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D E C I S I O N
of 23 July 1999

Case Number: T 0150/95 - 3.3.4

Application Number: 88305828.1

Publication Number: 0298640

IPC: A61K 35/66

Language of the proceedings: EN

Title of invention:

A new antimicrobial agent, FR109615 and production thereof

Patentee:

Fujisawa Pharmaceutical Co., Ltd.

Opponent:

Zeneca Limited

Headword:

Antimicrobial agent/FUJISAWA PHARMACEUTICAL CO.

Relevant legal provisions:

EPC Art. 52(4), 52(2), 123(2), (3)

Keyword:

"Main request: patentability of claim 7 - (no) - (method for treatment of the human/animal body by thereapy)"

Decisions cited:

G 0005/83, G 0002/88, G 0006/88

Catchword:

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Boards of Appeal

Chambres de recours

Case Number: T 0150/95 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 23 July 1999

Respondent:
(Opponent)

Zeneca Limited
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Appellant:
(Proprietor of the patent)

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Representative:

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Decision under appeal:

Interlocutory decision of the Opposition Division
of the European Patent Office posted 16 December
1994 concerning maintenance of European patent
No. 0 298 640 in amended form.

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: R. E. Gramaglia
S. C. Perryman

Summary of Facts and Submissions

I. European patent No. 0 298 640 (application No. 88 305 828.1) was granted on the basis of 6 claims. The patent relates to a new antimicrobial agent, FR109615 and production thereof. Claims 1, 3 and 4 as granted for all the contracting states read as follows:

"1. A process for the production of FR-109615 [(1R,2S)-2-aminocyclopentanecarboxylic acid] or its salts, which comprises culturing a FR109615-producing strain belonging to the genus Streptomyces in a nutrient medium and recovering the FR109615 or its salts from the resultant cultured broth.

3. Use of FR109615 or pharmaceutically acceptable salts thereof for the manufacture of an antimicrobial agent.

4. Use as claimed in claim 3, wherein the antimicrobial agent is manufactured in solid, semi-solid or liquid form."

II. Notice of opposition was filed by the Respondent (Opponent). Revocation of the patent in its entirety was requested on the grounds of lack of novelty and of inventive step (Articles 54, 56 and 100(a) EPC) of the process of claim 1. Insofar as claims 3 and 4 related to non-medical uses of the compound FR109615, these also lacked novelty and inventive step. The disclosure of the patent in suit was also insufficient (Article 83 and 100(b) EPC) insofar as it related to non-medical uses.

III. The Opposition Division maintained the patent on the basis of the claims of the 6th auxiliary request. Claims 3 and 4 read as follows (amendments over granted claims 3 and 4 are shown in bold):

"3. Use of FR109615 or pharmaceutically acceptable salts thereof for the manufacture of an antimicrobial **pharmaceutical preparation**.

4. Use as claimed in claim 3, wherein the antimicrobial **pharmaceutical preparation** is manufactured in solid, semi-solid or liquid form.

IV. The Appellant (Patentee) filed a notice of appeal against this decision together with a statement of grounds of appeal. The Respondent (Opponent) filed counterarguments to the appeal. The following document is referred to in the present decision:

(2) Goto et al., Nucleic Acids Research, Symposium Series, Vol. 8, pages 73 to 74 (1980)

V. On 15 April 1999, the Board issued a communication pursuant to Article 11(2) of the Procedure before the Boards of Appeal expressing its provisional opinion. Inter alia, the view was expressed that if the appellant wished to cover non-therapeutic uses of FR109615 as an antimicrobial agent, the claim would have to be formulated in a different way to present claim 3.

VI. With the submission of 22 June 1999, the Appellant filed a new main request. The claims of this request were identical with those of the 6th auxiliary request

found to be allowable by the Opposition Division (see paragraph III supra), with the exception of an additional claim 7:

"7. Use of FR109615 or salts thereof as an antimicrobial agent."

The Appellant argued that new claim 7 was directed to the use of FR109615 as an antimicrobial agent in general, ie, extending to the non-medical or non-therapeutical use of FR109615. In the same submission, it was stated that the Appellant was prepared to amend claim 7 to read (amendment is shown in bold):

"7. Use **of an effective amount** of FR109615 or salts thereof as an antimicrobial agent."

if necessary.

- VII. Oral proceedings were held on 23 July 1999, at which neither party was present.
- VIII. The submissions provided by the Appellant can be summarized as follows:

Article 54 EPC

- There was no disclosure in document (2) that FR109615 alone had antimicrobial properties. Therefore, claims covering the use of FR109615 for the manufacture of an antimicrobial agent, be it against pathogenic microorganisms of plants or be it against human or animal pathogens, were novel over document (2) by virtue of decisions G 5/83

(OJ EPO 1985, 64), G 2/88 (OJ EPO 1990, 93) and G 6/88 (OJ EPO 1990, 114).

Article 123(2) EPC

- There was support in the patent in suit for non-medical uses of FR109615.

Article 123(3) EPC

- Since the Opposition Division held that claim 3 as granted related to both the medical and the non-medical use, there could be no broadening of the scope of protection in splitting this claim.

Article 83 EPC

- The patent in suit gave details enabling the use of FR109615 as antimicrobial agent in general, whether for pharmaceutical or for non-pharmaceutical applications. It would have been a routine matter to develop suitable formulations for non-medical application in the light of the disclosure of the patent in suit.

IX. The submissions provided by the Respondent can be summarized as follows:

Article 123(2) EPC

- There was no support in the patent in suit for non-medical uses of FR109615. All the examples related to medical uses of FR109615.

Article 123(3) EPC

- There had been broadening of the scope of protection in splitting granted claim 3 to yield claims 3 and 7 of the main request.

X. The Appellant requests that the decision under appeal be set aside and the patent be maintained on the basis of the claims of the main request submitted on 22 June 1999, or as auxiliary request, that the patent be maintained on the basis of the set of claims found to be allowable by the Opposition Division.

The Respondent requests that the patent be maintained on the basis of the set of claims found to be allowable by the Opposition Division

Reasons for the Decision

1. The appeal is admissible

Main request

Patentability of Claim 7 under Articles 54(4) and 52(1) EPC

2. The Appellant submits that the wording of claim 7 of the main request means that the claim is directed to the use of FR109615 as an antimicrobial agent in general, ie, extending to the non-medical or non-therapeutic use of FR109615 (see paragraph VI supra). The Board agrees that the claim now extends to non-medical use, but the wording also directly covers a

method for the treatment of the human or animal body by (antimicrobial) therapy contrary to Article 52(4) EPC. The Appellant has thus ignored the comment by the Board that if he wishes to cover **non-therapeutic** uses of FR109615 as an antimicrobial agent, a different claim formulation should be used.

3. In fact, for a medical use of the "antimicrobial agent", the format of the claim turns out to be the same as that of claim 5 as originally filed, namely "use of compound X to treat disease Y", which the Examining Division already refused on the same grounds (see communication of 21 May 1990, point 4). Claim 7 of the main request is thus not patentable under Article 52(4) in combination with Article 52(1) EPC. Therefore, the main request comprising a non-allowable claim must be refused. The Board also notes that the introduction of the expression "of an effective amount" into claim 7 of the main request (see paragraph VI *supra*) would not cure this deficiency.

Auxiliary request

4. The claims of this request are those found to be allowable by the Opposition Division. The Respondent has not appealed. This request asks for no changes in the decision of the Opposition Division, so that there is no reason to set aside this decision. The Board thus complies with this request by dismissing the Appeal.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman

U. Bultmann

U. M. Kinkeldey