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Datasheet for the decision of 9 March 2007

Case Number: T 0316/06 - 3.3.02

Application Number: 92200153.2

Publication Number: 0499299

IPC: A61K 9/51

Language of the proceedings: EN

Title of invention:
Surface modified drug nanoparticles

Patentee:
Elan Pharma International Limited

Opponent:
SmithKline Beecham plc

Headword:
Nanoparticles/ELAN PHARMA INTERNATIONAL LIMITED

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
"Main and first auxiliary requests - added matter - yes : feature not disclosed"

Decisions cited:
T 0553/90

Catchword:
-

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Case Number: T 0316/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 9 March 2007

Appellant: (Patent proprietor)	Elan Pharma International Limited WIL House Shannon Business Park Shannon Country Clare (IE)
Representative:	Gilbert, Penny Xenia Powell Gilbert LLP 25 Southampton Buildings Chancery Lane London WC2A 1AL (GB)
Respondent: (Opponent)	SmithKline Beecham plc New Horizons Court Great West Road Brentford Middlesex TW8 9GS (GB)
Representative:	Rutter, Keith GlaxoSmithKline Corporate Intellectual Property (CN9.25.1) 980 Great West Road Brentford Middlesex TW89GS (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 17 January 2006 revoking European patent No. 0499299 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Willems

Summary of Facts and Submissions

I. European Patent No. 0 499 299 based on application No. 92 200 153.2 was granted on the basis of 27 claims.

Independent claim 1 as granted read as follows:

"1. Mechanically obtained particles having an effective average particle size of less than 400 nm, and being free of solvent contamination deriving from solvent precipitation, wherein the particles consist essentially of a crystalline drug substance and a surface modifier, said crystalline drug substance having been mechanically ground to an effective average particle size of less than 400 nm and having said surface modifier adhered to the surfaces of said particle essentially by adsorption with individually adsorbed molecules of said surface modifier being essentially free of intermolecular crosslinkages, said surface modifier being present in an amount of 0.1 to 90% by weight based on the total weight of dry particles so as to maintain said effective average particle size, wherein at least 90% of the particles have a weight average particle size of less than 400 nm, and wherein the surface modifier is selected so as to be compatible with the drug substance through a screening process so that the dispersion containing the particles exhibits no flocculation or particle agglomeration visible to the naked eye and particularly when viewed under the optical microscope at l000x at least two days after preparation."

II. Oppositions were filed against the granted patent by opponents 1 and 2. The patent was opposed under

Article 100(b) EPC for insufficiency of disclosure, under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(c) for added matter extending beyond the content of the application as filed.

On 1 August 2001, opponent 2 withdrew its opposition.

III. The decision of the Opposition Division pronounced on 14 November 2005 revoked the patent under Article 102(1) EPC.

The Opposition Division took the view that the patent in suit did not meet the requirements of the EPC, as neither the main request nor auxiliary requests 1 to 3, presented before the Opposition Division, complied with the requirements of Article 123(2) EPC.

It held that the replacement of the definition in the description of the application as filed given for the expression "an effective average particle size of less than 400 nm", namely "at least 90% of the particles have **a weight average particle size** of less than about 400 nm", by the definition "at least 90% of the particles have **particle size** of less than about 400 nm" in the patent as granted contravened the requirements of Article 123(2) EPC as the two definitions have two different meanings.

The same conclusions as to Article 123(2) EPC applied to the addition of the feature "free of solvent contamination deriving from solvent precipitation" added in claim 1 as granted since it was not disclosed in the application as originally filed.

The Opposition Division also considered that the replacement in claim 1 of the expression "surface modifier adsorbed on the surface thereof" by "having said surface modifier adhered to the surfaces of said particle **essentially** by adsorption" added subject-matter because the application as filed did not disclosed other mechanisms than adsorption.

IV. The appellant (patentee) lodged an appeal against the said decision.

V. With its letter dated 9 February 2007, the appellant filed a main request and a first and a second auxiliary request.

Independent claim 1 of the set of claims of the main request is identical to claim 1 in the set of claims of the first auxiliary request.

It differs from claim 1 of the set of claims as granted merely in that the word "essentially" has been deleted in the expression "essentially by adsorption" and in that the optional feature "and particularly when viewed under the optical microscope at l000x" has also been deleted.

The description of the main request was identical to the description as granted, whereas the description of the first auxiliary request was amended to come closer to the wording as originally filed.

Claim 1 of the set of claims of the second auxiliary request reads:

1. A method of preparing mechanically obtained particles having an effective average particle size of less than 400 nm, and consisting essentially of a crystalline drug substance and a surface modifier, comprising the steps of dispersing larger size particles of the drug substance in a liquid dispersion medium consisting essentially of water or an aqueous salt solution, and wet grinding said drug substance in the presence of rigid grinding media having an average particle size of less than 3 mm and the surface modifier to reduce the particle size of said drug substance to an effective average particle size of less than 400 nm; wherein said crystalline drug substance having been mechanically ground to an effective average particle size of less than 400 nm has said surface modifier adhered to the surface of said particles by adsorption with individually adsorbed molecules of said surface modifier being essentially free of intermolecular crosslinkages, said surface modifier being present in an amount of 0.1 to 90 % by weight based on the total weight of dry particles so as to maintain said effective average particle size, wherein, at least 90 % of the particles have a weight average particle size of less than 400 nm, and wherein the surface modifier is selected so as to be compatible with the drug substance through a screening process so that the dispersion containing the particles exhibits no flocculation or particle agglomeration visible to the naked eye at least two days after preparation.

VI. Oral proceedings were held before the Board on 9 March 2007.

VII. The appellant first argued that its appeal was admissible because it was filed in due time by the party mentioned in the Register of European Patents as the proprietor of the patent in suit.

As to the amendments in the description, it held that they did not affect the original meaning of the definition given for the expression "an effective average particle size of less than 400 nm".

As to the feature "free of solvent contamination deriving from solvent precipitation" in claim 1, it argued that support for this could be found on page 3, lines 10 to 15 in conjunction with page 4, lines 28 to 31 of the application as filed.

In fact, page 3, lines 10 to 15 of the application as filed follows on from the general discussion about precipitation techniques, earlier in the paragraph, in connection with prior art document EP 0 275 796, which concerns a precipitation technique. This passage of the application as filed explains that precipitation techniques for preparing particles "tend to provide particles contaminated with solvents".

Page 4, lines 28 to 31 of the application as filed states that a wide variety of surface modified drug nanoparticles free of unacceptable contamination can be prepared in accordance with the invention.

Therefore, in its view, the "unacceptable contamination" referred to on page 4, line 30 of the application as filed must at least include the solvent contamination deriving from solvent precipitation that

is discussed only a page before and separated only by statements concerning the features of the present invention.

VIII. The respondent contested the admissibility of the appeal on the grounds that the assignment of the patent application to the predecessor of the appellant did not comply with Article 72 EPC, as it was only signed by one of the parties to that assignment.

As to the amendments in the description, it submitted that they changed the original meaning of the definition given for the expression "an effective average particle size of less than 400 nm".

Concerning the feature "free of solvent contamination deriving from solvent precipitation" in claim 1, it was of the opinion that it could not be derived directly and unambiguously from the original disclosure as required by the case law relating to the assessment of the requirements of Article 123(2) EPC.

IX. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance with the set of claims and the description of the main request or of the first auxiliary request, both filed on 9 February 2007.

The respondent requested that the appeal be rejected as inadmissible or that the appeal be dismissed.

Reasons for the Decision

1. *Admissibility of the appeal*

The appeal is admissible.

It was filed in due time by the appellant, who at that time was registered as the proprietor of the patent in the Register of European Patents. Where there was no obvious error of the Legal Division when entering the assignment of the patent application to the appellant, where that decision of the Legal Division is not an object of this appeal (T 553/90 OJ 1993, 666)and there was presented no irrefutable evidence that the appellant was at the relevant time not the proprietor of the patent, there is no possibility for this Board to go into the matter of the assignment of the patent to the appellant and the registration of the appellant as the proprietor in the register of European Patents.

The respondent has also argued that the appellant was not entitled to an appeal as it, not being the proprietor of the patent, could not be adversely affected by the decision under appeal.

That argumentation is not convincing. It is clear from the documents presented that it was the will of all parties, concerned with the transfer of the application, that the application of the patent in suit should be transferred to the appellant and that all those parties regard the application/patent in suit as being the property of the appellant. There has been presented no irrefutable evidence about the question which law was applicable to this transfer, nor that

this transfer according to that law was not legally valid.

2. *Admissibility of the requests and documents presented on 9 February 2007*

Main request, first auxiliary request and second declaration by Mr. Aulton.

Independent claim 1 of the set of claims of the main request is identical to claim 1 in the set of claims of the first auxiliary request.

Moreover, it differs from claim 1 of the main request before the Opposition Division merely in that the word "essentially" has been deleted in the expression "essentially by adsorption" and the description of the first auxiliary request has been amended so that it comes closer to the original wording.

Accordingly, as these requests do not seem to complicate the proceedings in any way, they are admitted into the proceedings.

The same applies to the second declaration, which was merely intended to show that these requests were also in agreement with the requirements of Article 123(3) EPC.

Second auxiliary request and new documents D67 and D68

The main rule is that all requests have to be in the grounds of appeal (Article 10c ROP).

According to the jurisprudence of the Board, new requests are admissible if they are a direct reaction to new arguments or new points of discussion.

That does not seem to be applicable in this case, as the second auxiliary request, which differs considerably from the previous requests, and the documents were filed one month before the oral proceedings without a single explanations as to they relevance. Nor did the appellant provide a basis in the application as originally filed for the subject-matter of this set of claims.

Under these circumstances, this request and these documents are not admitted into the proceedings.

3. *Main request*

Article 123(2) EPC

The Board shares the Opposition Division's conclusions that the feature "free of solvent contamination deriving from solvent precipitation" added subsequently to claim 1 as granted was not disclosed in the application as originally filed.

The application as filed does indeed make various statements about contamination levels obtainable with the invention (page 4, line 30; page 13, line 1; page 16, line 25; page 22, line 3).

However, the identity or nature of the contaminations is either not specified or, when specified or implied, it refers only to the grinding media.

Under these circumstances, the Board concludes that the feature added in claim 1 as granted contravenes Article 123(2) EPC.

The Board does not agree with the appellant's reasoning mentioned under point VII above.

In fact, even if the skilled person assumed that the expression "free of unacceptable contamination" used on page 4, lines 28 to 31, referred to the contaminations in the prior art, it would not know whether these contaminations were those in the prior art identified in connection with wet milling (page 2, lines 5 to 8), emulsion polymerisation technologies (page 2, lines 21 to 25) or precipitation techniques (page 3, lines 10 to 13), or even all of them.

Moreover, as the application as originally filed itself envisages the use of solvents suitable for precipitation techniques (page 6, lines 9 to 13), it cannot be concluded that the contested feature "free of solvent contamination deriving from solvent precipitation" can be directly and unambiguously derived from the content of the application as originally field.

4. *First auxiliary request*

Independent claim 1 of the set of claims of the main request is identical to claim 1 in the set of claims of the first auxiliary request, so that the above conclusion also applies to this request.

Order

For these reasons it is decided that:

1. The appeal is admissible.

2. The appeal is dismissed

The Registrar: The Chairman:

A. Townend U. Oswald