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**Datasheet for the decision
of 11 April 2018**

Case Number: T 1831/15 - 3.5.05

Application Number: 04813654.3

Publication Number: 1689362

IPC: G06F19/00, A61K9/00

Language of the proceedings: EN

Title of invention:

PHARMACEUTICAL COMPOUNDING SYSTEMS AND METHODS AND INFORMATION
MANAGEMENT SYSTEM FOR SAME

Patent Proprietor:

B. BRAUN MEDICAL, INC.

Opponent:

Fresenius Kabi Deutschland GmbH

Headword:

Compounding of pumped solutions/BRAUN MEDICAL

Relevant legal provisions:

EPC Art. 123(2), 84, 54, 56

Keyword:

Amendments - added subject-matter (no)

Claims - clarity (yes)

Inventive step - (yes)

Decisions cited:

Catchword:



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Case Number: T 1831/15 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 11 April 2018

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Decision under appeal: **Interlocutory decision of the Opposition**
Division of the European Patent Office posted on
17 July 2015 concerning maintenance of European
patent No. 1689362 in amended form

Composition of the Board:

Chair A. Ritzka
Members: P. Cretaine
D. Prietzel-Funk

Summary of Facts and Submissions

I. This appeal is against the interlocutory decision of the opposition division, pronounced at the oral proceedings dated 1 July 2015 and despatched on 17 July 2015, to maintain European patent No. 1 689 362 in amended form according to a main request filed by letter of 29 May 2015. The opposition was based on the grounds of Article 100(a) EPC. The opposition division decided that the main request was admissible and met the requirements of Articles 84 and 123(2) EPC and that the subject-matter of independent claims 1 and 19 involved an inventive step (Article 56 EPC), having regard to the disclosure of the closest prior art

D6: US 2003/0158508.

Due to the outcome of the opposition proceedings, the opposition division did not deal with the question of the admissibility of auxiliary requests 1 to 3 further filed by the patent proprietor by letter of 29 May 2015. For the same reason, it did not deal with the admissibility of the following documents D10 and D11, submitted by the opponent by letter of 23 June 2015 in case auxiliary requests 1 to 3 were admitted:

D10: Schneemann et al. (eds.): "Hagers Handbuch der Pharmazeutischen Praxis", Chapter 2, Springer-Verlag Berlin Heidelberg, 1995

D11: "ASPH Guidelines on the Safe Use of Automated Compounding Devices for the Preparation of Parental Nutrition Admixtures", American Journal of Health-System Pharmacy, vol. 57, pages 1343 to 1348,

15 July 2000.

- II. The opponent's notice of appeal was received on 16 September 2015, and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 26 November 2015. The opponent (appellant) requested that the decision be set aside and that the patent be revoked in its entirety on the grounds of added subject-matter, lack of clarity and lack of novelty and/or inventive step, having regard to the disclosure of D6 and the common general knowledge as illustrated by D10 or D11. Oral proceedings were requested on an auxiliary basis. The appellant further re-filed documents D10 and D11.
- III. By letter of response dated 2 May 2016, the patent proprietor (respondent) requested that the appeal be dismissed and that the patent be maintained in amended form according to the main request, or according to auxiliary requests 1 to 3 filed by letter of 29 May 2015 before the opposition division. Oral proceedings were requested on an auxiliary basis. Finally, the respondent requested that documents D10 and D11 not be admitted into the proceedings.
- IV. A summons to oral proceedings was issued on 30 January 2018. In a communication annexed to the summons, the board indicated the points which would be discussed during the oral proceedings. It expressed its preliminary opinion that the claims according to the main request met the requirements of Article 123(2) EPC. Further, it indicated that it considered the appellant's clarity objection (Article 84 EPC) relating to the terms "alert", "first alert signal" and "second alert signal" to be non-admissible following G 3/14.

V. With a letter of response dated 9 March 2018, the appellant requested that auxiliary requests 1 to 3 not be admitted and further provided arguments in respect of the non-compliance of the auxiliary requests with the requirements of Articles 123(2), 84 and 54/56 EPC.

VI. With a letter of response dated 12 March 2018, the respondent provided arguments with respect to inventive step for the main request, and to admissibility and inventive step for the auxiliary requests.

Oral proceedings were held on 11 April 2018. The appellant requested that the decision under appeal be set aside and that the European patent be revoked. The respondent requested that the appeal be dismissed, or that the patent be maintained on the basis of the claims of one of auxiliary requests 1 to 3 submitted with the letter dated 29 May 2015. The parties also submitted contradictory requests regarding the admission of documents D10 and D11 into the proceedings. At the end of the oral proceedings, the board's decision was pronounced.

VII. Claim 1 of the main request (submitted on 29 May 2015) reads as follows:

"A compounding control method to prepare a compounded mixture for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle, the method comprising the steps of:

- a) determining whether said plurality of source solutions conform to a predetermined configuration;
- b) at least one of providing an alert to an operator and preventing compounding based on said determining step a);

c) determining respective expiration dates of said plurality of source solutions;
d) at least one of providing a warning and preventing use of any of said plurality of source solutions based on said determination step c);
e) accepting mixture inputs for one or more of said plurality of source solutions;
f) urging at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture;
g) determining a state of motion of a plurality of pump elements of said compounding device;
h) generating a first alert signal if any of said plurality of pump elements are in a state of motion that should otherwise be stationary, said first alert advising of a defective compounded mixture; and
i) generating a second alert signal if any of said plurality of pump elements are in a stationary state that should otherwise be in motion, said second alert advising of a malfunction."

The main request further comprises an independent claim directed to a corresponding compounding control system (claim 19).

Due to the outcome of the appeal, there is no need to give details with respect to the claims of auxiliary requests 1 to 3.

Reasons for the Decision

1. Admissibility of the appeal

The appeal of the opponent (appellant) complies with

the provisions of Articles 106 to 108 EPC (cf. point II above) and is therefore admissible.

2. Main request - Article 123(2) EPC

2.1 Independent system claim 19

The appellant objected that the originally filed application did not disclose all the features of independent system claim 19 since the features added to the single originally filed system claim 21, on which claim 19 was based, were taken from originally filed method claim 11 and were not disclosed as system features (means) in the originally filed application. The board is not convinced by this line of argument, because the description as originally filed clearly discloses a method and a system for compounding mixtures (see for instance page 1, lines 2 and 3 and 24 to 26, and all the Figures). The board agrees in that respect with the opposition division that for every functional feature present in the application a corresponding means is implicitly present. Moreover, the last three features of claim 19, corresponding, with the exception of the wording "said second alert advising of a malfunction", to the features of claim 11 as originally filed but in terms of system features, are additionally supported by the passage on page 17, line 35, to page 18, line 6, which discloses that such alarms are generated by the system.

The appellant further objected that the above-mentioned wording "said second alert advising of a malfunction" in claim 19 represented an intermediate generalisation since it was mentioned in the passage from page 17, line 35, to page 18, line 6, only with respect to a specific embodiment comprising rotors, a peripheral

processing unit PPU and Hall-effect sensors. In that respect, the board first notes that originally filed claim 1 clearly makes a distinction between the two alarms, the second alarm being generated when a pump element is not moving when it should be. Further, the board considers that the terms "motor", "rotor", "pump rotor", "pump motor" and "pump element" are used interchangeably in the whole description to designate the entity which should be controlled in order to achieve a desired quantity of each solution in the resulting mixture. Thus, the board holds that the skilled person would clearly understand from the passage from page 17, line 35, to page 18, line 6, together with originally filed claim 11 that the second alarm generated is not limited to reporting a malfunction of a rotor controlled using a PPU and Hall sensors but encompasses the reporting of any malfunctioning controlled pump element.

Moreover, the appellant argued that the terms "alert" and "advising" were not present in the passage from page 17, line 35, to page 18, line 6, which instead used the terms "alarm" and "reported", respectively. The board however holds that the technical teaching of these terms is similar in the context of the application, the term "alert" furthermore already being used in originally filed claims 11 and 21.

In conclusion, the board judges that independent claim 19 meets the requirements of Article 123(2) EPC.

2.2 Dependent claims

The appellant stated that every originally filed dependent claim referred back solely to independent claim 1. Thus, according to the appellant, the present

dependent claims referring to claim 1, which itself comprised features of originally filed dependent claim 11, were not supported by the application documents as originally filed. The board is not convinced by this argument, for the reason that the description as originally filed relates to a single embodiment, the features of the originally filed dependent claims being additional features of this embodiment which are not mutually exclusive and can thus be combined. In particular, the two different embodiments mentioned on page 4, lines 13 to 18, with reference to Figures 2B/2C and 2D/2E, cited by the appellant, actually correspond to two different physical structures of the manifold, which are not the subject-matter of the originally filed claims. Therefore, the subject-matter of original claims 1 and 11 can be combined with the features of the original dependent claims.

The appellant further argued that in particular dependent claim 9, comprising the features of originally filed claims 1, 11 and 9, was not supported by the originally filed documents. In that respect, the appellant pointed out that claim 9 comprised, in addition to the detection of the state of the pump elements, the detection of the pump motor speed. According to the appellant, if a pump motor speed were to be zero, both a second alert signal advising of a malfunction of the pump and a correction signal for that pump would be generated, following the teaching of claim 9. The appellant pointed out that the description as originally filed, in particular the passage from page 16, line 13, to page 17, line 34, did not disclose issuing an alert signal when a motor speed error was detected. The board however agrees with the patent proprietor that the detection of a motor speed error is part of the controlling scheme of a running pump, where

the detected motor speed is not supposed to be zero, whereas the detection of a stationary state of a pump relates to the detection of a malfunction. Both tasks are disclosed separately and independently in the originally filed description, and the skilled person would readily understand that they can be performed in parallel.

In conclusion, the board judges that the dependent claims, in particular claim 9, meet the requirements of Article 123(2) EPC.

3. Main request - Article 84 EPC

The appellant argued that dependent claim 9, comprising a new combination of features of the granted claims 1, 9 and 11, could be objected to under Article 84 EPC. According to the appellant, claim 9 was not clear since it defined two alternatives in case the motor speed of a pump element were zero, namely either to send a correction signal to the pump element or to generate an alert signal indicative of a malfunction, without indicating which action took precedence over the other. The board however agrees with the respondent that, as mentioned above in point 2.2, the detection of a motor speed error is part of the controlling scheme of a running pump, where the detected motor speed is not supposed to be zero, whereas the detection of a stationary state of a pump relates to the detection of a malfunction. Both tasks are disclosed separately and independently in the originally filed description, and the skilled person would readily understand that they can be performed in parallel. In that respect, the skilled person would unambiguously understand that the detection of a motor speed equal to zero would lead to the generation of the alert signal indicative of a

malfunction of the pump element and not to a correction signal sent to the pump element.

Further, the appellant objected in writing that the presence of the term "alert signal" together with the terms "first alert signal" and "second alert signal" led to unclarity in respect of the designation of the alerts. The board however holds that these three different terms clearly define three different alerts to the operator based on the results of three different determining means, which the skilled person would not confuse.

For these reasons, the board judges that claims 9 and 19 meet the requirements of Article 84 EPC.

4. Main request - Article 54 EPC

It was common ground during the proceedings that the issue under Article 54 EPC was whether the last two features of independent claims 1 and 19 relating to the first and second alert signals (denominated steps h) and i) in method claim 1) were disclosed in D6.

The appellant correctly pointed out that D6 was a patent application of the respondent comprising most of the description in common with the patent and identical Figures 1 to 14.

According to the appellant, the "load cell" described in paragraph [0045] and shown in Figure 13 of D6 was adapted, in co-operation with the three layers of processing units PPU, CPU and MPU, to generate alarms according to steps h) and i). In particular, the appellant stated that alert signals were generated as alarms displayed to the operator (see paragraph [0050])

indicating over-pumping (see paragraph [0049]: "over-delivery"; paragraph [0074]: "overflow") or no pumping (see PUMPING icon in Figure 9M; Figure 9N: "No flow"; Figure 9V: "No solution flow alarm") of the different pump elements.

The board however is not convinced by this line of argument for the following reasons. It is clear from Figure 3 and paragraphs [0039] and [0097] that the load cell 30 belongs to a weight station 26 which measures the weight of the compounded mixture in the final solution container 14. The alarm generated by the load cell and displayed on the operator's screen (Figures 9N and 9V) indicates that there is no liquid transfer into the final container 14 (see paragraph [0101] and Figure 9N) and does not indicate, contrary to what is required by step i) of claim 1, that one of the pump elements that should be in motion is in a stationary state. The alarm generated by the load cell, and indicated as "No flow" on Figure 9N, may well be caused by other circumstances occurring during the functioning of the compounding device, for instance a leak in the final container 14 or leaks in one or more pump segments 34. Further, the alarm mentioned in paragraph [0049] and relating to "over-delivery" does not seem to be delivered as an alert signal on the operator's screen but rather to be an internal alarm in the device for stopping compounding. It may also be caused by circumstances occurring during the functioning of the compounding device which are not, as in step h) of claim 1, that a pump element that should be stationary is in a state of motion. For instance, over-delivery may be caused by having pump elements delivering prescribed solutions, but in excess. Therefore the specific conditions under which the first and second alert signals are generated are not disclosed in D6,

and so steps h) and i) of claim 1, and the corresponding means in claim 19, are not disclosed in D6.

Thus, the board judges that the subject-matter of claims 1 and 19 is new having regard to the disclosure of D6 (Article 54 EPC).

5. Main request - Article 56 EPC

The technical effect of the distinguishing steps h) and i) in claim 1 is that the difference between two dysfunctions of the compounding device is indicated to the operator: the first alert indicates that at least one of the solutions is in excess in the final container and that the mixture should be immediately disposed of, whereas the second alert signal indicates a lack of at least one of the solutions in the final container and that the mixture can still be corrected.

The objective technical problem can thus be formulated, as proposed by the respondent, as how to save time by throwing away defective mixtures while avoiding waste of solutions.

The skilled person starting from D6 and trying to solve this problem would rely on the closed-loop feedback control of the pump elements described in D6 and try to precisely adjust the delivery of each solution to achieve the prescribed mixture composition and avoid the compounding of defective mixtures, rather than creating new alarms.

The appellant argued that the provision of different alarms in compounding systems was known at the priority

date. However, the board holds that neither D6 nor the common knowledge would motivate the skilled person to make a distinction between the two specific types of error defined in features h) and i), leading respectively to a composition beyond remedy and to a remediable composition. The appellant has plausibly argued that the operator will be immediately prompted by the alarms according to features h) and i) either to throw the composition mixture away, or to store the composition mixture, look for the specific pump or pumps where the alarm originated, and take corrective action.

For these reasons the board judges that the subject-matter of claims 1 and 19 involves an inventive step having regard to the disclosure of D6 (Article 56 EPC).

6. In conclusion, the board judges that the grounds for opposition under Article 100(a) EPC pursued by the appellant in the appeal proceedings do not prejudice the maintenance of the patent as amended according to the main request. This finding confirms the interlocutory decision of the opposition division.

There was no need to decide on the admission of documents D10 and D11, as the appellant did not use them as a basis for the arguments it presented at the oral proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



K. Götz-Wein

A. Ritzka

Decision electronically authenticated