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Datasheet for the decision of 6 December 2022

Case Number: T 2474/18 - 3.2.02

Application Number: 11008865.5

Publication Number: 2457550

IPC: A61J3/00, B65B59/00, B65B31/02

Language of the proceedings: EN

Title of invention:
Automated pharmacy admixture system (APAS)

Patent Proprietor:
ARxIUM Inc.

Opponent:
SWISSLOG ITALIA S.p.A.

Headword:

Relevant legal provisions:
EPC Art. 100(a), 100(b), 100(c)
RPBA Art. 12(4)

Keyword:

Grounds for opposition - added subject-matter (no) - insufficiency of disclosure (no)
Late-filed facts - submitted with the statement of grounds of appeal - admitted (no)
Oral proceedings - withdrawal of request for oral proceedings

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2474/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 December 2022

Appellant: (Opponent)	SWISSLOG ITALIA S.p.A. Via Vittor Pisani, 20 20124 Milano (MI) (IT)
Representative:	Provvisionato, Paolo Provvisionato & Co S.r.l. Piazza di Porta Mascarella 7 40126 Bologna (IT)
Respondent: (Patent Proprietor)	ARxIUM Inc. 96 Nature Park Way Winnipeg, MB R3P 0X8 (CA)
Representative:	Barker Brettell LLP 100 Hagley Road Edgbaston Birmingham B16 8QQ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 23 July 2018 rejecting the opposition filed against European patent No. 2457550 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	Y. Podbielski

Summary of Facts and Submissions

I. The appeal is directed against the decision of the Opposition Division rejecting the opposition against European patent No. 2457550.

II. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (proprietor) requested that the appeal be dismissed. As an auxiliary measure, they requested that the case be remitted to the Opposition Division for further prosecution or maintained on the basis of one of first to third auxiliary requests filed with the reply to the statement of grounds of appeal.

III. Both parties requested oral proceedings on an auxiliary basis.

The Board summoned the parties to oral proceedings and sent a communication dated 25 July 2022 setting out its preliminary opinion that none of the objections raised by the appellant prejudiced maintenance of the patent as granted.

The appellant announced on 17 November 2022 that it would neither be attending nor be represented at the oral proceedings.

The Board then cancelled the oral proceedings.

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

"A system to automate pharmaceutical compounding comprising:

a robotic arm (318) to convey medical containers (1102, 1104, 1106);
a compounding system to transfer medicaments between the medical containers;
a syringe manipulator (5200) adapted to push/pull a plunger of a syringe for transferring fluids to/from a medical container, and configured to maintain a negative pressure in the medical container to prevent aerosolizing of contents in the medial [sic] container during the transferring of the fluids;
a needle-removing station to remove a needle from a syringe after the syringe has been loaded with a desired quantity of one or more of the medicaments;
the system being characterized in that the syringe manipulator is configured to limit plunger speed to account for limitations of fluid flow through a needle of the syringe by a needle diameter and a fluid viscosity or to calculate a wait time."

V. The following documents are relevant to this decision:

D2: GB 1168263
D5: US 5431201

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

Article 100(c) EPC

It was clear from the application as filed that the syringe whose plunger was limited in speed was not the same as the syringe whose needle was removed. Both operations were described in completely different

embodiments. There was thus no support for a system combining both operations on a syringe, as defined by the last two features of claim 1.

Article 100(b) EPC

Paragraph [0424] of the patent specification was the only part discussing the issue of limiting the plunger speed or calculating a wait time. However, it did not explain how to configure the syringe manipulator to limit plunger speed or to calculate a wait time. There was no indication on the correlation between the syringe parameters and the pharmaceutical products nor on how they might influence the limit speed or the wait time. The invention was thus not sufficiently disclosed.

Article 100(a) EPC

The subject-matter of claim 1 was not inventive starting from D5 and in view of D2, which taught manual control of the plunger's advancement. D5 addressed the problem of disposing the needle by disposing it together with the disposable syringe.

VII. The respondent's arguments relevant the decision can be summarised as follows.

Article 100(c) EPC

Claim 1 did not require that the syringe whose plunger was limited in speed was the same as the syringe whose needle was removed because it used the term "a syringe" in both features. A system combining a syringe manipulator with limitation of the plunger speed and a needle removing station was disclosed in Figure 3 of

the application as filed. Hence, no subject-matter was added by combining these two features.

Article 100(b) EPC

Several parts of the application as filed discussed control of plunger movement and speed, with paragraph [0424] specifically discussing viscosity and needle diameter as parameters to be taken into account to limit plunger speed or calculate a wait time. A person skilled in the art would have no difficulty in implementing the speed limitation or wait time calculation using common general knowledge.

Article 100(a) EPC

D5 was cited by the Examining Division as D1 during prosecution of the contested patent. The appellant used D5 in their notice of opposition only in relation to the dependent claims. There was thus no reason for submitting on appeal a new objection of lack of inventive step to claim 1 starting from D5. Moreover, neither D5 nor D2 disclosed the last two features of claim 1, so that claim 1 was inventive over the combination of D5 and D2.

Reasons for the Decision

1. The invention

Medications are often delivered to a patient from an intravenous bag or using a syringe. Sometimes, the medications have to be mixed with a diluent prior to their administration. Such mixtures are then usually performed by pharmacy staff in a hospital pharmacy.

Automation of mixing of medications may be of advantage when preparing a number of similar intravenous bags in a batch or when a particularly accurate control of diluent and medication is needed.

The invention relates to a system to automate pharmaceutical compounding, also known as an automated pharmacy admixture system (APAS). Such a system may autonomously admix contents of syringes and intravenous bags. The system as defined in claim 1 comprises a robotic arm, a compounding system, a syringe manipulator and a needle-removing station.

2. Article 100(c) EPC

The appellant's objection is based on a wrong claim construction. Claim 1 is directed to a system to automate pharmaceutical compounding, the system comprising several components. Two of these components, namely the needle-removing station and the syringe manipulator, operate on a syringe. However, claim 1 does not require that these two components operate on the same syringe. This is reflected also by the claim wording, which recites twice "a syringe" ("push/pull a plunger of a syringe" and "remove a needle from a syringe") and twice "a needle" ("remove a needle from a syringe" and "to account for limitations of fluid flow through a needle").

A system comprising both components and thus supporting the combination of claim 1 is disclosed in Figure 3 of the application as filed, which comprises a needle-removing station 320 ("deneedler station" in the paragraph bridging pages 12 and 13, corresponding to paragraph [0029] of the patent specification) and a

syringe manipulator 334 (see third paragraph on page 27 and third paragraph on page 113, corresponding to paragraphs [0075] and [0381] of the patent specification and disclosing that manipulator 334 is an example of manipulator 1504; see also second paragraph on page 125, corresponding to paragraph [0424] of the patent specification).

Hence, the Board is not convinced by the appellant's objection of added subject-matter.

3. Article 100(b) EPC

The contested patent teaches control of the syringe plunger based on different characteristics (see for example paragraphs [0302], [0373] and [0394]-[0395]). Paragraph [0424] of the contested patent, which appears to be the most relevant passage for the disputed feature, teaches that plunger speed should be limited or a wait time used to avoid pressure imbalance and delayed fluid flow.

Neither claim 1 nor paragraph [0424] define a specific formula or relationship relating the plunger speed to needle diameter and fluid viscosity. However, the person skilled in the art is aware of the influence of those parameters on fluid flow through the needle, e.g. an increased needle diameter allows more fluid flow and thus an increased plunger speed. Hence, the person skilled in the art would be able to implement a plunger speed limitation or wait time calculation as defined by claim 1 in the plunger control taking into account the corresponding limitations.

It follows that the invention is sufficiently disclosed to be carried out by a person skilled in the art.

4. Article 100(a) EPC

The appellant submitted in its statement of grounds of appeal a new objection of lack of inventive step starting from D5, a document which had been cited in the European Search Report and used by the appellant to support objections to some of the dependent claims in its notice of opposition.

The appellant did not justify why it raised this objection to claim 1 as granted only at this stage and not in the first-instance opposition proceedings. The Board is not able to see any reasons for this delay either. Hence, the Board does not admit the objection into the proceedings using its discretion under Article 12(4) RPBA 2007.

For the sake of completeness, the Board notes that the objection is not prima facie relevant. D5 discloses neither the characterising portion of claim 1 nor the feature "a needle-removing station". As to the latter feature, the appellant acknowledged in its statement of grounds of appeal (page 7, 5th paragraph) that in D5 the needle was disposed together with the disposable syringe. D2 does not teach any of the two features either. The passage of D2 referred to by the appellant (page 5, line 119 - page 6, line 20) teaches instead manual control of the plunger's speed. Thus, even if the person skilled in the art would combine D5 with D2, he would not arrive at a system as defined by claim 1.

5. The objections raised in appeal proceedings do not prejudice maintenance of the patent as granted. There is thus no reason to set aside the Opposition

Division's decision rejecting the opposition. Accordingly, the appeal is to be dismissed.

6. The Board considers, in accordance with established case law (see Case Law of the Boards of Appeal, 10th edition 2022, III.C.4.3.2), the appellant's submission that it would neither attend nor be represented at the oral proceedings to be equivalent to a withdrawal of the appellant's request for oral proceedings since, by doing so, the appellant unequivocally expressed that it only wished to rely on its submissions made in writing.

The respondent's main request, on the other hand, was that the appeal be dismissed. Therefore the decision can be rendered in writing without holding oral proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated