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Datasheet for the decision of 21 January 2021

Case Number: T 0798/17 - 3.3.02

Application Number: 10840130.8

Publication Number: 2515906

IPC: A01N37/10, A61K31/19, A61P29/02

Language of the proceedings: EN

Title of invention:
TREATING CRITICALLY ILL PATIENTS WITH INTRAVENOUS IBUPROFEN

Applicant:
Cumberland Pharmaceuticals Inc.

Headword:

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - added subject-matter

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0798/17 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 21 January 2021

Appellant: (Applicant)	Cumberland Pharmaceuticals Inc. 2525 West End Avenue Suite 950 Nashville, TN 37203 (US)
Representative:	Michalski Hüttermann & Partner Patentanwälte mbB Speditionstraße 21 40221 Düsseldorf (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 18 November 2016 refusing European patent application No. 10840130.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	S. Bertrand
	L. Bühler

Summary of Facts and Submissions

I. The appeal by the applicant (hereinafter "appellant") lies from the examining division's decision to refuse European patent application No. 10840130.8 on the basis of the then pending sole request.

II. Documents D1 and D4-D7 are used in the present decision:

D1 WO 03/039532 A1

D4 Bernard et al., The New England Journal of Medicine, The Effects of Ibuprofen on the Physiology and Survival of Patients with Sepsis, 1997, p. 912-918

D5 Giordano, Pain Physician., The Neurobiology of Nociceptive and Anti-nociceptive Systems, 2005, 8, p. 277-290

D6 Woolf, Ann. Intern. Med., Moving from Symptom Control toward Mechanism-Specific Pharmacologic Management, 2004, 140, p. 441-451

D7 Supplemental technical data submitted to the examining division by letter of 26 October 2016

D1 and D4-D6 are prior-art documents according to Article 54(2) EPC. D7 is a post-published document.

III. The examining division came to the conclusion that the claimed subject-matter of the sole request did not

involve an inventive step in view of D1 as the closest prior art.

IV. In its statement setting out the grounds of appeal, the appellant contested the examining division's reasoning and argued that the subject-matter claimed in the main request involved an inventive step in view of D1 as the closest prior art. D4 to D6 (see above) were submitted to support the appellant's arguments.

V. The appellant was summoned to oral proceedings, in accordance with its request. The board, in preparation for the oral proceedings, issued a communication pursuant to Article 15(1) RPBA in which it expressed the preliminary opinion that the claim request was not clear as required by Article 84 EPC and did not meet the requirements of Article 123(2) EPC. Moreover, the claimed subject-matter did not seem to involve an inventive step in view of D1 as the closest prior art.

VI. By fax of 15 December 2020, the appellant withdrew its request for oral proceedings. Oral proceedings were cancelled by letter of 22 December 2020. The present decision is based on the written submissions made during the written proceedings.

VII. The appellant's request was to set aside the appealed decision and to grant a patent on the basis of the claims filed by letter dated 5 January 2016 and bearing the date of 28 December 2015.

VIII. The appellant's case, where relevant for the present decision, can be summarised as follows:

- Considering D1 as the closest prior art, it would not have been obvious to use 800 mg intravenous ibuprofen to treat pain in critically ill patients not suffering from inflammation, i.e. nociceptive

pain. Nociceptive pain (various kinds of problems in tissues, transmitted to the brain by the nervous system) and inflammatory pain were two different pains, as reported by D5 and D6. Ibuprofen was generally considered to be useful for pain arising from inflammation rather than nociceptive pain. It was demonstrated by D7 that nociceptive pain was treated with an 800 mg intravenous composition of ibuprofen. This was not suggested in D1.

- The treatment of pain had been demonstrated in the application as filed and in D7. In D4 the practice of fever control with ibuprofen in critically ill patients was controversial (page 916, last full paragraph of the right-hand column), indicating that the treatment of fever with ibuprofen was not advised in critically ill patients.

- The application showed that critically ill patients had a lower Cmax in comparison with non-critically ill patients (example 1 of the application). This was surprising and the skilled person could not expect that pain in critically ill patients could be treated with a plasma concentration which is 50% of that obtained in non-critically ill patients.

Reasons for the Decision

The decision is based on the sole claim request filed by letter dated 5 January 2016 and bearing the date of 28 December 2015.

Article 123(2) EPC

1. In the communication pursuant to Article 15(1) RPBA, the board already expressed its preliminary view on the following points regarding Article 123(2) EPC. The appellant did not contest the board's preliminary view in that respect.

1.1 Claim 1 of the request on file relates to "*An intravenous ibuprofen pharmaceutical composition for treating pain in critically ill patients in need thereof, characterized in that an intravenous ibuprofen pharmaceutical composition is administered to critically ill patients who are in pain, not suffering from inflammation and are selected from the group consisting of patients who are receiving vasopressor support, are receiving mechanical ventilation; are being treated in an Intensive Care Unit; are being administered large volumes of blood products; are receiving multiple antibiotics; are undergoing dialysis; have a pulmonary artery catheter or an arterial blood pressure catheter inserted; and combinations of any of the foregoing in a dose of 800 mg such that the dose reduces pain in the critically ill patients*".

1.2 The dose of 800 mg in claim 1 of the request on file is not based on any of independent claims 1, 6 and 17 as originally filed.

Claim 1 as originally filed refers to "*a dose from about 400 mg to about 800 mg* ***every 4 to 6 hours, to attain a mean Cmax of about 20.8 µg/ml to about 75 µg/ml***" (emphasis added).

Claim 6 as originally filed in combination with claim 9 as originally filed and claim 17 as originally filed

refer to a dose or dosage of "*800 mg ibuprofen* ***to attain a mean Cmax within 80-125% of about 60 µg/ml***" (emphasis added).

The dose in the present claim 1 has been generalised from the disclosure of claims 1, 6 and 17 as originally filed since the dose of 800 mg in those claims is linked to at least a specific mean Cmax (maximum serum concentration that a drug achieves).

The description, particularly in paragraphs [012]-[014], [020], [021] and [043]-[045] of the application as filed, does not provide a valid basis for the amendment in the present claim 1 for the reasons set out above. More specifically, these passages of the application as filed also disclose the dose of 800 mg only in combination with further features that are not present in claim 1 of the main request.

1.3 The application as filed does not disclose the "*critically ill patients who are in pain,* ***not suffering from inflammation***" (emphasis added). The term "not suffering from inflammation" is not directly and unambiguously disclosed in the application as filed in connection with the patients since the application as filed does not refer to **patients** who are suffering or not suffering from inflammation. The term "inflammation" is only disclosed in connection with the **therapeutic uses** disclosed in the application as filed (see e.g. first sentence of paragraph [012] "... *treating at least one condition chosen from pain, inflammation and fever* ..."). The application as filed therefore only discloses treating inflammation but does not disclose patients who are suffering or not suffering from inflammation.

1.4 Even if, for the sake of argument, both features discussed above under sections 1.2 and 1.3 were disclosed individually in the application as filed, their combination as now present in claim 1 would still not be directly and unambiguously disclosed.

2. For the reasons set out above, claim 1 does not meet the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin M. O. Müller

Decision electronically authenticated