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Datasheet for the decision of 14 November 2022

Case Number: T 1550/19 - 3.2.02

Application Number: 13721801.2

Publication Number: 2822526

IPC: A61J1/20

Language of the proceedings: EN

Title of invention:
DRUG RECONSTITUTION SYSTEM

Patent Proprietor:
Sensile Pat AG

Opponent:
Eveon

Headword:

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 56

Keyword:

Late-filed evidence - document could have been filed in first instance proceedings (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

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Case Number: T 1550/19 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 14 November 2022

Appellant: (Opponent)	Eveon 345 rue Lavoisier Zirst 2, Innovallée 38330 Montbonnot Saint Martin (FR)
Representative:	Regimbeau 20, rue de Chazelles 75847 Paris Cedex 17 (FR)
Respondent: (Patent Proprietor)	Sensile Pat AG Fabrikstrasse 10 4614 Haegendorf (CH)
Representative:	reuteler & cie SA Chemin de la Vuarpillière 29 1260 Nyon (CH)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 29 March 2019 rejecting the opposition filed against European patent No. 2822526 pursuant to Article 101(2) EPC**

Composition of the Board:

Chair	N. Obrovski
Members:	D. Ceccarelli
	S. Dennler

Summary of Facts and Submissions

I. The opponent appealed against the Opposition Division's decision to reject the opposition against the European patent. The opposition was based on the ground of lack of inventive step.

II. Oral proceedings before the Board took place on 14 November 2022.

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

IV. The respondent requested that the appeal be dismissed.

V. The following documents are relevant to this decision:

D3: WO 2007/074363 A2

D5: "Micropumps for a Novel Combination Device: Lyo Reconstitution and Injection", Déhan C, EVEON France, Proceedings of the 2011 Parenteral Drug Association (PDA) Europe Conference in Basel, Switzerland, 8-9 November 2011, slides 1-16

D17: WO 2012/019641 A1

VI. Claim 1 of the patent as granted reads as follows:

"A drug reconstitution device comprising a single use disposable liquid transfer unit (18), a reusable control and drive unit (16) removably connectable to the liquid transfer unit (18), and a pump engine (28), the disposable liquid transfer unit (18) including a housing (26), a docking interface (30) configured for coupling at least one of first and second constituent containers (2, 4) to the housing (26), and fluid flow

system (37) configured for transferring liquid from the first constituent container (2) to the second constituent container (4), the control and drive unit (16) comprising a pump drive (22) configured to drive the pump engine (28) during a fluid pumping action, the pump drive (22) comprising a transmission output coupling (34) removably engaged with a transmission input coupling (50) of the pump engine (28), characterized in that the pump engine (28) is configured as a bi-directional rotary pump comprising a rotor rotatably moveable in a stator wherein said pump engine is integrally mounted in the liquid transfer unit (18), the transmission output coupling (34) of the pump drive (22) engaging with the transmission coupling (50) of the pump engine (28) when the liquid transfer unit (18) and control and drive unit (16) are connected."

Claims 2 to 11 are dependent claims.

VII. The appellant's arguments relevant to the decision can be summarised as follows:

Admittance of D17

D17 had been filed with the statement of grounds of appeal following substantial changes of personnel in the appellant's intellectual property department, which resulted in a change of view on the case with respect to the prior art. A new search for relevant prior art had to be conducted. This search revealed D17, a highly relevant document. In view of these circumstances and the *prima facie* relevance of D17, this document and the inventive-step objection based on the combination of D17 with D3 should be admitted into the appeal proceedings.

Inventive step

The subject-matter of claim 1 of the patent as granted was not inventive over D5 in combination with D3.

D5 disclosed a drug reconstitution device with a disposable liquid transfer unit including a pump engine, in the form of a micropump.

The terms "pump engine" and "rotary pump" used in the claim did not have well-defined meanings. The micropump disclosed in D5 seemed to be a rotary pump. Claim 1 covered docking interfaces configured for coupling only one container to a housing of the drug reconstitution device, and did not require the presence of a second container. Accordingly, there was no requirement in claim 1 of the patent as granted that fluid could be pumped back and forth between two fluid containers.

Hence the objective technical problem was merely to provide a technical implementation of the micropump disclosed in D5. In the absence of a second container, the problem of enhancing mixing of the content of the drug reconstitution device of D5 could not be addressed. Paragraph [0033] of the patent, which explained how mixing of the contents of a drug reconstitution device could be improved, was much more precise than claim 1.

In view of this objective technical problem, it would have been obvious to the person skilled in the art to implement the micropump disclosed in D5 in the form of a rotary bi-directional pump, to perform both reconstitution and injection of a medicament with a simpler fluidic circuit, without the need for complex

valves. Moreover, D3 disclosed a bi-directional disposable micropump adapted to be provided in the device of D5. Hence the subject-matter of claim 1 of the patent as granted would have been arrived at in an obvious way.

VIII. The respondent's arguments relevant to the decision can be summarised as follows:

Admittance of D17

D17 could and should have been filed during the first-instance proceedings, at the latest in response to the preliminary opinion of the Opposition Division dated 8 August 2018, according to which the subject-matter of claim 1 of the patent as granted was inventive over the cited prior art. Changes of personnel in the intellectual property department of the appellant should not be to the respondent's disadvantage. Moreover, D17 was not more relevant than the prior art already on file. Hence D17 should not be admitted into the appeal proceedings.

Inventive step

The subject-matter of claim 1 of the patent as granted was inventive over D5 in combination with D3.

D5 did not disclose a bi-directional rotary pump as defined in the claim. This was derivable from paragraph [0033] of the patent, which explained the advantages of recirculating fluid between two containers using a bi-directional pump. Claim 1 specifically defined a fluid flow system for transferring liquid from a first to a second container. The person skilled in the art would have understood that the claimed bi-directional

pump was in the defined fluid flow system.

The person skilled in the art would have had no obvious reason to implement a bi-directional pump in the device of D5. The use of valves was common in the field.

Reasons for the Decision

1. The invention

The invention relates to a drug reconstitution device.

Drug reconstitution devices are generally used for reconstituting a drug from two constituents, one in a liquid form and the other in a dry lyophilised form. Certain pharmaceutical products are only available in lyophilised form.

The drug reconstitution device according to the invention as defined in claim 1 of the patent as granted is depicted in Figure 1, reproduced below.

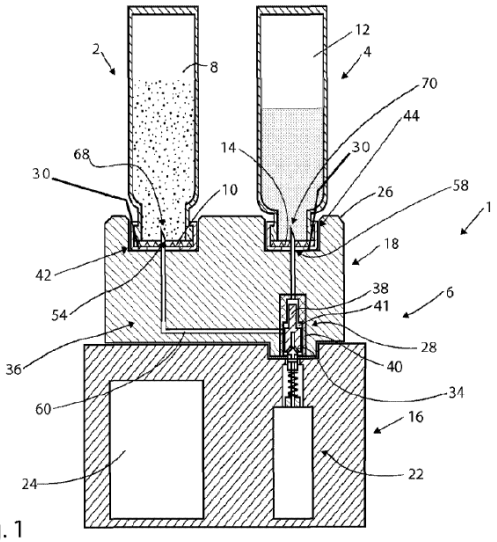


Fig. 1

It comprises a single use disposable liquid transfer unit (18), a reusable control and drive unit (16) removably connectable to the liquid transfer unit, and a pump engine (28) integrally mounted in the liquid transfer unit. The disposable liquid transfer unit includes a housing (26), a docking interface (30) for coupling at least one of first and second constituent containers (2, 4) to the housing, and a fluid flow system for transferring liquid from the first constituent container (2) to the second constituent container (4).

The control and drive unit comprises a pump drive (22) for driving the pump engine (28). The pump drive comprises a transmission output coupling (34), removably engaged with a transmission input coupling of the pump engine when the liquid transfer unit (18) and the control and drive unit (16) are connected.

The pump engine is configured as a bi-directional rotary pump comprising a rotor rotatably moveable in a stator.

According to paragraph [0033] of the patent, the bi-directional pump may be used to enhance the mixing and dissolving process of a poorly dissolvable lyophilised substance by pumping liquid from the first constituent container to the second constituent container (initially containing the lyophilised substance), then reversing the pumping direction back to the first constituent container, and repeating the back-and-forth pumping cycle until the lyophilised substance is completely dissolved.

2. Admittance of D17

D17 was filed for the first time with the statement of grounds of appeal.

The respondent objected to the admittance of this document into the appeal proceedings.

The admittance of D17 is subject to Article 12(4) RPBA 2007, which applies by virtue of Article 25(2) RPBA 2020. Under Article 12(4) RPBA 2007, the Board has discretionary power not to admit evidence which could have been filed in the first-instance proceedings.

The appellant has not provided any convincing reasons why D17 could not have been filed in the first-instance proceedings. As the respondent pointed out, in the preliminary opinion in preparation for the oral proceedings at first instance, the Opposition Division considered the objections of lack of inventive step on file not convincing. In response to the preliminary opinion, the appellant filed further evidence which did not include D17. D17, however, could and should also have been filed already at this point in time, and in any case before the final decision of the Opposition Division, which confirmed its previous preliminary opinion. A change of personnel in the intellectual property department of the appellant is a purely internal matter and not a reason which might objectively justify the late filing of D17. Under such circumstances, the possible *prima facie* relevance of D17 is not decisive either.

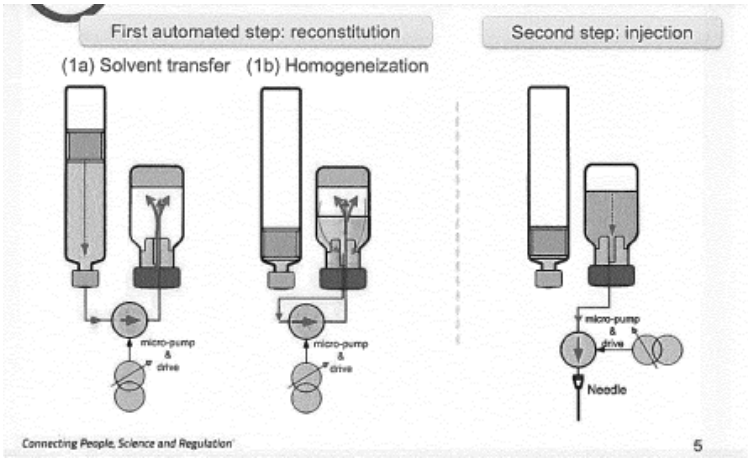
For these reasons, the Board exercised its discretionary power under Article 12(4) RPBA 2007 and decided not to admit D17 into the appeal proceedings.

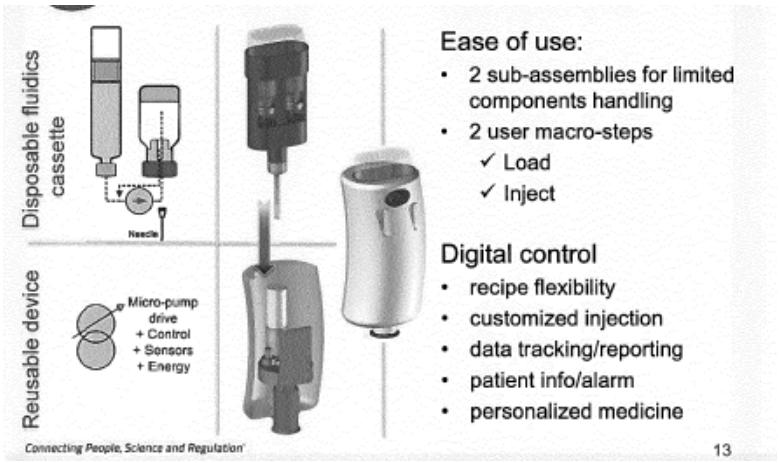
Consequently, the objections based on D17 were not admitted either.

3. Inventive step

The appellant argued that the subject-matter of claim 1 of the patent as granted was not inventive over D5 in combination with D3.

It is common ground that D5 discloses (slides 5 and 13 reproduced below) a drug reconstitution device with a disposable liquid transfer unit (disposable fluidics cassette on slide 13) including a pump engine, and a reusable control and drive unit (reusable device on slide 13).





The disposable liquid transfer unit includes a housing, a docking interface configured for coupling a first and a second constituent container to the housing, and a fluid flow system configured for transferring liquid from the first constituent container to the second constituent container. The control and drive unit comprises a pump drive configured to removably couple and drive the pump engine.

The subject-matter of claim 1 of the patent as granted differs from the disclosure of D5 in that the pump engine is configured as a bi-directional rotary pump comprising a rotor rotatably moveable in a stator.

The appellant argued that claim 1 did not require the presence of two containers or the suitability of the reconstitution device for fluid being pumped back and forth between two constituent containers.

The Board does not share this view. Claim 1 specifically defines a drug reconstitution device comprising a fluid flow system configured for transferring liquid from a first to a second container. Moreover, the claim defines a pump engine for performing a pumping action. When interpreting the claim, the person skilled in the art will clearly understand that the pumping action has to be performed within the fluid flow system between the two containers, which is the only movement of liquid mentioned in the claim.

The description supports this understanding. Paragraph [0033] of the patent describes the effects of a bi-directional rotary pump as defined in the claim. It explains that the bi-directional pump can be used to pump liquid several times from the first to the second

container and vice versa. This ensures that a poorly dissolvable lyophilised substance is completely dissolved. In this respect it is irrelevant what precise limitations are derivable from the terms "pump engine" and "rotary pump". The technical effect explained above results essentially from the fact that the pump is bi-directional.

Hence the objective technical problem solved by the distinguishing feature is not to provide a technical implementation of the micropump generally disclosed in D5, but rather how to conveniently and reliably obtain complete reconstitution of the drug.

According to D5, homogenisation and complete reconstitution may be obtained by recirculating the two constituents within a single container (slide 5).

It is common ground that D3 discloses a bi-directional rotary pump (page 12, lines 29 to 31) for medical applications (page 1, lines 3 and 4). However, there is no indication in D3 that such a pump should be used for solving the objective technical problem as formulated above. In particular, there is no indication in D3 or D5 that a recirculation between the two containers should be implemented.

According to the appellant, the objective technical problem consisted of providing a concrete implementation of the schematic micropump disclosed in D5. Formulating the objective technical problem in this manner does not take account of the technical effect of the bi-directionality of the pump as explained above. Moreover, reconstitution of a drug from two components in D5 is achieved by recirculation within a single container, which does not need a bi-directional pump.

Hence, contrary to the appellant's argument, the person skilled in the art faced with the task of technically implementing the schematic micropump disclosed in D5 would have had no obvious reason to make it bi-directional. For reasons of cost they would, rather, have implemented a unidirectional pump with suitable valves to provide the functions disclosed on slide 5. Such valves, as the respondent correctly submitted, are not complex, and are commonly used in the field.

Hence the subject-matter of claim 1 is inventive over the combination of D5 with D3.

4. It follows that the ground for opposition of lack of inventive step (Article 100(a) EPC and Article 56 EPC) raised by the respondent does not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

A. Chavinier-Tomsic N. Obrovski

Decision electronically authenticated