redox Catalyst", OJ 1986, 95 and T 206/83, "Herbicides", OJ 1987, 5).

III. If a document is part of the common general knowledge and is the closest prior art, it may have to be introduced into the description (Rule 27(1)c) EPC). Article 123(2) EPC is not thereby contravened (following decision T 11/82).

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Boards of Appeal

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Chambres de recours



Case Number : T 51/87

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 8 December 1988

Appellant :
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Decision under appeal : Decision of the Opposition Division of the European
Patent Office dated 01.12.86 revoking
European patent No. 2615 pursuant to Article 102(1)
EPC

Composition of the Board :

Chairman : P. Lançon

Members : A. Nuss

J Stephens-Ofner

Summary of Facts and Submissions

I. European patent No. 0 002 615 was granted on 5 October 1983, with twelve claims, pursuant to European patent application No. 78 300 831.1, filed on 15 December 1978 and claiming priority from two prior US applications, Nos. 861 810 and 861 919, both filed on 19 December 1977. Independent Claim 1 of the patent as granted reads as follows:

1. A compound obtainable by the reaction of one of C-076 A1a, C-076 A2a, C-076 B1a, C-076 B2a, C-076 A1b, C-076 A2b, C-076 B1b and C-076 B2b, as follows:

- (a) removing the α -L-oleandrosyl- α -L-oleandrose group by hydrolysis;
- (b) replacing the 13-hydroxy group resulting from step (a) with a 13-halo group by reaction with a sufficiently reactive benzenesulfonyl halide in the presence of a base;
- (c) optionally removing the 13-halo group with a selective reducing agent;
- (d) optionally reducing the 22,23-double bond on the A1a, B1a, A1b and B1b compounds to a single bond by hydrogenation using a solvent and a catalyst of the formula $[(R_5)_3P]_3RhX$ where R_5 is loweralkyl, phenyl, or loweralkyl-substituted phenyl and X is a halogen;
- (e) optionally C_{2-6} alkanoylating the 5- or 23- hydroxy group of the A2a, B1a, A2b or B1b compound or on one or both of the 5- and 23- hydroxy groups in the B2a or B2b compound;

- (f) optionally preparing a 23-(C₁₋₆ alkoxy) or 23-(C₁₋₆ alkylthio) derivative of the A1a, B1a, A1b or B1b type compounds by reaction with a C₁₋₆ alkanol or C₁₋₆ alkylthiol in the presence of an acid; and
- (g) optionally oxidizing a 23-(C₁₋₆ alkylthio) derivative prepared in step (f) to a C₁₋₆ alkylsulphonyl or a C₁₋₆ alkylsulphonyl group.

II. On 3 July 1984 the Respondent (Opponent) filed notice of opposition against the European patent on the ground that it did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

In support of the Opposition, the Respondent has filed Affidavits from Professor A.T. Bull dated 9 July 1984 and 15 August 1985, and an Affidavit from Professor L. Hough, dated 25 July 1985.

III. The Appellant (Proprietor of the patent) contested the alleged lack of sufficiency of disclosure, relying inter alia, on document DE-A-2 717 040 (5) and an Affidavit from Professor S.V. Ley dated 7 February 1985 stating that on the basis of his common general knowledge at the relevant time, he would not have had undue difficulties in repeating the invention as described.

IV. The Opposition Division, accepting the evidence of Professor Bull that using his common general knowledge at the relevant time he would not have been able to prepare and separate the necessary starting materials, revoked the patent by a decision of 1 December 1986, holding inter alia, that the description did not contain a general teaching of how to separate, isolate and identify the eight C-076 starting compounds. The description was considered

only to disclose a method of producing C-076 compounds by fermentation, but not a way of separating and recognising the individual starting compounds.

The Opposition Division further held that it followed from decisions T 171/86 and T 206/83, that patent specifications were not normally part of the common general knowledge, and could not, therefore, be used to cure prima facie insufficiency. It therefore came to the conclusion that document (5) did not form part of the common general knowledge available to the skilled reader, so that the patent was insufficient (Article 83 EPC).

- V. The Appellant filed a notice of appeal on 23 January 1987, against this decision. The appeal fee was paid in due time and a Statement of Grounds of Appeal dated 7 April 1987 was filed on 9 April 1987.
- VI. After an exchange of written submissions by the parties, oral proceedings took place on 8 December 1988. In the course of those proceedings, the parties made the following main submissions:
- (i) In the Appellant's view, the common general knowledge of the man skilled in the art could not be confined to ordinary chemical literature. It was an established fact in a specialized and newly developing area of research, such as the field of C-076 chemistry, that the man skilled in the art did not receive his knowledge solely from textbooks which were always several years behind the leading edge of research. Furthermore, in this field, there was no recognised textbook at the relevant date, so persons skilled in the art would not only consult the standard chemical literature to replenish their "common general knowledge", but would also seek up-to-date specialized

publications, e.g. recently published patent literature, to take but one example. Document (5) was, accordingly, part of the common general knowledge at the relevant date.

In the alternative, document (5), which clearly disclosed the preparation of the C-076 starting compounds, and which was published more than a month before the priority date of the patent in suit, had to be considered as additional prior art within the meaning of Rule 27(1)(c) EPC.

- (ii) Contesting this view, the Respondent relied upon the fact that the Appellant failed to file any credible evidence to establish that the man of ordinary skill might have been aware of document (5) before the priority date of the patent in suit, let alone that this document had become part of the common general knowledge. Published patent documents, like any other documents, could in certain cases form part of the common general knowledge, and whilst it was accepted that a seminal patent specification could form part of this knowledge, such cases were, of necessity, extremely rare. In the absence of evidence to displace it, the presumption had to be that, at the priority date of the patent in suit, document (5) had not formed part of the relevant common general knowledge.

This presumption was cogently supported by the absence of any cross-reference to document (5) in the patent in suit, and of the absence of any literature which might have alerted the man of ordinary skill to the need to refer to document (5).

- (iii) Furthermore, since the teaching of this document was needed for preparing the starting compounds, the

preparation of which was nowhere mentioned in the patent in suit, the invention of the patent in suit could not be carried out by following the teaching of the specification without reference to anything else. This deficiency could not be cured by introducing the document into the description without contravening Article 123(2) EPC.

(iv) The Appellant requested that the decision under appeal be set aside, and that the patent be maintained; as first auxiliary request that the patent be maintained in amended form by including an indication to document (5) in accordance with Rule 27(1)(c) EPC; as second auxiliary request that in the case the appeal be dismissed, the following question be referred to the Enlarged Board of Appeal: "Do in recent, rapidly growing fields of the art, where relevant text books are not yet available to the skilled person, published patent documents form part of the common general knowledge in that field?"

(v) The Respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.
2. The present appeal is concerned with the sufficiency of the disclosure under Article 83 EPC, allowably raised in opposition proceedings under Article 100(b) EPC.

3. The EPC requires that the disclosure of the invention must be clear and complete so as to be sufficient for a person skilled in the art to carry it out (Art. 83 EPC). In the present case, the invention as claimed in the main claim consists of the chemical transformations of a series of eight starting compounds (C-076 compounds), which transformations involve at least the following two compulsory steps:

- (a) removing the α -L-oleandrosyl- α -L-oleandrose group by hydrolysis;
- (b) replacing the hydroxy group resulting from step (a) with a halo group by reaction with a sufficiently reactive benzenesulfonyl halide in the presence of a base.

From the wording of the claims, as well as from that of the description, it is clear that the invention as such does not cover the preparation of starting compounds, as those were all assumed to be known compounds. This is entirely consistent with paragraph 7 of Professor Ley's affidavit where he stated, inter alia, that "given supplies of the starting compounds as indicated, the subsequent chemistry as reported is more than adequate in preparative detail to permit a skilled synthetic chemist to repeat the transformations". This statement is not contradicted by the affidavits of either Professor Bull or of Hough, which both indicate that once the starting compounds are available, their further transformation would cause no practical difficulty to a person skilled in the art, so that the disclosure of the patent in suit cannot in this respect be considered insufficient.

Accordingly, the requirements of Article 83 appear to be satisfied, which was also the conclusion of the Examining Division, since it granted the patent without having called

into question the sufficiency of the disclosure. It is significant in this respect that at the end of the appeal proceedings, even the Respondent no longer denied that the disclosure of the invention, as defined above, was actually sufficient.

4. However, the Respondent's objection goes wider than this, alleging that because in the description, as originally filed, the starting compounds had not been described at all, the man skilled in the art was not in a position to carry out the claimed invention.

In the present case, the starting compounds to be used cover a series of eight chemically related compounds, called C-076 compounds, which are α -oleandrosyl- α -oleandroside derivatives of pentacyclic 16-membered lactones related to the milbemycins and designated A1a through B2b as follows: C-076 A1a, C-076 A1b, C-076 A2a, C-076 A2b, C-076 B1a, C-076 B1b, C-076 B2a, C-076 B2b. The preparation, isolation and characterisation of these eight compounds is described in detail in document (5).

The Respondent conceded that the information contained in document (5) was sufficient to prepare all eight starting compounds, and that a combination of this information with that contained in the patent in suit would have been sufficient to dispose of any practical difficulties in carrying out the claimed invention. However, this document had neither been mentioned in the priority documents, nor in the application as originally filed, nor for that matter in the patent in suit. Thus the sole question which arises is whether or not this document may be introduced into the description at the appeal stage of the proceedings, having regard to the provision of Article 123(2) EPC.

5. Document (5) relates to a new family of eight chemically related agents exhibiting anthelmintic activity, collectively identified as C-076 compounds, which are produced by a previously undescribed species of the genus *Streptomyces*, which has been named *Streptomyces avermitilis*. The document also describes a method for the recovery and purification of these compounds, which may be described by the structural formula indicated in the introductory part of the patent in suit where all eight compound are described in detail (see page 2, line 40 ff).

A comparison of the structural formula describing these known compounds with that of the compounds now claimed (cf. page 4, lines 1 to 41 of the description) shows that the C-076 starting compounds certainly belong to those compounds which are structurally the closest related to the derivatives obtained by the process described in the patent in suit. Document (5) therefore belongs to those documents which need to be taken into consideration when assessing inventive step, as had been done by the first instance at the very beginning of these proceedings. Thus the Examining Division correctly considered this document when assessing inventive step, although it selected another document as closest prior art (see Communication dated 6.5.82, last paragraph).

In the opinion of the Board, the inclusion of a reference to document (5) could not only have been done at this early stage of the proceedings without any difficulty, but should indeed have been done in view of the manifest relevance of this document.

The Board cannot see why this document had not been specifically mentioned in the European Search Report, since:

- both the starting compounds and their derivatives belong to the same subgroup in the hierarchy of the International Patent Classification, which is the smallest unit of the classification to be consulted for the search;
- the Appellant repeatedly referred to this document when defending his case before the Examining Division, (see letters dated 28.1.82 and 18.10.82).

Thus, notwithstanding that document (5) contains information necessary for carrying out the invention as claimed, it still undoubtedly belongs to the state of the art, and is probably even the closest prior art.

6. The Board is therefore of the opinion that the inclusion of document (5) in the description is permissible under Rule 27(1)(c) EPC, and is in line with a previous decision that the subsequent inclusion into a specification of a prior art document does not contravene Article 123(2) EPC (see decision T 11/82, "Control circuit/LANSING BAGNALL", OJ EPO 12/1983, 479-522, at point 22.
7. In the circumstances, it is indeed surprising that the Examining Division was fully satisfied with the information provided by the description as filed, although its attention had quite clearly been directed to the relevance of document (5) by a series of critical observations filed under Article 115 EPC. Be that as it may, the Examining Division did not make any use of the opportunity to introduce a reference to this document in the appropriate part of the description. A reason for this could be that some technical information not mentioned in the priority documents and concerning the preparation of the starting compounds had been included in the description when originally filed (see page 47 to 51). However, no attempt

to clear the origin of that information was made at the stage of examination of the application. This question was only touched upon at the opposition stage, which could explain why document (5) had not been recognised by the first instance as relevant background art in the sense of Rule 27(1)(c) EPC. If this had been done initially, the matter could have been settled right at the beginning of the proceedings, and so no question under Article 83 EPC would have arisen later on.

8. Although it follows from the above, that the inclusion of a reference to document (5) in the description is required by Rule 27(1)(c) EPC, and is permissible under Article 123(2) EPC, the Board wishes to deal also with the general question of common general knowledge as arising in these proceedings.

From the two earlier published decisions mentioned in the course of the proceedings i.e. decision T 171/84, "Redox Catalyst" and T 206/83, "Herbicides" the Respondent considered that the latter should not apply in the present case. In both decisions the same Board held that patent specifications were not normally part of the common general knowledge of the natural skilled addressee.

9. In the present case, the C-076 starting compounds are highly elaborated microbial metabolites opening a brand new field of research, so that any technical knowledge acquired in this field at the beginning, through basic pioneering work had not yet been distilled into the form of textbooks. By contrast, in the prior decision T 206/83 the situation was quite a different one, namely that the man skilled in the art was a person working in the field of classical herbicide chemistry, which was not a new developing field like that of the chemistry of C-076 compounds. The man

skilled in the art, therefore, cannot be presumed to possess the same common general knowledge in both cases. Accordingly, the facts of the prior decisions are not on all fours with those of the instant case, which could, were this necessary, be decided on its own merits, with the result that document (5) would be considered as part of the relevant common general knowledge, thus defeating the allegation of insufficiency under Article 83 EPC.

10. It follows from the above, that document (5) is to be included in the description of the patent in suit.

Consequently the Appellant's main request to maintain the patent in unamended form, must be rejected.

Since the description has not yet been amended in conformity with this request, the maintenance of the patent is therefore subject to the filing of a properly amended description by the Appellant.

As matters stand, the Appellant's second auxiliary request has become purposeless.

Order

For these reasons, it is decided that:

- The decision of the Opposition Division is set aside.

- The case is remitted to the Opposition Division with the order to maintain the patent in amended form by including an indication to DE-A-2 717 040 in accordance with Rule 27(1)(c) EPC.

The Registrar:

The Chairman:

F.Klein

P.Lançon