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D E C I S I O N
of 20 March 2002

Case Number: T 0003/98 - 3.3.2

Application Number: 87309286.0

Publication Number: 0266119

IPC: A61K 9/50

Language of the proceedings: EN

Title of invention:
Method and formulation for orally administering bioactive agents to and through the Peyer's patch

Patentee:
SOUTHERN RESEARCH INSTITUTE, et al

Opponents:
Chiron Corporation
Alkermes, Inc.

Headword:
Oral composition/SOUTHERN RESEARCH INSTITUTE

Relevant legal provisions:
EPC Art. 111(1)

Keyword:
"Remittal to the first instance: yes - fresh case"

Decisions cited:
-

Catchword:
-

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D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 20 March 2002

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Decision under appeal: Interlocutory decision of the Opposition Division of the European Patent Office posted 13 October 1997 concerning maintenance of European patent No. 0 266 119 in amended form.

Composition of the Board:

Chairman: P. A. M. Lançon
Members: J. Riolo
C. Rennie-Smith
G. F. E. Rampold
R. E. Teschemacher

Summary of Facts and Submissions

I. European patent No. 0 266 119 based on application No. 87 309 286.0 was granted on the basis of a set of 25 claims for the Contracting States DE, GB, FR, IT, NL, SE, LI, CH, BE, AT and LU and a set of 25 claims for the Contracting States ES and GR.

The independent product claims as granted of the set of claims for the Contracting States other than ES and GR read as follows:

"1. An oral composition to be administered to animals, including humans, and capable of delivering a bioactive agent to the Peyer's patch of said animal, comprising an effective amount of the bioactive agent encapsulated in a biodegradable, biocompatible excipient so as to form microcapsules having a size less than or equal to 10 μm, being capable of being taken up selectively by the Peyer's patch and capable of passing through the gastrointestinal tract without degradation.

24. An oral composition to be administered to an animal, especially a human, for providing systemic and mucosal immunity in said animal, comprising an effective amount of an antigen encapsulated in a biodegradable, biocompatible excipient so as to form microcapsules of less than or equal to 10 μm in size, being capable of being taken up selectively by the Peyer's patch and capable of passing through the gastrointestinal tract without degradation and capable of delivering said antigen to the Peyer's patch of said animal."

II. Notices of opposition were filed against the granted patent by the appellant (opponent 01) and the opponent 02.

The patent was opposed under Article 100(a), (b) and (c) EPC.

The following documents inter alia were cited during the opposition proceedings:

(D1) *Int. Archs. Allergy appl. Immun.*, 75, pp 126-131 (1984)

(D7) A declaration of Dr D. T. O'Hagan (relating to an alleged oral prior public disclosure)

(D9) *J. Pharm. Sci.*, 73, No. 11, pp 1507-1511 (1984)

III. In its interlocutory decision the Opposition Division held that the patent could be maintained in an amended form on the basis of the text submitted during the oral proceedings since it met the requirements of Articles 123, 83, 54 and 56 EPC. In this text the set of the claims for the Contracting States other than ES and GR differed from the set of claims as granted in that the method claims 16 to 23 were deleted.

As to Article 83 EPC, the Opposition Division expressed the view that, since the patent disclosed the uptake of some particles up to 10 µm in the Peyer's patch, it could not be concluded, without evidence to the contrary, that the subject-matter of the claims was only operative in the range of 1 to 5 µm, as alleged by the opponents.

Concerning novelty, the Opposition Division found that the content of the alleged public oral disclosure made by O'Hagan (document D7) was not sufficiently substantiated to be considered.

The Opposition Division was moreover of the opinion that the term "oral composition" in the wording of claim 1 established novelty over the disclosure in document D9, which described biodegradable microparticles for intravenous injection; as the enzymatic degradation of the microparticles *via* oral administration and intravenous administration was different, different concepts of formulation were required for these types of administration.

As regards inventive step, the Opposition Division was of the opinion that it was not derivable from the closest prior art document D1, whether taken alone or in combination with the other prior art documents, that a microencapsulated product having a specific particle size could produce an immune response after being taken up by the Peyer's patch.

In fact, document D1, which disclosed particulate antigens wherein the antigen is attached to polyacrylamide, did not give any hint of encapsulation.

IV. The appellant lodged an appeal against the said decision.

It filed 11 new documents (A1 to A11) with its grounds of appeal. The arguments set out in the grounds of appeal were supported by reference to both these documents and those filed during the opposition proceedings.

V. The respondents (patentees) in written submissions of 14 September 1998 argued that the appellant was making a fresh case on appeal which had not been considered by the first instance and that the new case was no more meritworthy than that which had been rejected by the Opposition Division.

VI. In a communication of the Board dated 12 October 2000, preliminary views were expressed about the various points at issue in the light of the new documents filed by the appellant and in particular with respect to documents A9 *(Immunol.* 54, pp. 189-193, 1985) and A11 *(Proc. Natl. Acad. Sci. USA*, 81, pp. 5845-5848, 1984).

VII. In response to this communication, the respondents filed a main and three auxiliary requests on 26 April 2001.

In the main request, claim 1 of the set of claims for the Contracting States other than ES and GR has been amended by defining the composition as "composition for oral immunisation" and by defining the active agent as "immunogen". The set of claims for ES and GR has been adapted accordingly.

In the first auxiliary request, claim 1 of the set of claims for the Contracting States other than ES and GR has been amended by defining the excipient as a polymer or copolymer. The set of claims for ES and GR has been adapted accordingly.

In the second auxiliary request, claim 1 of the set of claims for the Contracting States other than ES and GR has been reworded as a use claim wherein the immunogen is used to prepare a composition for oral immunisation to immunise animals. The set of claims for ES and GR has been adapted accordingly.

The third auxiliary request covers all Contracting States and corresponds to the second with, however, claims 16 and 17 converted to use claims.

VIII. In its response of 4 May 2001 to the said communication the appellant maintained the grounds of opposition under Article 100(b) EPC and under Article 100(a) EPC

as to the lack of novelty and inventive step and filed six further documents (A12 to A17) in support of its arguments.

IX. In a further communication of 21 June 2001, the Board indicated to the parties that it considered the written proceedings to be closed.

The respondents in their letter of 15 January 2002 referred back to their observations of 14 September 1998 that the appellant was making a fresh case on appeal and requested that the Board remit the case to the Opposition Division for consideration of the patent's validity in the light of the newly cited prior art.

The appellant subsequently filed a further document (A18) with a letter of 21 January 2002, to which the respondents replied by filing, under cover of a letter of 20 February 2002, three further documents (A19 to A21) and a declaration by the author of A18. Some of the documents A12 to A18 were only published after the time limit for filing the grounds of appeal had expired.

X. In the oral proceedings held before the Board on 20 March 2002 the question of possible remittal was dealt with as a preliminary issue.

XI. The appellant argued against the request for remittal that it was not making a fresh case but only responding to the first instance decision and in particular that:

- some of the new documents were cited by them on appeal in order to establish the actual content of the prior disclosure by Dr O'Hagan since his declaration D7 had been found insufficient;

- some of the newly-cited documents could not have been cited earlier because they were simply not published; such documents had been filed as soon as they were available;

- the application for the patent was filed in 1985, i.e. over fifteen years ago, so that it would not be appropriate, by remitting the case to the first instance, to delay the result for several more years;

- the respondents had only requested remittal in their letter of 15 January 2002, i.e. at a very late stage of the proceedings.

XII. The respondents submitted in support of their request for remittal that:

- the nature of the prior art relied upon by the appellant had dramatically changed its case which was now based in particular on the new liposome prior art which had not been considered by the Opposition Division;

- the documents filed on appeal allegedly to overcome the Opposition Division's rejection of D7 could have been filed in the first instance proceedings since they were known to Dr O'Hagan and referred to by him in documents D24 and D25;

- the argument that certain documents only came into existence after the appeal was filed was inherently flawed since, if such an argument was acceptable, litigation might never be concluded;

- while they had not made a request for remittal in terms until 15 January 2002, the respondents had in reply to the grounds of appeal asserted that

the appellant was making a fresh case on appeal; and that, while their original response to this new case had been to defend the patent against it, the filing by the appellant of yet further new documents after the respondents' new requests, produced in response to the rapporteur's communication of 12 October 2000, had caused the respondents to reconsider their position and request remittal;

- the respondents were content to continue with the appeal proceedings if the new documents filed in the appeal proceedings were not considered but otherwise they should not be deprived of the opportunity of having the validity of the patent over the new prior art considered at two instances;

- although remittal would lead to further delay in proceedings which had already been pending for several years, the prejudice this would cause would affect the respondents as well as the appellant since the respondents would be inhibited in any attempts to enforce the patent against alleged infringers.

XIII. The appellant requested that the decision under appeal be set aside and that the European patent No. 0 226 119 be revoked.

The respondents requested as main request that the decision under appeal set aside and that the case be remitted to the first instance for further prosecution on the basis of the requests filed with its letter of 26 April 2001; and alternatively, as auxiliary request, that the patent be maintained by the Board in accordance with one of those requests.

The opponent O2, a party as of right to the appeal, took no part in the appeal proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. The question which falls for consideration by the Board is whether, in a case where a large volume of new evidence has been filed on appeal in three tranches by the appellant, remittal of the case to the first instance is appropriate even when the respondent patentees have produced arguments against the first tranche of such new evidence and, despite protesting at the outset against a "fresh case", only actually requested remittal two months before the oral proceedings after the filing of the second and third tranches of new evidence. The Board would observe at the outset that, as appears from the summary of facts and submissions above, the circumstances of this case are exceptional.

3. As regards the admissibility of documents A1 to A11, filed by the appellant with its grounds of appeal, the Board considers this is no longer a live issue. The respondents, for all they protested in reply to the grounds of appeal that the production of these documents amounted to a fresh case, can no longer object to their admissibility since they have of their own volition filed arguments against them and, in response to the Board's communication referring to two of these documents, have filed new sets of claims in reaction to the Board's comments. The appellant claims that it filed these documents to make good criticisms of its case made by the Opposition Division and the respondents asserted in reply to the grounds of appeal

that these new documents were as capable of answer as those cited at first instance. It was on the basis of these positions of the parties that the Board sent its communication indicating that two of the new documents could be seen as threatening the novelty of the patent in suit. In the circumstances, these 11 documents filed with the grounds of appeal have been considered by the parties and the Board as admitted into the proceedings and to now hold otherwise would be inconsistent. (As to the admissibility of documents A12 to A21, see paragraph 7 below.)

4. As to the question of remittal, a brief consideration of the sequence of events shows that a fresh case may have arisen but when the grounds of appeal were filed a remittal did not appear as appropriate. Certainly, the appellant filed eleven new documents with its appeal and the grounds of appeal draw support from both old and new documents. The respondents replied that this amounted to a fresh case but none the less answered fully the substantive case then made against them and did not, at that point, request either remittal or that the new evidence be not admitted. The Board sent a communication indicating that it considered two of the new documents to be possibly prejudicial to the novelty of the patent in suit. The respondents replied by producing four new sets of claims in order to take account of the new prior art and which would have necessitated the likely assessment of inventive step as against a new and different view of the closest state of the art, namely the newly-cited prior art relating to liposomes.

5. Accordingly, given the particular history of the appeal proceedings as they thus developed, the Board considers that the "fresh case" warranting remittal arose at the point in time when the respondents filed those new sets of claims. It is apparent from those claims, and the

parties' arguments in relation to them, that the state of the art to be considered for the purposes of inventive step will be significantly different from that previously considered at first instance - that art will include liposomes which played no part in the decision under appeal. And a different state of the art means the closest prior art will be different and a different problem to be solved will have to be formulated. The solution to that problem, as the respondents will argue, will be provided by the different claims they now rely on.

6. In those circumstances, there is considerable force in the respondents' argument for remittal. It is true that, as the appellant has observed, the request for remittal was only made very recently and not in response to the new documents filed with the grounds of appeal. However, it is clear that, as indicated above, the essential cause of the fresh case was not the filing of those documents in February 1998 but the more recent amendment of the claims following the Board's communication of October 2000. It was then that the respondents appreciated that the new evidence could not perhaps be rebutted as easily as they first thought. Nevertheless it could be added that, while the immediate cause of the fresh case was the filing of the new requests by the respondent, the responsibility for this rests primarily on the appellant which should have known perfectly well that the probability of a remittal would increase with the volume of late-filed facts and evidence. Having filed at the appeal stage no less than 18 new documents, the appellant's argument as to delay is unconvincing. In the exercise of its discretion, the Board considers the case against the patent has now altered to such an extent that the respondents have a legitimate reason to have their full case considered at

two instances. Therefore remittal of the case to the first instance is appropriate (Article 111(1) EPC).

7. There remains the question of further documents filed on both sides since the respondents filed their amended claims. It follows from the Board's finding that the fresh case arose when those claims were filed and from the decision to remit the fresh case to the Opposition Division that the decision on the admissibility of those documents should be left to the Opposition Division.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution.

The Registrar: The Chairman:

A. Townend P. A. M. Lançon