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Datasheet for the decision of 9 June 2010

Case Number: T 0365/07 - 3.3.02

Application Number: 97925141.0

Publication Number: 0918507

IPC: A61K 9/12

Language of the proceedings: EN

Title of invention:
Aerosol Formulations

Patentee:
NORTON HEALTHCARE LIMITED

Opponent:
3M Innovative Properties Company
Generics [UK] Limited

Headword:
-

Relevant legal provisions:
EPC Art. 111(1)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Remittal - yes: Highly relevant document"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0365/07 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 9 June 2010

Party as of right:
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 13 December 2006 concerning maintenance of European patent No. 0918507 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Van Moer

Summary of Facts and Submissions

I. European patent No. 0 918 507 based on application No. 97 925 141.0 was granted on the basis of a set of 17 claims.

Independent claim 1 as granted read as follows:

"1. A medicinal aerosol formulation comprising a particulate medicament, a fluorocarbon propellant and 6% to 25% w/w of the total formulation of a polar co-solvent, such formulation being substantially free of surfactant."

II. Notices of opposition were filed against the granted patent by the appellant (opponent O2) and opponent O1.

The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(b) EPC for insufficiency of disclosure.

The following documents *inter alia* were filed during the proceedings before the Opposition Division and the Board of Appeal:

(1) WO9311747
(18a) Letter to Medicines Control Agency dated 21 April 1995
(18b) Licence from Medicines Control Agency for Airomir Inhaler dated 10 March 1995
(24) Email correspondence with the UK Medicines and Healthcare Products Regulatory Agency.

III. In its interlocutory decision dated 12 September 2006, the Opposition Division held that the request received on 25 August 2003 with letter of 22 August 2003 met the requirements of Articles 83, 54 and 56 EPC.

Claim 1 of this request read:

"1. A product comprising a canister, suitable for delivering a pharmaceutical aerosol formulation, fitted into an actuator with a spray orifice aperture of 100-300 microns, wherein the canister comprises a container capable of withstanding the vapour pressure of the propellant used, which container is closed with a metering valve and contains a pharmaceutical aerosol formulation comprising particulate medicament, a fluorocarbon propellant and 6% to 25% of a polar co-solvent, which is substantially free of surfactant, wherein the medicament is a broncho dilator selected from ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenyipropanolamine, pirbuterol, reproterol, rimiterol, salbutamol, salmeterol, terbutaline, isoetharine, tolubuterol and orciprenaline or a salt thereof."

As to Article 100(b) EPC, the Opposition Division expressed the view that this objection raised with respect to the term "substantially" in claim 1 was in fact relevant to Article 84 EPC, which was not a ground of opposition. In addition, it considered that the further objection, according to which the broad term "medicaments" in claim 1 encompassed medicaments which would not be particulate as they would dissolve in the propellant/co-solvent mixture, was not longer pertinent

in view of the limitation of claim 1 to a specific and restricted list of bronchodilators.

Concerning novelty, the Opposition Division found that the content of the alleged prior use relating to the product Airomir® Inhaler (18a) and (18b) was not sufficiently substantiated as regards the spray orifice size.

The Opposition Division was moreover of the opinion that the spray orifice size in claim 1 established novelty over the prior art disclosures.

As regards inventive step, the Opposition Division was of the opinion that it was not derivable from the closest prior art document (1), taken alone or in combination with the other prior art documents, that the selection of a spray orifice aperture in the range of 100 to 300 microns would provide the most appropriate way to deliver the aerosol suspension formulation and promote the evaporation of large amounts of co-solvent.

IV. The appellant lodged an appeal against the said decision with its letter dated 16 February 2007.

It filed document (24) with its grounds of appeal to substantiate the allegation of prior use relating to the product Airomir® Inhaler, which failed before the Opposition Division. The arguments set out in the grounds of appeal were supported by reference to this document.

V. Opponent O1 is a party of right to the appeal proceedings.

VI. The respondent (patent proprietor) argued in its written submissions that by introducing document (24) the appellant was raising new issues on appeal which had not been considered by the first instance and requested that the case be immediately remitted to the first instance.

VII. In a communication of the Board dated 26 May 2010, the Board indicated that document (24) was highly relevant for the assessment of both novelty and inventive step and informed the parties of its intention to discuss remittal of the case to the first instance at the oral proceedings scheduled for 9 June 2010.

VIII. In the oral proceedings held before the Board on 9 June 2010 the question of possible remittal was dealt with as announced in the Board's communication dated 26 May 2010. The Board indicated also that it agreed with the favourable conclusions of the Opposition Division's decision as to sufficiency of disclosure.

IX. Against the request for remittal the appellant argued that the respondent had had enough time to study the new document, which moreover it had cited on appeal in order to react to the Opposition Division's decision that the prior use was not sufficiently substantiated.

It also submitted that it would not be appropriate, in the public interest, to delay the result by remitting the case to the first instance.

In addition, the appellant repeated the objections in relation to sufficiency of disclosure made before the Opposition Division and relied merely on its written objections as to this objection during the oral proceedings.

Opponent O1 neither filed written arguments nor attended the oral proceedings.

X. The respondent submitted in substance in support of its request for remittal that the nature of the prior art relied upon by the appellant changed its case, which was now based on document (24) which had not been considered by the Opposition Division.

In its opinion, it should not be deprived of the opportunity of having the validity of the patent over the newly filed document (24) considered at two instances.

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

The respondent requested as a main request that the case be remitted to the Opposition Division or, in the alternative, that the appeal be dismissed and that the patent be maintained on the basis of the main request filed with letter dated 12 May 2010 or of auxiliary requests 1, 2 or 3, filed with letter dated 20 November 2007 or of auxiliary request 4 filed with letter dated 12 May 2010.

Reasons for the Decision

1. The appeal is admissible.

2. *Article 100(b) EPC*

The Board agrees with the Opposition Division's favourable conclusions as to Article 100(b) EPC that the term "substantially" in claim 1 is in fact relevant to Article 84 EPC, which is not a ground of opposition, and that the further objection, according to which the broad term "medicaments" in claim 1 encompassed medicaments which would not be particulate as they would dissolve in the propellant/co-solvent mixture, is no longer pertinent in view of the limitation of claim 1 to a specific and restricted list of bronchodilators.

Having regard to the fact that the appellant has neither put forward new arguments compared with those submitted and dealt with before the Opposition division nor indicated how the Opposition Division's decision was wrong in that respect, there would appear to be no need to devote further attention to this issue.

Accordingly, the Board concludes that the subject-matter of the main request fulfils the requirements of Article 100(b) EPC (see above under III, and the Opposition Division’s decision, pages 6, last paragraph, to page 7, first paragraph.

3. *Remittal to the first instance*

It is the established jurisprudence that a case of public prior use has to prove what was made available, where, when, how and by whom. In the present case, what remains disputed is the question of what exactly was made available, since the answers as to where, when, how and by whom have already been settled during the opposition proceedings (appealed decision, reasons, page 8, paragraph 3; page 10, last paragraph and document 18(a) and (b) relating to the Airomir® Inhaler product).

Indeed, the Opposition Division concluded in the decision under appeal that it had yet not been established that the spray orifice aperture of the product Airomir® Inhaler was within the range of 100-300 micron.

Document (24) filed during the appeal proceeding deals precisely with this lacking piece of information, so that the alleged prior use would then represent the most relevant prior art for the assessment of both novelty and inventive step, with the possible consequence of revocation of the maintained patent as indicated by the Board in its preliminary communication dated 26 May 2010.

In those circumstances, the Board considers that there is indeed considerable force in the respondents' argument for remittal.

This is moreover fully in line with the case law of the boards of appeal in exercising this discretion, which

recognises the desirability of remittal when new evidence filed for the first time in appeal puts or may put the patent in jeopardy, particularly when the new evidence becomes the closest prior art or is highly relevant (see for instance T 273/84, OJ 1986, 346 or T 326/87, OJ 1992, 522).

It is true that, as the appellant had observed, it is in the interest of the public and of legal certainty to have a final decision as quickly as possible and that prior use was already challenged before the first instance. However, it is clear that the essential cause of the fresh case was not caused by the respondent but by the new evidence filed by the appellant at the appeal stage. Thus, the responsibility for a remittal lay primarily with the appellant who should have been well aware that the probability of a remittal would increase with the relevance of the documents it submitted.

Accordingly, in the exercise of its discretion, the Board considers that the case against the patent has now altered to such an extent that the respondent has a legitimate reason to have its full case considered at two instances. Therefore, remittal to the first instance is appropriate (Article 111(1) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

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

The Registrar The Chairman

N. Maslin U. Oswald