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Datasheet for the decision of 14 October 2022

Case Number: T 2769/19 - 3.2.02

Application Number: 10191221.0

Publication Number: 2455126

IPC: A61J1/05, A61M5/172, A61J1/14, A61M5/38

Language of the proceedings: EN

Title of invention:
Container for storing medical or pharmaceutical liquids

Patent Proprietors:
F. Hoffmann-La Roche AG
Roche Diabetes Care GmbH

Opponent:
Debiotech S.A.

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)
EPC R. 99(2)
RPBA Art. 12(4)

Keyword:

Novelty - (yes)
Inventive step - (yes)
Amendments - added subject-matter (no)
Late-filed evidence - submitted with the statement of grounds of appeal - admitted (yes/no)
Late-filed objection - submitted with the statement of grounds of appeal - should have been submitted in first-instance proceedings (no/yes) - admitted (yes/no)
Objection withdrawn in first-instance proceedings, resubmitted with the statement of grounds of appeal - admitted (no)
Objection sufficiently substantiated (yes) - admitted (yes)

Decisions cited:

T 2117/18

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Case Number: T 2769/19 - 3.2.02

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

Appellant: (Opponent)	Debiotech S.A. Immeuble "Le Portique" Av. de Sévelin 28 1004 Lausanne (CH)
Representative:	Weihs, Bruno Konrad André Roland SA P.O. Box 352 1000 Lausanne 22 (CH)
Respondent 1: (Patent Proprietor 1)	F. Hoffmann-La Roche AG Grenzacherstrasse 124 4070 Basel (CH)
Respondent 2: (Patent Proprietor 2)	Roche Diabetes Care GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Representative:	Rentsch Partner AG Kirchenweg 8 Postfach 8034 Zürich (CH)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 9 August 2019 concerning maintenance of the European Patent No. 2455126 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	N. Obrovski

Summary of Facts and Submissions

I. This appeal was filed by the opponent against the Opposition Division's interlocutory decision to maintain the contested patent on the basis of the proprietors' main request submitted on 20 March 2019.

II. In its decision, the Opposition Division held that the subject-matter of claim 1 of the main request did not comprise added subject-matter and that it was novel and involved an inventive step, especially in view of the following document:

D05 WO 93/20863 A1

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

IV. The respondents (proprietors) requested as their main request that the appeal be dismissed or, as auxiliary measures, that the patent be maintained on the basis of one of auxiliary requests 1, 4 to 6, 2, 7 to 9, 3, 3a, and 10 to 12, ranked in this order (auxiliary requests 1 to 3 filed with the reply to the statement of grounds of appeal; and auxiliary requests 3a and 4 to 12 filed with the submission dated 25 May 2021).

V. This decision also refers to the following documents:

D02 US 4,013,072
D03 WO 2009/128959 A1
D05US US 5,205,820
D10 EP 2 229 970 A1
D17 US 2002/0040208 A1

D18 US 2009/0173673 A1
D19 WO 2010/023567 A1
D20 Wikipedia page "Insulin (medication)"
D21 US 2010/0282779 A1
D22 EP 2 163 273 A1
D23 "Plastic Bottle Manufacturing", copy of web page https://www.thomasnet.com/articles/materials-handling/plastic-bottle-manufacturing
D24 "Review of Data on Gas Migration through Polymer Encapsulants", Report to NDA - Radioactive Waste Management Directorate

VI. Claim 1 of the **main request** ("claim 1") reads as follows:

"Container for storing a medical or pharmaceutical liquid, the medical or pharmaceutical liquid being an insulin preparation, the container comprising a storage compartment (4) for storing the liquid (9), the storage compartment (4) comprising an outlet opening (6) for discharging liquid out of the storage compartment (4), wherein storage compartment (4) comprises at least one flexible wall sheet (3, 3'),
with a hydrophilic membrane layer (7; 8) within the storage compartment (4), which is gas-tight in a wet condition, and which at least covers the outlet opening (6) such that any air or gas within the liquid-filled container cannot pass the outlet opening (6) and will remain in the storage compartment (4),
wherein the membrane layer (7; 8) extends at least along 50% of a length of the storage compartment (4) at least in one dimension, such that the membrane layer (7.8) contacts the liquid (9) stored within the storage compartment (4) substantially independent of a container orientation with respect to gravity and a filling level of the container,

wherein the storage compartment (4) has a volume in a range of 1ml to 5ml."

VII. The **appellant's arguments** relevant for this decision can be summarised as follows.

Admittance issues

(a) Documents D18 to D23, D05US and D24

D18 to D23 had been filed during the opposition proceedings in response to claim amendments submitted by the respondents. These documents had been admitted by the Opposition Division and were therefore to be taken into account in the appeal proceedings.

D05US was filed on appeal in reaction to the unexpected change of opinion of the Opposition Division during the oral proceedings on the properties of the flow-regulating membrane layer disclosed in D05 (see point 16.1.3 of the decision under appeal). D05US, which was derived from the application from which D05 claimed priority, was directed to the same invention but contained additional information on the membrane layer which countered the Opposition Division's view. D05US was thus highly relevant and should be admitted into the proceedings.

D24 was filed on appeal in response to the Opposition Division's opinion on the permeability of the elastic outer membrane disclosed in D05 and the impermeability of the corresponding membrane in the contested patent. D24 was prior art under Article 54(2) EPC. The copyright mention "© NDA 2010" on page 3 did not mean that D24 had been published in 2010. Rather, the first page of D24 bore the date of September 2008; many

articles and books also cited D24 with the publication year 2008. Moreover, D24 was *prima facie* relevant. D24 should therefore be admitted into the appeal proceedings as well.

(b) Inventive-step objections against claim 1 raised for the first time in the statement of grounds of appeal

In the statement of grounds of appeal, the appellant submitted that the subject-matter of claim 1 lacked an inventive step over the combination of at least two documents selected from D02, D03, D05, D05US, D10, D17 and D19 (page 2, last paragraph), with only objections based on D03, D05, D05US, D10, D17 and D19, each regarded as the starting point, being substantiated (section 10).

Apart from the inventive-step attacks starting from D05 already submitted in the opposition proceedings and addressed in the decision under appeal, the further inventive-step objections substantiated in the statement of grounds of appeal were raised for the first time on appeal. Indeed, the Opposition Division had, in its preliminary opinion, considered that D05 was novelty-destroying for claim 1. For the sake of procedural economy, the appellant had thus not deemed it necessary to prepare and file these further inventive-step attacks in advance of the oral proceedings before the Opposition Division. Therefore, following the unexpected change of opinion of the Opposition Division on D05 at the oral proceedings, it had only been possible to submit these objections with the statement of grounds of appeal.

Apart from D05US, all the documents on which these objections were based had been filed during the opposition proceedings and were thus known to the respondents. The relevant passages of these documents had been discussed in detail in the course of the opposition proceedings. Thus, the inventive-step objections newly filed on appeal merely constituted new arguments.

The inventive-step objection starting from D05US, as explained in support of the admittance of this document, elaborated on the inventive-step objection starting from D05 discussed in the decision under appeal.

For these reasons, all the inventive-step objections substantiated in the statement of grounds of appeal, including those submitted for the first time on appeal, should be taken into account in the appeal proceedings.

(c) Objection of insufficiency of disclosure

The invention of the patent was not sufficiently disclosed for it to be carried out by a person skilled in the art, especially with regard to the requirement that the membrane layer should contact the liquid stored within the storage compartment substantially independently of container orientation with respect to gravity and filling level of the container.

The appellant had never withdrawn this objection, originally substantiated in the notice of opposition (point 7). The statement "*the opponent stated that he did not attack the Main Request based on Art. 83 EPC*" reported on page 1 of the minutes of the oral proceedings before the Opposition Division was

incorrect. The appellant had merely declared that it would not present this objection again orally at the oral proceedings. The decision under appeal explicitly mentioned the appellant's request that the patent be revoked on the ground of Article 100(b) EPC (see point 2 on page 1).

This objection should therefore be taken into account in the appeal proceedings.

(d) Objection of added subject-matter against claim 1

The appellant did not comment on the admittance of this objection.

Claim 1 - added subject-matter

The addition of the feature "wherein the storage compartment (4) has a volume in a range of 1ml to 5ml" in claim 1 violated Article 123(2) EPC. The original description disclosed only a container having a volume of 3 ml (page 15, lines 10-11). The range of "about 1ml to 5ml" was mentioned there only as a justification for this particular choice of 3 ml. Moreover, due to the term "about", this range was different from the claimed range of 1 to 5 ml.

Claim 1 - novelty over D05

D05 disclosed (see e.g. Figure 3) a container for storing a medical liquid comprising all the features of claim 1. In particular, D05 disclosed that the membrane layer 215 might be a hydrophilic layer (page 15, lines 10-11). A hydrophilic membrane layer was inherently gas-tight in a wet condition. Moreover, like the contested patent, D05 aimed at providing a

container in which the fluid flow through the outlet opening was precisely controlled. This implicitly required the flow-regulating membrane layer 215 to be gas-tight, otherwise air bubbles would pass through the membrane layer and cause dosing errors. Therefore, the subject-matter of claim 1 was not novel over D05.

Claim 1 - novelty over D05US

In view of the similarities between D05 and D05US, claim 1 also lacked novelty over D05US for the same reasons. In addition, D05US disclosed (column 8, lines 50-11) that the membrane layer could be made of cellulose acetate, i.e. of the same hydrophilic material disclosed in the contested patent (paragraph [0031]). For the largest pore size of 50 µm disclosed in D05US (column 8, lines 53-55), the bubble point calculated by the Young-Laplace equation was 52.2 cmH_2O. As long as the pressure differential was smaller than this value, the membrane layers disclosed in D05US were gas-tight in a wet condition, as required by claim 1.

Claim 1 - inventive step starting from D05 and D05US

Even if the feature that the hydrophilic membrane layer is gas-tight in a wet condition were to be found novel over D05 and D05US, it would not lend inventive step to the subject-matter of claim 1.

This feature prevented gas present in the storage compartment from passing through the outlet opening and being administrated to the patient. In D05 and D05US, this effect was at least partially achieved by the flexible outer wall sheet of the storage compartment being gas permeable so that gas could be released from

the storage compartment (D05, page 4, sixth paragraph; D05US, column 3, lines 1-3). Gas bubbles produced during use by the degassing of the liquid (paragraph [0012] of the contested patent) could, however, remain in the storage compartment, especially in unfavourable orientations of the container in which they could not escape through the gas-permeable wall sheet.

The objective technical problem to be solved starting from D05 or D05US could thus be formulated as to provide an alternative or improved way of preventing injection of air to the patient, in lieu of or in addition to the outer gas-permeable wall sheet of the storage compartment disclosed in these documents.

Alternatively, the objective problem to be solved could also be formulated as to improve the precision of the flow rate control achieved with the container since preventing air bubbles from passing through the membrane layer also avoided dosing errors, as explained in paragraph [0018] of the patent.

As explained in D02, hydrophilic filters capable of passing liquid while simultaneously blocking air when wetted were well known to the person skilled in the art (column 2, line 64 to column 3, line 2; column 4, lines 57-60). Using this common general knowledge, it would have been obvious to the person skilled in the art faced with one of the problems above to modify the hydrophilic flow control membrane disclosed in D05 or D05US to make it additionally gas-tight in a wet condition.

Moreover, this kind of gas filter was also disclosed in D19 (page 4, lines 5-7; page 7, lines 28-31), for example, in Figure 2, where such a filter was shown

within the storage compartment of a container (page 7, lines 12-13). Therefore, consulting D19 or D2 itself would have also motivated the person skilled in the art to modify the hydrophilic membrane of the containers of D05 or D05US so that it is gas-tight in a wet condition or to add such a membrane layer within the storage compartment.

These modifications would not have been detrimental to the flow regulation achieved with the known containers because the elongated channels through which the liquid had to pass before being discharged would not have been easily clogged by air bubbles. Moreover, D05 and D05US also disclosed containers deprived of protuberance and thus of channels (see, for example, D05, page 15, lines 19-20).

Hence, the person skilled in the art would have arrived at the subject-matter of claim 1 without inventive step.

As acknowledged by the appellant, D17 did not disclose a hydrophilic membrane which was gas-tight in a wet condition.

VIII. The **respondents' arguments** relevant for this decision can be summarised as follows.

Admittance issues

(a) Documents D18 to D23, D05US and D24

D18 to D23 had not been filed during the opposition period and were thus late-filed. As held in the decision under appeal, none of them was detrimental for novelty and inventive step of claim 1. This clearly

demonstrated that they were not *prima facie* relevant. D18 to D23 should not, therefore, be admitted into the appeal proceedings.

The appellant's interpretation of the hydrophilic membrane layer of claim 1 had been challenged by the respondents prior to the oral proceedings before the Opposition Division on 22 May 2019, for example, in the respondents' submissions dated 18 April 2018 (points 3, 9, 52 and 121) and 20 March 2019 (points 8 ff). Therefore, the appellant should have expected that the Opposition Division might change its view on this membrane layer at the oral proceedings. Accordingly, the appellant should have filed D05US in advance of these oral proceedings or at the latest during them. The appellant must have been aware of D05US since this was the patent derived from the priority application claimed by D05. Moreover, for this last reason, D05US could not provide any additional information on the content of D05. Thus, D05US was not *prima facie* relevant and should not be admitted either.

The appellant had not convincingly demonstrated that D24 was prior art under Article 54(2) EPC. Moreover, like D05US, D24 could and should have filed by the appellant in the opposition proceedings. Therefore, D24 should not be admitted either.

(b) Inventive-step objections against claim 1 raised for the first time in the statement of grounds of appeal

The new inventive-step objections against claim 1 substantiated for the first time in the appellant's statement of grounds of appeal could and should have been filed in the opposition proceedings. The appellant

had not wished to present any further inventive-step attack during the oral proceedings before the Opposition Division, as reported in the minutes. These new objections should not therefore be admitted into the appeal proceedings.

(c) Objection of insufficiency of disclosure

The minutes of the oral proceedings before the Opposition Division unambiguously indicated that the objection of insufficiency of disclosure had not been maintained by the appellant. Thus, this objection should not be admitted into the appeal proceedings.

(d) Objection of added subject-matter against claim 1

In the statement of grounds of appeal, the appellant merely repeated the same argument on added subject-matter they had presented in the opposition proceedings. The appellant failed, however, to explain why the decision under appeal was incorrect in this regard. Thus, this objection should be held inadmissible.

Claim 1 - added subject-matter

The claimed feature that the storage compartment had a volume in a range of 1 to 5 ml was supported by page 15, lines 9-11 of the description as filed. Claim 1 thus did not include added subject-matter.

Claim 1 - novelty over D05

D05 did not directly and unambiguously disclose that the flow control membrane layer was gas-tight in a wet condition. A hydrophilic layer was not necessarily gas-

tight in a wet condition. Hence, the subject-matter of claim 1 was novel over D05.

Claim 1 - novelty over D05US

The subject-matter of claim 1 was also novel over D05US.

The bubble point calculation by the appellant using the Young-Laplace equation relied on assumptions which were hardly ever met by real devices. In reality, the bubble point was considerably smaller. Moreover, in the container of D05US, the pressure applied to the stored liquid by the outer distendable wall sheet had to overcome blood pressure to allow for injection. Thus, it was highly likely that the bubble point of the membrane layer was exceeded in practice. Hence, D05US did not directly and unambiguously disclose a hydrophilic flow control membrane which was gas-tight in a wet condition.

Furthermore, D05US disclosed (last paragraph of column 8) a large number of materials suitable for the flow control membrane, including well-known hydrophobic materials like PTFE. The disclosed pore size range was also very broad. In the absence of a specific teaching of a combination of a hydrophilic material and a pore size that resulted in a membrane that was gas-tight in a wet condition, such a membrane was not directly and unambiguously disclosed in D05US.

Claim 1 - inventive step starting from D05 and D05US

The function of the flow control membrane in D05 and D05US, which was at the core of the invention, was to ensure a predetermined flow rate of liquid out of the

container in a precise and controlled manner. There was no need to prevent gas from passing through the flow control membrane because venting of the storage compartment was already achieved in another way, namely, through the outer wall sheet, which was gas permeable. Using common general knowledge, the person skilled in the art starting from D05 and D05US would not have, therefore, been motivated to make the membrane gas-tight or to add a gas-tight membrane in the storage compartment, both options of which would have affected the primary flow rate control function of the membrane. Furthermore, the person skilled in the art would not have consulted D2, which was not related to a container but to a drip chamber, or D17, which did not disclose a hydrophilic membrane which was gas-tight in a wet condition. The combination with D19 would not have prompted the person skilled in the art toward the claimed subject-matter either.

Therefore, without hindsight, the person skilled in the art proceeding from D05 or D05US would not have arrived at the subject-matter of claim 1 in an obvious manner, even under consideration of common general knowledge or the disclosure of D2, D17 or D19. The subject-matter of claim 1 thus involved an inventive step starting from these documents.

Reasons for the Decision

1. The invention of the contested patent

The contested patent concerns a container for storing a medical or pharmaceutical liquid such as an insulin preparation. In this type of container, the storage compartment in which the liquid is stored includes a

flexible wall sheet which can be subjected to pressure exerted by a dosing apparatus to discharge liquid out of the storage compartment through an outlet opening of the container.

A common problem is the presence of air inside the storage compartment, for example, if the container has not been completely filled. As a result, air bubbles may be discharged through the outlet opening. This leads to potentially dangerous dosing errors. Furthermore, air may even be administrated into the patient's body, something which should also be avoided (paragraphs [0010]-[0013]).

The container proposed by the patent aims to avoid this drawback (paragraphs [0017]-[0019]). For this purpose, as defined in claim 1 and illustrated in Figure 1a, reproduced below, the container (1) comprises a hydrophilic membrane layer (7) within the storage compartment (4), which is gas-tight in a wet condition, and which at least covers the outlet opening (6) such that any air or gas within the liquid-filled container cannot pass through the outlet opening and will remain in the storage compartment (paragraphs [0021], [0023], [0063]).

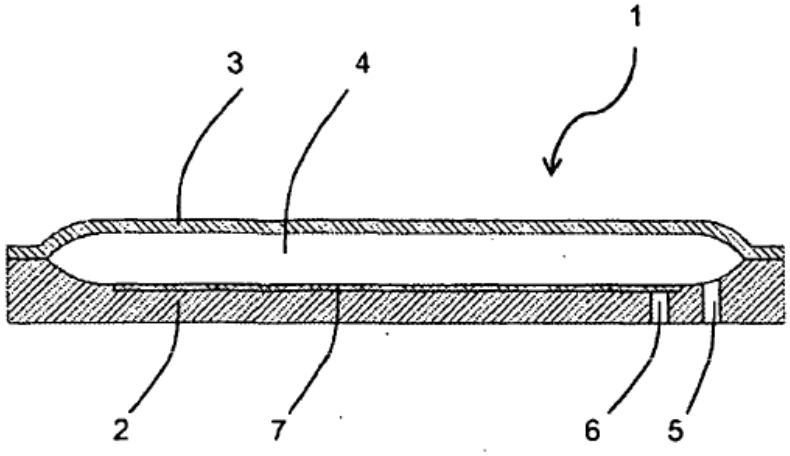


Fig. 1a

2. Admittance issues

The admittance into the appeal proceedings of the documents D18 to 23, D05US and D24; the inventive-step objections filed for the first time on appeal; the objection of insufficiency of disclosure; and the objection of added subject-matter, disputed between the parties, is governed by Article 12(4) RPBA 2007, which applies in the current case by virtue of the transitional provisions of Article 25(2) RPBA 2020. Under this article, a board has discretion to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first-instance proceedings.

2.1 Documents D18 to 23, D05US and D24

2.1.1 D18 to D23 were filed in the opposition proceedings but after expiry of the opposition period. Being late filed, these documents were nevertheless admitted by the Opposition Division in exercise of its discretion, as justified in point 14 of the decision under appeal.

The Board does not find any reason to doubt that the Opposition Division, in deciding to admit these documents, exercised its discretion in accordance with the right principles and in a reasonable way.

Accordingly, there is no reason for the Board to overturn the Opposition Division's decision. D18 to D23 are therefore taken into account in the appeal proceedings.

2.1.2 D05US and D24 were both filed for the first time with the appellant's statement of grounds of appeal.

D05US is a US patent derived from US application 870,269 from which D05 claims priority. It is directed to a container for a medical liquid which is substantially identical to the container disclosed in D05, in particular, also comprising a flow control membrane (see, for example, Figure 3 of D05 versus Figure 32 of D05US). However, in contrast to D05, D05US contains further information on the nature of this membrane layer, disclosing in column 8, lines 50-55 the same constitutive hydrophilic material (cellulose acetate) as mentioned in paragraph [0031] of the contested patent, as well as overlapping pore size ranges. D05US is therefore *prima facie* relevant.

D05US was used by the appellant to substantiate novelty and inventive-step objections against claim 1 which elaborate on corresponding objections raised in the opposition proceedings in view of D05. As argued by the appellant, the filing of D05US can be regarded as a reaction to the Opposition Division's change of view - only during the oral proceedings before it (see point 16.1.3 of the decision under appeal) - on the properties of the membrane layer of D05, which eventually led it to the conclusion that this membrane layer was not gas-tight in a wet condition as required by claim 1.

Contrary to the respondents' argument, this issue had not been addressed by the parties in the opposition proceedings. Points 3, 9, 52 of the respondents' submission dated 18 April 2018 were not on D05. Point 121 of that submission and points 8 ff of the respondents' submission dated 20 March 2019 concerned only the location and the extension of the membrane layer within the container of D05.

Accordingly, and given that the Opposition Division's preliminary opinion on D05 provided in advance of the oral proceedings had been in favour of the appellant (see point 2.4.2.1 of the communication annexed to the summons to oral proceedings), the appellant may not have considered it necessary to file further evidence in support of its argument in the opposition proceedings.

On appeal, D05US was then filed with the appellant's statement of grounds of appeal, i.e. at the earliest possible stage of the appeal proceedings.

For these reasons, the Board decided to admit D05US into the appeal proceedings.

2.1.3 D24 is a report to the UK Nuclear Decommissioning Authority (NDA) entitled "Review of Data on Gas Migration through Polymer Encapsulants". The appellant argued that D24 had been filed in response to the Opposition Division's view on the permeability of the elastic outer membrane disclosed in D05 and the impermeability of the corresponding membrane in the contested patent.

The Board is not convinced by the appellant's allegation that D24 was published in 2008. While D24 bears the date "September 2008" on its first page, it also includes on page 3 a section entitled "Conditions of Publication" ending with the mention "© Nuclear Decommissioning Authority 2010", and the section just above mentions that the report was "submitted to the NDA in January 2008" and then "reviewed by the NDA". It therefore appears that 2008 is the year in which the report was submitted to and reviewed by the NDA and that D24 was not made publicly available until 2010.

Therefore, given that the contested patent was filed on 15 November 2010, it is not unambiguously clear that D24 is prior art under Article 54(2) EPC as asserted by the appellant.

For this reason, the Board decided not to admit D24.

2.2 Inventive-step objections against claim 1 raised for the first time in the statement of grounds of appeal

In the statement of grounds of appeal (section 10), the appellant substantiated a number of inventive-step objections against claim 1, namely objections starting from D05 - or equally D05US - in combination with D02, D17 or D19, as well as further objections starting from D03, D10, D17 and D19.

As acknowledged by the appellant, most of these objections are new objections filed for the first time on appeal. The respondents contested the admittance of these new objections into the appeal proceedings.

2.2.1 While, in the opposition proceedings, the appellant objected to the subject-matter of claim 1 for lacking inventive step starting from D05 in combination with D17, D18, D19, D21 or D22 (see points 2c and 2d of the appellant's submission dated 15 May 2019, pages 4 to 5 of the minutes of the oral proceedings before the Opposition Division, and point 17.1 of the decision under appeal), no novelty objection over D03, D10, D17 and D19 or inventive-step objection starting from one of these documents was raised against claim 1.

2.2.2 For similar reasons as discussed above for the admittance of D05US, the appellant may have considered it necessary to adapt or supplement its earlier

inventive-step objections starting from D05 following the Opposition Division's change of view on the membrane of D05 during the oral proceedings.

The objections based on the combination of D05, or D05US, with D02 or D19 address the Opposition Division's view in point 17.1.2 of the decision under appeal that including in the known container a hydrophilic membrane which is gas-tight in a wet condition would not have been obvious to the person skilled in the art, even in light of D19. The objection based on the combination with D17 addresses the Opposition Division's assertion in the same passage of the decision that the "flexible wall sheet" defined in claim 1 of the main request is "pliable and not exercising any pressure on the fluid contained" and not elastic as in D05 or D05US.

Even if, as put forward by the respondents, the appellant might have, in theory, been able to submit adapted objections at the end of the oral proceedings before the Opposition Division, it is credible that the formulation of such objections was not immediately evident at that stage.

For these reasons, the Board decided to admit into the appeal proceedings the inventive-step objections starting from D05, as well as the corresponding objections starting from D05US, substantiated in the statement of grounds of appeal.

2.2.3 By contrast, the Board concurs with the respondents that the inventive-step objections starting from D03, D10, D17 and D19 - which, contrary to the appellant's assertion, are not merely new arguments filed for

objections raised previously - could and should have been filed during the opposition proceedings.

These objections indeed take as starting points documents which had been filed in advance of the oral proceedings before the Opposition Division (D03, D10 and D17 were filed with the notice of opposition; D19 was filed with the submission dated 15 May 2019 and then admitted by the Opposition Division during the oral proceedings). What is more, the appellant was given the opportunity to submit further inventive-step objections at the oral proceedings, but it decided not to (page 6 of the minutes, second paragraph).

The fact that the Opposition Division's preliminary opinion on claim 1 of the main request was in favour of the appellant did not prevent the appellant from submitting all its objections at the earliest possible stage of the opposition proceedings. Nor can the Opposition Division's change of view at the oral proceedings justify the admittance of these new inventive-step objections on appeal since, unlike the objections starting from D05 and D05US discussed above, they do not elaborate on previous submissions made in the first-instance proceedings.

For these reasons, the Board decided not to admit the substantiated inventive-step objections starting from D03, D10, D17 and D19.

The further inventive-step objections mentioned on page 2, last paragraph of the statement of grounds of appeal have not been substantiated and are therefore considered to not have been validly filed (T 2117/18, Reasons 2.2.17).

2.3 Objection of insufficiency of disclosure

The appellant's objection of insufficiency of disclosure substantiated in the statement of grounds of appeal had been raised in the opposition proceedings (section 7 of the notice of opposition).

However, the decision under appeal refers to Article 100(b) EPC in point 2 only as one of the grounds for opposition initially invoked by the appellant in its notice of opposition but does not address sufficiency of disclosure in its reasons. Contrary to the appellant's assertion, this does not mean that the Opposition Division implicitly came to the final conclusion that the appellant's objection was not founded, even if this had been the preliminary opinion expressed by the Opposition Division in its communication annexed to the summons to attend oral proceedings (point 2.4.1).

In fact, the minutes of the oral proceedings before the Opposition Division show that the appellant did not maintain this objection, as is unambiguously derivable from the statement "*in particular, the opponent stated that he did not attack the Main Request based on Art. 83 EPC*" on page 1. If, as alleged by the appellant, this statement incorrectly reflected its intention, the appellant should have requested a correction of the minutes from the Opposition Division. However, it did not.

In the Board's view, the discretion conferred to the Board by Article 12(4) RPBA 2007 to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first-instance proceedings applies all the more to objections which

were filed and then not maintained in the first-instance proceedings. By not maintaining its objection, the appellant prevented the Opposition Division from giving a reasoned decision on the issue of sufficiency of disclosure. Admitting this objection on appeal would compel the Board either to give a first ruling on this issue or to remit the case to the Opposition Division. The purpose of an appeal, however, is to review what was decided by the department of first instance (Article 12(2) RPBA 2020); not to decide on an issue for the first time.

As a consequence, the Board decided to hold this objection inadmissible.

2.4 Objection of added subject-matter against claim 1

In section 8 of the statement of grounds of appeal, the appellant explained why, in its view, the Opposition Division's finding that claim 1 did not comprise added subject-matter was incorrect. The appellant argued that the passage of the original description on page 15, lines 9-11 considered by the Opposition Division in the decision under appeal (points 15.2 to 15.4) could not support the claimed feature "wherein the storage compartment (4) has a volume in a range of 1ml to 5ml" of claim 1.

Contrary to the respondents' view, the Board considers the explanations provided by the appellant sufficiently substantiated to meet the requirements of Article 12(3) RPBA 2020 that the statement of grounds of appeal must "set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed [...], and should specify expressly all the requests, facts, objections, arguments and evidence relied on".

Therefore, the appellant's added-matter objection against claim 1 is to be taken into account in the appeal proceedings.

3. Claim 1 - added subject-matter

As stated above, the appellant's added-matter objection concerns the feature of claim 1 "wherein the storage compartment (4) has a volume in a range of 1ml to 5ml".

As pointed out by the respondents, the original description on page 15, lines 9-11 states:

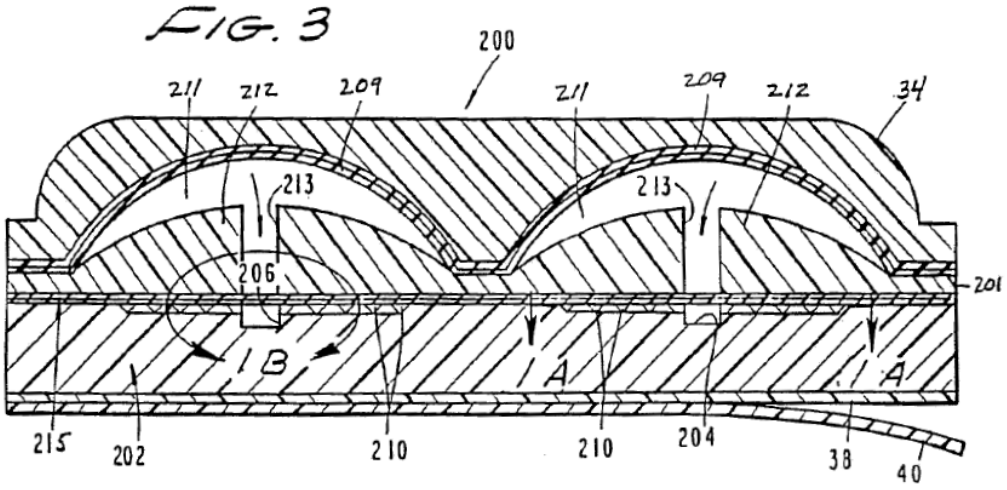
"*The storage compartment 4 has a volume of 3ml. In the context of insulin therapy, the volume is typically in a range of about 1ml to 5ml.*"

While this passage explicitly indicates a volume of 3 ml for the storage compartment of the container disclosed in the preceding sentences, the person skilled in the art directly and unambiguously derives that, when this container or the other containers disclosed in the application are adapted to store an insulin preparation - which is the case of the container defined in claim 1 - their storage compartment may have a volume of "about 1ml to 5ml", hence, in particular, a volume of "1ml to 5ml" as claimed.

The Board therefore concludes that, contrary to the appellant's view, claim 1 does not comprise added subject-matter.

4. Claim 1 - novelty over D05

4.1 It is common ground that D05 discloses a container 200 for storing a medical or pharmaceutical liquid, shown for example in cross-section in Figure 3, reproduced below.



This container includes a storage compartment 211 for storing the liquid, which comprises a flexible, distendable wall sheet 209 defining the upper wall of the storage compartment, and an outlet opening for discharging liquid out of the storage compartment (page 10, first three paragraph).

The container further comprises a flow control membrane 215 consisting of one or more layers, the function of which is to regulate the flow of the liquid discharged through the outlet opening (page 10, third paragraph; page 11, first paragraph).

The parties disagree on whether this membrane 215 is a hydrophilic membrane layer which is gas-tight in a wet condition as required by claim 1.

4.2 It is true that D05 discloses that "[c]ertain regimes of the various layers" forming the membrane 215, which

may be porous (page 11, first paragraph), may be "rendered hydrophilic" (page 15, lines 10-11).

However, even admitting that this constitutes a disclosure of a hydrophilic membrane layer does not mean that this layer is necessarily gas-tight in a wet condition as alleged by the appellant.

Indeed, whether a porous hydrophilic membrane layer is gas-tight in a wet condition does not inherently result from the hydrophilic nature of the layer but depends, *inter alia*, on the size of the pores in the layer, as explained in paragraph [0031] of the contested patent. This was also acknowledged by the appellant in its discussion of the Young-Laplace equation for D05US (see point 5. below).

D05 is, however, silent about the size of the membrane pores. In situations where a high flow of liquid through the membrane 215 is desired, which is not excluded in D05, the pore size could well be large enough for gas - if gas were present in the storage compartment (see point 4.3 below) - to pass through the membrane.

4.3 The appellant also argued that the membrane 215 *implicitly* had to be gas-tight to allow for the flow rate through the membrane to be predictably controlled because otherwise gas bubbles passing through the membrane would cause dosing errors.

This argument is not convincing. D05 is silent about preventing gas possibly contained within the storage compartment from passing through the membrane and being discharged out of the container. D05 instead discloses a mechanism for venting gas out of the storage

compartment, namely through the distendable wall sheet 209 defining the upper wall of the storage compartment, which is gas permeable (page 11, penultimate paragraph; page 12, last paragraph). Hence, in normal use of the container of D05, gas initially present in the storage compartment, or appearing from degassing of the stored liquid, does not remain in the storage compartment, and there is no risk that gas bubbles will pass through the membrane and be injected into the patient.

4.4 The Board therefore concurs with the respondents that D05 does not directly and unambiguously disclose that the membrane 215 is gas-tight in a wet condition as required by claim 1. It follows that the subject-matter of claim 1 is novel over D05.

5. Claim 1 - novelty over D05US

5.1 As mentioned in point 2.1.2 above, the container disclosed in D05US is substantially identical to the container disclosed in D05 (the flow control membrane and the gas-permeable upper wall sheet of the storage compartment having in D05US the reference signs 26 and 24, respectively). The considerations in point 4. above therefore apply similarly.

5.2 Additionally, the appellant put forward that in D05US (see the last paragraph of column 8) the flow control membrane may be formed of cellulose acetate, i.e. of the same hydrophilic material as disclosed in the contested patent (paragraph [0031]). D05US also discloses that the flow control membrane may have a porosity which can vary "from angstroms to 50 microns in diameter", i.e. in a range which contains the range of 0.2 to 1.2 µm according to the contested patent (paragraph [0031]; claim 15 of the main request).

The relationship between the bubble point ΔP (i.e. the pressure differential beyond which gas starts to flow through a wetted membrane) and the pore diameter D of a porous membrane is given by the Young-Laplace equation:

$$D = \frac{4\gamma_L cos\theta}{\Delta P}$$

where θ is the contact angle at the gas/liquid/solid interface and γ_L the tension surface of the liquid. Assuming insulin as the liquid (as contemplated by claim 1) and a complete wetting of the membrane (i.e. θ=0°), the appellant thus submitted that even for the largest pore size of 50 µm disclosed in D05US, a membrane layer made of cellulose acetate was implicitly gas-tight in a wet condition - at least when the pressure differential was below the calculated bubble point of 52.2 cmH_2O, which was significant.

5.3 This line of argument does not convince the Board.

5.3.1 As argued by the respondents, the containers of D05US are configured to allow injection of the stored liquid into the patient under the sole pressure exerted on the liquid by the outer distendable wall sheet, i.e. without a pump, for example, via a needle incorporated in the container (Figure 16). This pressure has therefore to be sufficiently high, especially compared to blood pressure, to allow for injection of the liquid. The Board is not convinced that, in this context, the pressure differential at the membrane would remain under the bubble point of 52.2 cmH_2O calculated by the appellant. As submitted by the respondents, this value of bubble point may in fact be even smaller in real systems, depending on the surface state of the membrane, which is not specified in D05US.

It follows that, contrary to the appellant's view, a membrane made of cellulose acetate and having a pore diameter of 50 µm is not necessarily gas-tight in a wet condition. This conclusion is consistent with the teaching in D2, to which the appellant also referred, according to which hydrophilic membrane filters capable of blocking air have a pore size of less than 14 µm (column 2, lines 61-63), i.e. much less than 50 µm.

5.3.2 The Board acknowledges that a hydrophilic membrane with a much smaller pore size, for example in the angstrom range, might, in theory, be gas-tight in a wet condition. However, D05US does not provide any guidance on how to select the membrane's material and porosity from the numerous options disclosed in the last paragraph of column 8 except that these parameters are to be selected "[d]epending on the medicinal agent to be delivered and the required flow rate regime". As argued by the respondents, the suitable materials disclosed are not even limited to hydrophilic materials but also include hydrophobic materials such as PTFE. The disclosed pore size range is also very broad, covering five orders of magnitude.

In the absence of any further teaching in D05US that the membrane should block the passage of gas (see last paragraph of point 4.3 above, which applies similarly to D05US), the person skilled in the art would not contemplate using a membrane made of a hydrophilic material and having a small pore size in the angstrom range. Accordingly, a hydrophilic membrane layer which is gas-tight in a wet condition as required by claim 1 is not directly and unambiguously disclosed in D05US.

5.4 The subject-matter of claim 1 is therefore also novel over D05US.

6. Claim 1 - inventive step starting from D05 and D05US

6.1 As discussed above for novelty, the subject-matter of claim 1 differs from the containers disclosed in D05 or D05US at least by the membrane layer being gas-tight in a wet condition. With this distinguishing feature, air or gas potentially present in the storage compartment cannot pass through the membrane layer. Thus, injection of gas into the patient as well as dosing errors are prevented, as explained in paragraph [0023] in combination with paragraph [0013] of the contested patent.

6.2 D05 and D05US also recognise the need to avoid administration of air to the patient (D05, page 4, lines 27-29; D05US, column 3, first three lines). As discussed in point 4.3 above, this effect is achieved in these documents by making the outer wall sheet of the storage compartment gas permeable so that any gas potentially present in the storage compartment can be released (D05, page 15, second paragraph; D05US, column 2, last line to column 3, line 3, as well as column 7, lines 2-3).

As a result, the properties of the flow control membrane can be optimised with the desired flow rate regime as the sole constraint (D05US, column 8, lines 17-21). Hence, an arbitrary flow rate - possibly high if the pores are sufficiently large - can be achieved in a controlled and predictable way. This key function of the flow control membrane is stressed throughout D05 and D05US (see e.g. D05US, column 6, lines 22-23: "Forming an important aspect of the apparatus [...] provision of flow control means").

Given this *ad hoc* construction of the containers described in D05 and D05US, the person skilled in the art would not, without hindsight, have modified these containers on the basis of their common general knowledge to make the membrane hydrophilic and gas-tight in a wet condition. Nor would they have added such a membrane in the storage compartment. This would, without necessity, have significantly restricted the flow rate of liquid expelled from the container.

6.3 As put forward by the appellant, D19 teaches that the filtrating module disclosed in that document can also prevent gas bubbles from exiting the reservoir by providing the filtering membrane with hydrophilic surface properties (page 7, lines 28-31).

However, the filtering membrane of D19 is not aimed, like the membranes of D05 and D05US, at controlling the flow rate of the liquid discharged from the container but to filter insulin nucleation seeds to prevent them from flowing downstream to a pump. While it might be possible, as disclosed on page 7, lines 23-31, to optimise a single membrane or a combination of two distinct membranes to filter both gas bubbles and nucleation seeds, D19 does not teach or suggest how to filter gas bubbles without affecting the flow rate of the liquid flowing through the membrane. Moreover, as argued by the respondents, D19 stipulates that filtration may take place "at any place along the fluid pathway" downstream of the storage compartment and not necessarily within the storage compartment itself. Hence, the Board does not concur with the appellant that D19 would have prompted the person skilled in the art toward the subject-matter of claim 1.

6.4 Furthermore, the Board is not convinced by the appellant's argument that the person skilled in the art would have consulted D2 and that, prompted by this document, they would have arrived at the claimed subject-matter.

D2 deals indeed with a drip chamber, which by nature keeps a vertical orientation in use. Thus, no air can pass through the outlet opening as long as the chamber is filled with liquid. This results in the hydrophilic filter element in D2 only playing a role when the source of the liquid to be administered empties, namely to prevent air from the empty drip chamber from passing through the filter element and getting into the patient (column 3, line 67 to column 4, line 2). In this way, flow of liquid can easily and safely be restarted from another source of liquid without the need to reprime the system (column 1, line 65 to column 2, line 6). This function is, however, irrelevant for the kind of container disclosed in D05 and D05US.

6.5 As acknowledged by the appellant, D17 does not disclose a hydrophilic membrane which is gas-tight in a wet condition. Hence, the combination of D05 with D17 would not have prompted the person skilled in the art to include such a membrane in the container of D05 or D05US either.

6.6 The Board therefore concludes that the subject-matter of claim 1 involves an inventive step starting from D05 or D05US.

7. Conclusion

It follows from the above considerations that none of the appellant's objections admitted into the appeal

proceedings prejudices the maintenance of the contested patent according to the respondents' main request, i.e. in the form held allowable by the Opposition Division.

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