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Datasheet for the decision of 11 December 2018

Case Number: T 0899/14 - 3.3.01

Application Number: 06717499.5

Publication Number: 1841458

IPC: A61K45/00, A61K45/06

Language of the proceedings: EN

Title of invention:
SURFACTANT TREATMENT REGIMEN FOR TREATING OR PREVENTING BRONCHOPULMONARY DYSPLASIA

Patent Proprietor:
Discovery Laboratories, Inc.

Opponent:
CHIESI FARMACEUTICI S.p.A.

Relevant legal provisions:
EPC Art. 100(b)

Keyword:
Sufficiency of disclosure - (no)

Decisions cited:
T 0609/02, G 0005/83, G 0002/08

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Case Number: T 0899/14 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 11 December 2018

Appellant: (Patent Proprietor)	Discovery Laboratories, Inc. 2600 Kelly Road Warrington PA 18976 (US)
Representative:	Lock, Graham James Fry Heath & Spence LLP Unit A, Faraday Court Faraday Road Crawley, West Sussex RH10 9PU (GB)
Respondent: (Opponent)	CHIESI FARMACEUTICI S.p.A. Via Palermo, 26/A 43122 Parma (IT)
Representative:	Dempster, Robert Charles Maschio & Soames IP Limited 30 Carlton Crescent Southampton SO15 2EW (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 March 2014 revoking European patent No. 1841458 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	R. Hauss
	P. de Heij

Summary of Facts and Submissions

I. European patent No. 1 841 458 was granted with a set of twenty-four claims. The independent claims read as follows:

*"**1.** Use of a pulmonary surfactant in the preparation of a medicament for the prevention of bronchopulmonary dysplasia in an infant, wherein the infant has been treated with pulmonary surfactant for respiratory distress syndrome*

in a dosage regime which comprises administration of the pulmonary surfactant for bronchopulmonary dysplasia after the treatment for respiratory distress syndrome with pulmonary surfactant has been concluded,

and wherein the dosage regime comprises administration of an effective amount of the pulmonary surfactant for bronchopulmonary dysplasia continued through at least day 10 of the life of the infant.

***7.** Use of a pulmonary surfactant in the preparation of a medicament for the prevention of bronchopulmonary dysplasia in an infant requiring respiratory support and who is at risk of developing bronchopulmonary dysplasia*

and wherein the pulmonary surfactant is for use in a dosage regime which comprises administration of an effective amount of the pulmonary surfactant through at least day 10 of the life of the infant."

II. The patent was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled

in the art, and extended beyond the content of the application as filed.

III. The documents cited in the opposition proceedings included the following:

D13: Pediatrics 123(1), 89-96 (2009)

IV. The decision under appeal is the decision of the opposition division revoking the patent, announced on 6 February 2014 and posted on 14 March 2014.

V. The decision is based on the claims as granted (main request, see point I above) and the claims of auxiliary request 1 filed on 6 February 2014 during oral proceedings before the opposition division.

- Claim 1 of auxiliary request 1 is identical to claim 1 as granted (see point I above) except that the passage *"continued through at least day 10"* was replaced by *"continued through at least day 14"*.
- Independent claim 6 of auxiliary request 1 is identical to claim 7 as granted.

VI. According to the decision under appeal, claim 1 as granted contained subject-matter going beyond the content of the application as filed (Articles 100(c) and 123(2) EPC), with regard to the feature "continued through at least day 10". That objection was overcome by auxiliary request 1.

Taking into account the disclosure of post-published document D13 (providing data from a clinical trial), the opposition division deemed that the prophylactic benefit of the surfactant treatment defined in the claims of auxiliary request 1 had not been established, and hence the claimed subject-matter was not disclosed

in the patent in suit and the application as filed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Articles 101(3) and 83 EPC).

VII. The patent proprietor (appellant) lodged an appeal against that decision. With the statement setting out the grounds of appeal, the appellant submitted a set of claims entitled "Auxiliary Request 1", identical to the claims of former auxiliary request 1 examined in the decision under appeal (see point V above).

VIII. With further letters dated 11 October 2018 and 12 October 2018, the appellant submitted declarations from technical experts relating to the issues of either added subject-matter or the content and evidentiary value of document D13. These declarations, referred to as documents D32 to D37 in the appeal proceedings, are listed and identified in points VII and VIII of the board's communication dated 31 October 2018.

IX. In that communication, issued pursuant to Article 15(1) RPBA in preparation for oral proceedings and advising the parties of its preliminary opinion, the board mentioned the following points (see section 4 of the communication):

- In order to meet the requirement of sufficiency of disclosure where a further medical use claimed in the "Swiss-type" format was concerned, the patent must disclose the efficacy of the product to be manufactured with regard to the claimed therapeutic indication, unless this was already known to the person skilled in the art.

- The patent in suit mentioned a clinical trial but did not provide any test data. Thus it might be asked,

(a) whether the indication "prevention of pulmonary dysplasia" would have been credible anyway, on the basis of common general knowledge,

(b) if the answer was no, whether the indication was rendered initially plausible by the information provided in the patent (in light of common general knowledge, if applicable), so that supplementary data might be taken into account,

(c) provided it was necessary and permissible to take supplementary data into account, whether the available supplementary data (D13) provided evidence of the efficacy of the medicament for preventing pulmonary dysplasia.

X. Oral proceedings before the board took place on 11 December 2018. The issue of sufficiency of disclosure was discussed.

(a) The respondent (opponent) argued that the patent application did not provide any information rendering it credible that the claimed therapeutic effect (i.e. the prevention of bronchopulmonary dysplasia) was achieved by following a treatment protocol defined in the independent claims of the current requests. While example 1 did not provide any experimental data at all, the treatment protocol according to example 2 was not covered by the claims of the pending requests.

(b) The appellant contested this view, contending that the application provided the person skilled in the art with sufficient guidance to implement the claimed subject-matter, especially by observing the

treatment protocol described in example 1. The therapeutic effect could be inferred from examples 1 and 2, in particular from the observation reported therein that 15 of the 17 neonates showed no signs of BPD (bronchopulmonary dysplasia) at day 28 (paragraph [0116] of the application as filed). The supplementary data provided in document D13 confirmed that the treatment according to example 1 could provide the desired prophylactic benefit. The respondent had not provided any data to the contrary.

XI. The appellant requested that the decision under appeal be set aside and:

- that the case be remitted to the opposition division for further prosecution on the basis of the claims as granted (main request);

- in the alternative, that the patent be maintained as granted - i.e. that the opposition be rejected;

- in the further alternative, that the case be remitted to the opposition division for a decision on the issue of inventive step, on the basis of the claims of auxiliary request 1 filed with the statement setting out the grounds of appeal;

- in the further alternative, that the patent be maintained on the basis of the claims of auxiliary request 1.

XII. The respondent requested:

- that the case not be remitted to the opposition division;

- that the appeal be dismissed;

- that documents D32-D37 not be admitted into the proceedings;

- that the appellant's technical expert Mr Simonson not be permitted to speak at the oral proceedings.

Reasons for the Decision

1. Admissibility of the appeal

The appeal complies with Articles 106 to 108 EPC and Rule 99 EPC and is therefore admissible.

2. Sufficiency of disclosure - main request

2.1 Independent claims 1 and 7 relate to a therapeutic application - namely the prevention of bronchopulmonary dysplasia in an infant.

2.2 The patent in suit explains (see paragraphs [0003] to [0005]) that natural pulmonary surfactants, which are critical to the lungs' ability to absorb oxygen, cover the entire alveolar surface of the lungs and the terminal conducting airways leading to the alveoli. In the absence of sufficient quantities of surfactant, or should the surfactant degrade, the alveoli tend to collapse and the lungs do not absorb sufficient oxygen.

2.2.1 Natural and synthetic pulmonary surfactants are commonly used to treat respiratory distress syndrome (RDS), an acute condition, in premature infants shortly after birth. Typically, infant RDS is treated via pulmonary surfactant therapy within the first few hours to one or two days after birth (see the patent in suit, paragraph [0036]).

2.2.2 Bronchopulmonary dysplasia (BPD), also referred to as chronic lung disease (CLD), is a common, occasionally life-threatening, lung disease typically

occurring in premature infants who survive RDS and other complications of prematurity.

2.2.3 BPD can also develop in full-term infants who require respiratory support at birth or soon thereafter.

2.3 What is proposed and claimed in the patent in suit is

(a) following the completed treatment for RDS, a second course of surfactant treatment with the same or a different surfactant, to prevent BPD (see claim 1);

(b) a treatment for preventing BPD in an infant requiring respiratory support, who may or may not exhibit RDS (see claim 7 and dependent claims 14 and 15).

2.4 The claims are drafted in the so-called "Swiss-type" format as instituted by Enlarged Board of Appeal decision G 5/83 (OJ EPO 3/1985, 64, Order: 2), which ruled that "a European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application." It was not in dispute that this is a valid claim format for the patent in suit (see Enlarged Board of Appeal decision G 2/08, OJ EPO 10/2010, 456, Reasons: 7.1.4).

2.5 According to the established case law of the Boards of Appeal, where a medical application is claimed in the so-called "Swiss-type" format (as in the present instance), attaining the claimed therapeutic effect is regarded as a functional technical feature of the claim (see for example T 0609/02 of 17 October 2005, Reasons: 9). In order to meet the requirement of sufficiency of disclosure, the efficacy of the product to be manufactured in the claimed therapeutic

indication must therefore be disclosed, unless this was already known to the person skilled in the art.

2.6 Contrary to the appellant's view, it is thus not sufficient merely to describe an administration regimen to be followed, without any evidence of the therapeutic efficacy of the proposed treatment.

2.7 Hence, the issue of sufficiency of disclosure revolves around the question of evidence of the efficacy of the treatment protocols defined in the independent claims for the prevention of pulmonary dysplasia.

2.8 Sufficiency of disclosure must be satisfied at the effective date of the patent, i.e. on the basis of the information in the patent application as filed, together with the common general knowledge then available to the person skilled in the art (see T 0609/02, Reasons: 8).

2.9 In the present case, the appellant did not argue that the benefit of the treatments according to claims 1 and 7 in the prevention of BPD was common general knowledge (see point IX.(a) above), but relied instead on the examples described in the application as filed (present in identical form in the patent in suit).

2.10 Thus the question to be answered is whether the information presented in the examples can render the alleged efficacy credible, or at least establish its initial plausibility (see point IX.(b) above).

2.11 Example 2

2.11.1 Example 2 (see paragraphs [0112] to [0116] of the application as filed, corresponding to paragraphs [0115] to [0119] of the patent in suit) relates to the prevention of RDS rather than to the prevention of BPD.

Surfactant was administered from 30 minutes up to 48 hours after birth. There is no disclosure in example 2 of a regimen that continued through to at least day 10 or at least day 14.

2.11.2 Hence, example 2 has no relevance to the disclosure of the claimed subject-matter, since it does not relate to a treatment for the prevention of BPD and does not disclose the required dosage regimen.

2.12 Example 1

2.12.1 Example 1 (see paragraphs [0108] to [0111] of the application as filed, identical to paragraphs [0111] to [0114] of the patent in suit) discloses a protocol for the administration of a pulmonary surfactant ("lucinactant") to premature infants at risk of bronchopulmonary dysplasia. The protocol involves treatment on days 3, 5, 7, 10 and 14. It is mentioned that "the protocol has been used in a clinical trial."

2.12.2 However, no actual data obtained in that clinical trial are shown in the application as filed or in the patent, nor are the (preliminary or final) findings of the trial discussed. In the statement setting out the grounds of appeal (see page 5, third paragraph), the appellant mentioned that, at the filing date, the clinical trial had commenced and had provided preliminary findings but was in fact only completed two years later. The trial results were subsequently published in document D13.

2.12.3 Thus example 1 does not contain any evidence of the efficacy of the treatments defined in claims 1 and 7.

2.13 Nor do the application as filed and the patent in suit provide any theoretical or technical reasons why the

proposed treatment would be effective in preventing BPD.

2.14 While results of clinical trials or animal studies are not always necessary to establish sufficiency of disclosure, a mere verbal statement in the application is not enough to establish even the initial plausibility of an alleged therapeutic benefit.

2.15 Subsequently filed supplementary evidence (in the present case, the content of document D13) may only be taken into account to back up any findings in the patent application, but may not be used to establish sufficiency of disclosure on its own. Otherwise, this would result in a patent being granted for a technical teaching which was achieved, and thus for an invention which was made, at a date later than the effective date of the patent.

2.16 Therefore, the additional evidence provided in document D13 cannot be taken into account in favour of the sufficiency argumentation of the appellant.

2.17 As a consequence, the subject-matter of independent claims 1 and 7 as granted is not disclosed in a manner that is sufficiently clear and complete for it to be carried out by a person skilled in the art, and thus the ground for opposition pursuant to Article 100 (b) EPC prejudices the maintenance of the patent.

3. Sufficiency of disclosure - auxiliary request 1

3.1 The independent claims of auxiliary request 1 differ from those of the main request only in that the passage *"continued through at least day 10"* in claim 1 was replaced by *"continued through at least day 14"*.

Independent claim 6 of auxiliary request 1 is identical to independent claim 7 of the main request (see points I, V and VII above).

3.2 As a consequence, the reasoning set out in section 2 above with regard to the independent claims of the main request applies equally to those of the auxiliary request.

3.3 Hence, the subject-matter of independent claims 1 and 6 of auxiliary request 1 is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Articles 100(b), 101(3) and 83 EPC).

4. Admission of evidence and oral submissions

4.1 Since the appellant

- did not seek to rely on documents D32 to D37 (which relate to different issues, see point VIII above) in its arguments concerning initial plausibility,
- and likewise did not seek to rely on oral submissions by the accompanying technical expert,

a decision on their admission was not required.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated