BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS | BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE | CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Publication in the Official Journal ~~Yes~~ / No

File Number: T 495/90 - 3.3.2

Application No.: 82 200 841.3

Publication No.: 0 072 046

Title of invention: Inhalation drugs, methods for their production and pharmaceutical formulations containing them

Classification: A61K 9/72

DECISION
of 30 June 1992

Proprietor of the patent: Fisons Plc

Opponent: Hexal-Chemie GmbH

Headword: Inhalation Drugs/FISONS

EPC Article 54

Keyword: "Novelty of main and auxiliary requests I and II - (no)"

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 495/90 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 30 June 1992

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Decision under appeal :
Decision of Opposition Division of the European Patent Office dated 20 April 1990 revoking European patent No. 0 072 046 pursuant to Article 102(1) EPC.

Composition of the Board :

Chairman : P. Lançon
Members : U. Kinkeldey
R. Schulte

Summary of Facts and Submissions

I. European patent application No. 82 200 841.3 was granted as European patent No. 72 046 with 13 claims.

II. Notices of opposition against the European patent were filed and revocation of the patent was requested on the grounds of Article 100(a) and (c) EPC.

The Appellants submitted during the opposition proceedings a new request containing the following Claim 1:

"A free flowing spray-dried inhalation drug, unmixed with a bulk carrier in which more than 90% of the drug particles are less than 10μm in diameter, the drug being put up in a capsule, cartridge or pressurised aerosol container characterised in that a substantial proportion of the individual drug particles have a spherical, collapsed spherical or ring doughnut shape, the envelope surface area: total surface area ratio is in the range of 0.5 to 1.0 and in which a bulk of the particles are unagglomerated."

III. The Opposition Division revoked the patent essentially for the following reasons:

(a) Amended Claim 1 contained several features which contravened Article 123(3) EPC.

(b) GB-A-1 520 248 (document (1)), which had to be considered as the closest prior art, dealt with the same problem to be solved. It disclosed spray-drying a solution of the drug sodium cromoglycate.

Undisputedly the features in the precharacterising part of the claim were known from document (1). The

features of the characterising part of the claim which were the shape and the type of the surface of the particle were not disclosed in words in document (1). Since, however, the process to prepare said particles described in document (1) apparently was the same as that applied in the patent one had to assume that identical methods yielded identical products and therefore it was not shown how the claimed product could possibly be distinguishable from the product to be obtained according to the process disclosed in document (1).

As far as the feature "a bulk of the particles are unagglomerated" was concerned, the same reasoning applied. The claimed subject-matter, therefore, was not novel.

IV. The Appellants lodged an appeal against the decision and submitted a statement of grounds.

Oral proceedings took place on 30 June 1992.

V. During oral proceedings a new set of claims as a main request was filed wherein Claim 1 reads as follows:

"1. A free flowing atomised and dried inhalation drug comprising a therapeutically effective proportion of the individual drug particles capable of penetrating deep into the lung unmixed with a coarse carrier wherein more than 90% of the drug particles are less than 10μm in diameter and a bulk of the particles are unagglomerated the drug being put up in a capsule, cartridge or pressurised aerosol container carrier characterized in that a substantial proportion of the individual drug particles have a spherical, collapsed spherical or ring doughnut shape and the envelope surface area:total surface area

ratio is in the range of 0.5 to 1.0 and is prepared by spray drying a solution of the drug in a kinetic or pneumatic energy atomiser."
(amendments emphasised by the Board).

Two auxiliary requests I and II were filed. Claim 1 of auxiliary request I has the same wording as that of the main request but the atomiser being specified as being "of the type selected from a two-fluid syphon nozzle, a two-fluid pressure nozzle, an ultrasonic nozzle and a swirl air nozzle".

Claim 1 of auxiliary request II is worded like Claim 1 of auxiliary request I but the spray-drying apparatus being further characterised by "a main chamber and at least one cyclone or bag filter". Further the inhalation drug is sodium cromoglycate and the solution to be spray-dried is "a 10 to 15% aqueous solution of the drug".

The Appellants' main arguments were as follows:

(a) By amending the claim while replacing the word "bulk" by the word "coarse" in the precharacterising part of the claim and by incorporating the words "a solution" in relation to what was prepared by spray-drying the grounds for the Opposition Division to object to the claims with regard to Article 123(3) EPC were no longer relevant.

(b) As regards novelty, it was agreed that document (1) disclosed the closest prior art.

There it is disclosed to spray-dry a slurry of an inhalation drug, namely, sodium cromoglycate. In doing so one could not produce a substantial proportion of particles which were spherical,

collapsed spherical or ring doughnut shape. A slurry comprised a suspension of particles in a solvent, thus the particle shapes were already defined. Spray-drying of a slurry was merely a specialised method of drying a product which might otherwise be difficult to dry. New particles per se were not formed, although articles of agglomerated particles might be formed as those in document (1). Even if the disclosed process gave rise to spherical, collapsed spherical or ring doughnut shape particles, it was not conceivable that such particles would make up a "substantial portion" of the drug.

There was no disclosure in document (1) of the type of atomiser which should be used or of the concentration of the solution to be atomised. Since it was so, document (1) did not present an enabling disclosure within the meaning the decision T 206/83 Herbicides/ICI (OJ EPO 1987, 5).

Conversely, the present invention required the use of mist atomisers which were essential for the preparation of the particles of the present invention. If the disclosure of document (1) were construed broadly to include any spray-dried form of sodium cromoglycate, then the present invention could be deemed to be a selection invention from the disclosure of document (1).

In auxiliary requests I and II the type of atomiser was specified in a way to distinguish it from the disclosure of the prior art document (1).

Further, the concentration of the solution was not mentioned at all in document (1).

VI. The submissions by the Respondents substantially were as follows:

(a) Claim 1 of the main request was not novel because the particles were prepared by the same method as described in document (1). There each and every process step or means was already disclosed so that necessarily the same product must have been achieved. If there had been any gaps they could have easily been filled out by the common general knowledge which was represented for example by

Hagers Handbuch der Pharmazeutischen Praxis, 4th ed., Vol. 7, 1971 (document (5)).

There, under the chapter "Zerstäubungstrocknung", technical details as to the atomiser to be used in spray-drying processes were disclosed. Therefore, even in auxiliary requests I and II in which some more detail as to the atomiser used was contained, novelty could not be accepted with regard to document (1).

(b) As far as Claim 1 of auxiliary request II differed from the main claims of both other requests, namely by the mention of the concentration of the solution to be spray-dried, one could not consider this feature to be inventive because it was known from document (5) also that more concentrated solutions resulted when spray-dried in bigger particles, which implied that less concentrated solutions provided smaller particles. It was, therefore, an obvious step to use the claimed concentration of the solution, if a particle size as small as possible was desired.

VII. The Appellants requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims filed during oral proceedings.

The Respondents requested that the appeal be set aside.

Reasons for the Decision

1. The appeals are admissible.

2. Amendments (Article 123(2) and (3) EPC)

During oral proceedings it has been made clear that the features of Claims 1 of all requests are directly and unambiguously derivable from the specification of the patent in suit as originally filed.

Consequently there are no objections as to Article 123(2) EPC.

The main claims now on file differ from the granted Claim 1 essentially by replacing the feature "at least 50% of the drug particles are less than 60μm in diameter" by the now claimed feature "wherein more than 90% of the drug particles are less than 10μm in diameter" and by specifying the spray-drying being carried out by an atomiser, an aqueous solution and the inhalation drug being more specifically defined. It is immediately apparent that these amendments do not extend the scope of protection of the claim but rather limit it. There are, therefore, no objections as to Article 123(3) EPC either.

3. Novelty Article 54 EPC)

3.1 Main request

3.1.1 There is agreement among the parties and the Board that document (1) represents the closest state of the art.

This document discloses a free flowing spray-dried inhalation drug (page 1, left column, lines 12 to 37 in connection with page 4, left column, lines 28 and 29) comprising a therapeutically effective proportion of the individual drug particles capable of penetrating deep into the lung unmixed with a coarse carrier (page 1, right column, lines 49 to 56) wherein more than 90% of the drug particles are less than 10μm in diameter (page 1, right column, lines 87 to 95 and page 2, lines 74 to 85) the drug being put up in a capsule or cartridge (page 5, left column, lines 14 to 16) wherein the majority of the shaped articles are approximately spherical (page 4, right column, lines 114 to 116) and is prepared by spray-drying a solution of the drug (page 4, left column, lines 28 and 29).

When now comparing Claim 1 with this disclosure it is apparent, as the Appellants already acknowledged by wording the precharacterising part of the claim as they did, that these features are known from document (1). It remains, therefore, to examine whether the features comprised in the characterising part of the claim are suitable to distinguish the inhalation drug as claimed from that described in document (1).

3.1.2 The said features are the shape of the drug, being spherical, collapsed spherical or ring doughnut shaped and the surface character being defined by the envelope surface area : total surface area ratio being in the range of 0.5:1.0 and finally the type of the atomiser.

As to the shape and surface feature, the facts on file show that they result from the process by which the inhalation drug particles are prepared. Since the spray-drying process described in document (1) is no different from the spray-drying process mentioned in Claim 1, one has to conclude, as did the Opposition Division, that the particles achieved by the spray-drying process described in document (1) must inevitably have the same shape and surface characteristics as the particles obtained by the spray-drying process claimed in Claim 1.

3.1.3 Another difference lies in the mentioning of the atomiser used for the spray-drying process, being a kinetic or pneumatic energy atomiser. This difference, however, is not suited to render the product novel because a kinetic or pneumatic energy atomiser would be the means which is immediately, clearly and unambiguously understood by the skilled person to be used to produce the claimed product. The same spherical, collapsed spherical or ring doughnut shape particles having surface characteristics as those described in document (1) would thus be obtained.

3.1.4 For the purpose of an expert opinion the Board would like to draw attention to document (5), being a "Handbuch" in the field of pharmacy, i.e. being the very basis of common general knowledge. There, it is explained that spray-drying is carried out by a kinetic or pneumatic energy atomiser (page 78, second paragraph).

This is also in agreement with the statement in the patent in suit that "any suitable form of atomiser can be used", (page 4, line 38). No convincing arguments have been submitted during the proceedings that the use of a kinetic or pneumatic energy atomiser would produce particles being different from those produced according to the method

disclosed in document (1). It was thus the actual technical teaching of document (1) as understood by the skilled person to use for the spray-drying process an atomiser as now specified in Claim 1. This interpretation of the teaching of document (1) is in line with established case law of the Boards of Appeal, see for example, T 153/85, OJ EPO 1988, 1.

3.1.5 The present situation is further comparable with that of the decision T 12/81 "Diastereomers/BAYER" (OJ EPO 1982, 296). There it was decided that the information of a prior art document taken as a whole constituted a prior art description of the claimed compound prejudicial to its novelty, because it supplied a person skilled in the art with all the information he needed regarding the starting substance and the reaction conditions for preparing the claimed substance. In other words, the document also described the substance which was the inevitable product of the method described in the patent in question. It was held immaterial for the purposes of prejudice to novelty that the end product was not described in full detail (points 8 and 10 of the description).

3.1.6 The same reasoning holds good in the present case, because the information given in document (1) provides the skilled person, with all he needs regarding the starting material, being the inhalation drug solution and the spray-drying method, for preparing the claimed substance. It has again to be emphasised that Claim 1 is a **product** claim. Certain features of the product claim are defined by process elements, so that Claim 1 could be regarded as a product by process claim. But this definition of a product does not change the patent category. Claim 1 still remains a product claim and is only patentable if the product itself is novel. Even if the process were novel, this did not necessarily render the product of this process novel. It

is self-evident that by new and patentable processes known products may be produced, but this does not happen to be the case here.

3.1.7 The Appellants further cannot be heard with the argument that document (1) did not provide a sufficient disclosure for the skilled person to carry out the spray-drying process taught there, within the meaning of the decision T 206/83 (see above paragraph V(b)). As already stated above in detail, (see point 3.1.4) it was common general knowledge at the time of publication of document (1) what technical possibilities existed for carrying out the spray-drying process. The Board, therefore, considers document (1) as a teaching which was sufficiently disclosed within the meaning of Article 83 EPC.

Claim 1 of the main request, thus, is not novel.

3.2 Auxiliary requests I and II

3.2.1 Claim 1 of the first auxiliary request has the same wording as Claim 1 of the main request with the exception that the atomiser is further defined as to be one "of the type selected from a two-fluid syphon nozzle, a two-fluid pressure nozzle, an ultrasonic nozzle and a swirl air nozzle".

3.2.2 Claim 1 of the second auxiliary request has the same wording as Claim 1 of auxiliary request I with the exception of the spray-drying apparatus being further defined by a main chamber and at least one cyclone or bag filter and that the solution to be atomised and dried is a 10-15% aqueous solution of sodium cromoglycate.

3.2.3 For the judgment of novelty of Claims 1 of these requests the same reasons apply as to Claim 1 of the main request,

because it has not been shown that those particular nozzles or the newly introduced features of the spray-drying apparatus or the concentration of the solution (all of them process parameters) are the causal means to produce particles having a different shape and surface characteristic from those prepared according to the teaching of document (1), or even those as claimed in Claim 1 of the main request.

Therefore, Claim 1 of these requests cannot be considered as being novel as well.

4. From all the above it follows that the requirements of Article 54 EPC are not fulfilled by any of the requests on file.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

P. Martorana P. Lançon