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**Datasheet for the decision
of 12 December 2012**

Case Number: T 1498/09 - 3.3.02
Application Number: 00965255.3
Publication Number: 1216042
IPC: A61K 31/337, A61P 35/00,
A61K 9/51
Language of the proceedings: EN

Title of invention:

Formulations of paclitaxel entrapped into nanoparticles of polymeric micelles

Patentee:

DABUR PHARMA LTD.

Opponent:

Angiotech Pharmaceuticals, Inc.

Headword:

Formulations of paclitaxel/DABUR PHARMA

Relevant legal provisions:

EPC Art. 100(c), 123

Keyword:

"Main request not allowable"

Decisions cited:

G 0004/92, G 0001/93

Catchword:

-



Case Number: T 1498/09 - 3.3.02

DECISION
of the Technical Board of Appeal 3.3.02
of 12 December 2012

Appellant: DABUR PHARMA LTD.
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Respondent: Angiotech Pharmaceuticals, Inc.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 14 May 2009
revoking European patent No. 1216042 pursuant
to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
R. Cramer

Summary of Facts and Submissions

- I. European patent No. 1 216 042, which was filed as application number 00965255.3, based on international application PCT/US00/25914, published as WO 01/21174, was granted on the basis of eighteen claims.

Claim 1 as granted read as follows:

"1. A formulation containing nanoparticles of polymeric micelles containing a drug selected from paclitaxel, or a derivative thereof physically entrapped therein; said formulation further comprising an alcohol, a co-polymer [sic], an anionic surfactant, a buffering agent and an intravenous aqueous diluting fluid".

- II. Opposition was filed and revocation of the patent in its entirety was requested pursuant to Article 100(c) (the subject-matter of the patent extends beyond the content of the application as filed), 100(b) (lack of sufficiency of disclosure) and 100(a) EPC (lack of novelty and inventive step).
- III. The present appeal lies from the decision of the opposition division, posted on 14 May 2009, revoking the patent.
- IV. The opposition division considered that claim 1 of the main request, filed by fax with a letter dated 17 April 2009, did not meet the requirements of Article 123(2) EPC.
- Claim 1 of the main request before the opposition division read as follows:

"1. A formulation containing nanoparticles of radically polymerized micelles comprising a co-polymer derived from at least two monomers and a drug selected from paclitaxel, or a derivative thereof physically entrapped within said radically polymerized micelles; said formulation further comprising an alcohol solvent for dissolving said drug, an anionic surfactant, a buffering agent and an intravenous aqueous fluid, wherein at least one of said monomers is an amphiphilic monomer".

As regards the first auxiliary request filed with the letter dated 23 February 2009, the opposition division considered that the combination of claim 1 with dependent claim 2 was contrary to Article 123(2) EPC.

Claims 1 and 2 of the first auxiliary request before the opposition division read as follows:

"1. A formulation containing nanoparticles of radically polymerized micelles comprising a co-polymer formed from vinylpyrrolidone, N-isopropyl acrylamide, and a functionalized polyethylene glycol and a drug selected from paclitaxel, or a derivative thereof physically entrapped within said radically polymerized micelles; said formulation further comprising an alcohol solvent for dissolving said drug, an anionic surfactant, a buffering agent and an intravenous diluting fluid."

"2. The formulation as claimed in claim 1, wherein the molar ratio of vinylpyrrolidone [*sic*] to N-isopropyl acrylamide is 10-50:50-90."

As regards the second auxiliary request which was filed during the oral proceedings before the opposition division, the opposition division considered that claim 1 did not meet the requirements of Article 123(2) EPC.

Claim 1 of the second auxiliary request before the opposition division is identical to claim 1 of the first auxiliary request before the opposition division. In the second auxiliary request before the opposition division claim 2 of the previous request had been deleted.

- V. The patent proprietor lodged an appeal against the opposition division's decision.

The appellant requested in its letter dated 14 September 2009 that the decision under appeal "should be set aside". As annex to said letter it filed the document "grounds of appeal" (6 pages) and a new main request (as working and clean copy). In the grounds of appeal it submitted that the decision under appeal "be set aside on European Patent No. 1216042 as amended on the following grounds". Then it stated that "The Patentee submits the amended set of claims" and referred to the amendments in the new main request. Following this paragraph on page 1 of the grounds of appeal, it gave arguments concerning Articles 123(2) and (3) EPC.

The appellant did not maintain its first and second auxiliary requests before the opposition division and the grounds of appeal do not contain any arguments to contest the reasons given in the opposition division's decision.

VI. Claim 1 of the main request filed with the grounds of appeal reads as follows:

"1. A formulation containing nanoparticles of polymeric micelles containing a drug selected from paclitaxel, or a derivative thereof physically entrapped therein; said formulation further comprising an alcohol, a co-polymer formed from vinylpyrrolidone, N-isopropyl acrylamide, and functionalized polyethylene glycol, an anionic surfactant, a buffering agent, and an intravenous aqueous diluting fluid".

VII. The respondent (opponent) filed counter-arguments to the patent proprietor's appeal.

VIII. Summons to oral proceedings pursuant to Rule 115(1) EPC were sent to the parties on 12 July 2012. The board sent a communication pursuant to Article 15(1) RPBA as an annex thereto.

In said communication the board stated that the parties' requests according to the state of the file were as follows:

The appellant had requested that the decision under appeal be set aside and that a patent be maintained in amended form on the basis of the main request filed with its grounds of appeal.

The respondent had requested that the appeal be dismissed.

Moreover, the board pointed to the fact that with the new main request filed with the grounds of appeal the appellant had reverted to a claim 1 including again the wording of granted claim 1, into which the wording of claim 3 as granted had been incorporated, and that Article 100(c) was within the framework of the present appeal. Moreover, the board also expressed a preliminary negative opinion in respect of added matter for the main request. Additionally, the board reminded the appellant that it had not filed any counter-arguments to the respondent's objections under Article 123(2) EPC in relation to dependent claims in the main request filed with the grounds of appeal.

The parties were also reminded that the admissibility of any requests and submissions filed after the board's communication would have to be considered under Article 13 RPBA.

- IX. The respondent announced with its letter dated 26 September 2012 that it did not intend to attend the oral proceedings before the board of appeal.
- X. The appellant informed the board by a letter dated 6 December 2012 (filed by fax the same day) that "no one representing the Patentee will attend oral proceedings".
- XI. Oral proceedings took place on 12 December 2012 in the absence of both parties.
- XII. The appellant's arguments, as far as relevant for the present decision, may be summarised as follows:

A person skilled in the art would understand that the claimed formulation would not require an additional co-polymer because claim 1 simply referred to "polymeric micelles" without further describing that they were made from a co-polymer. Consequently, the term "further comprising" clarified the "polymeric" component of the micelles and that the co-polymer was employed to create those polymeric micelles. Furthermore, claim 1 listed the ingredients as contained in the "said formulation" and not in the said "nanoparticles". Therefore, the formulation, rather than the nanoparticles, was made from the listed items. The formulation containing nanoparticles of polymeric micelles was made from a co-polymer, among other listed items.

Additionally, claim 1 as originally filed included certain elements which were recited as distinct elements (using the words "a" or "an") and there was further language which referred "antecedently" back to earlier language (with the words "said" and "the"). Consequently, claim 1 as originally filed recited the seven distinct elements which corresponded to the seven distinct elements of claim 1 as granted.

Furthermore, upon consideration of the prosecution history the amendment made during prosecution had been correctly made in order to improve conciseness.

XIII. The respondents' arguments, as far as relevant for the present decision, may be summarised as follows:

The formulations claimed in the main request constituted added subject-matter pursuant to Article 100(c) EPC, since claim 1 presented the skilled

person with information that was not clearly and unambiguously derivable from the application as originally filed.

The respondent referred *inter alia* to page 1, lines 4 to 6, line 9, lines 27 *et seq.* and page 2, lines 10 to 12 (nanoparticles of polymeric micelles) and lines 24 to 27 of the application as filed. The respondent further submitted that the term "formulation" had been used in the application as filed to identify the product to be administered. Claim 1 as originally filed defined the formulation as comprising six constituents, namely: paclitaxel (or "the derivatives or the analogs"), an alcohol, a co-polymer, an anionic surfactant, a buffering agent and an intravenous aqueous diluting fluid. In contrast, the formulation in claim 1 of the main request included "seven integers". The expression "said formulation further comprising" meant that in addition to the nanoparticles of polymeric micelles containing a drug selected from paclitaxel, or a derivative thereof physically entrapped therein, the formulation also included an alcohol, a co-polymer formed from vinylpyrrolidone, N-isopropyl acrylamide and functionalised polyethylene glycol, an anionic surfactant, a buffering agent, and an intravenous aqueous diluting fluid. The skilled person considering the application as filed would consider that the formulation comprised six integers and not seven.

Furthermore, for the assessment of added matter it was irrelevant whether or not the amendment had been introduced during examination proceedings following a suggestion by the examiner, since the ultimate

responsibility for the amendment remained with the applicant (patentee) (see Enlarged Board of Appeal decision G 1/93, OJ EPO, 1994, 541, Reasons, section 13).

Additionally, there was no disclosure whatsoever in the application as originally filed that in addition to the nanoparticles of co-polymeric micelles containing the paclitaxel or derivative thereof, the formulation further included a co-polymer formed from vinylpyrrolidone, N-isopropyl acrylamide and functionalised polyethylene glycol.

Moreover, there was no basis in the application as originally filed for the combination of claim 1 with the dependent claims of the main request.

XIV. The appellant (patentee) requested that the decision under appeal be set aside. The board concluded that according to the state of the file the appellant also requested that the patent be maintained in amended form on the basis of the main request filed with the grounds of appeal.

The respondent (opponent) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.
2. The oral proceedings before the board took place in the absence of both parties who were duly summoned but

decided not to attend the oral proceedings as announced in their letters of 26 September 2012 (respondent) and 6 December 2012 (appellant).

The present decision is based on facts and evidence put forward during the written proceedings and on which the appellant and the respondent have had an opportunity to comment. Therefore, the conditions set forth in opinion G 4/92, OJ EPO 1994, 149 are met.

3. *Main request*

3.1 The main request filed with the grounds of appeal relates to claim 1 as granted, into which the wording of claim 3 as granted has been incorporated.

Article 100(c) EPC is within the framework of the present appeal proceedings.

3.2 Claim 1 as granted relates to a formulation containing

- nanoparticles of polymeric micelles containing
a drug selected from paclitaxel or
a derivative thereof physically entrapped
therein

and "said formulation"

further comprising

- an alcohol
- a co-polymer
- an anionic surfactant
- a buffering agent and
- an intravenous aqueous diluting fluid.

Neither the nature of the polymer in the expression "polymeric micelles" nor the nature and/or function of the "co-polymer" are specified in the claim. Therefore, the claim has to be taken in its broadest technically meaningful sense as including formulations in which the polymer forming the polymeric micelles from which the nanoparticles are constituted and the co-polymer "further" present in the formulation are different chemical entities. Thus, claim 1 as granted contains added matter which goes beyond the content of the application as filed (Article 100(c) EPC).

The incorporation of claim 3 as granted, in which the nature of the "co-polymer" is defined as "formed from vinylpyrrolidone, N-isopropyl acrylamide, and functionalized polyethylene glycol", does not overcome the objection of added matter in granted claim 1, since the amended claim still encompasses formulations in which the polymer forming the polymeric micelles is a different chemical entity to the co-polymer, which is defined as formed from the specific monomers recited in the claim.

The application as filed discloses compositions containing nanoparticles which may be formed by either a polymer (deriving from one type of amphiphilic monomer) which is then cross-linked, or a co-polymer (deriving from two types of amphiphilic monomers) which is then cross-linked (see page 3, lines 29 to 32 and page 4, lines 2 to 5). However, the application as filed does not contain any disclosure in relation to formulations containing polymeric micelles and further containing a co-polymer formed from the specific monomers recited in claim 1 of the main request.

Therefore, claim 1 of the main request includes subject-matter which goes beyond the content of the application as filed (Article 100(c) EPC).

3.3 The appellant's argument that the amendment causing the problem of added matter in the granted claims was made during examination proceedings as an attempt to respond to objections regarding lack of conciseness is not relevant for the examination of added matter pursuant to Article 100(c) EPC. Moreover, as stated by the Enlarged Board of Appeal in decision G 1/93 (see Reasons, 13): "*The ultimate responsibility for any amendment of a patent application (or a patent) always remains that of the applicant (or the patentee)*".

3.4 Moreover, the appellant did not file any reply to the respondent's objections pursuant to Articles 100(c) EPC and 123(2) EPC in relation to the combination of amended claim 1 in the main request with the dependent claims.

The board sees no reason to decide on this issue, since the request fails for the reasons given in points 3.1 and 3.2 above.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

N. Maslin

U. Oswald