UPC CFI, Central Division Paris, 18 December 2024, Tandem Diabetes Care v Roche Diabetes Care

System for ambulatory drug infusion comprising a filling apparatus for flexible containers

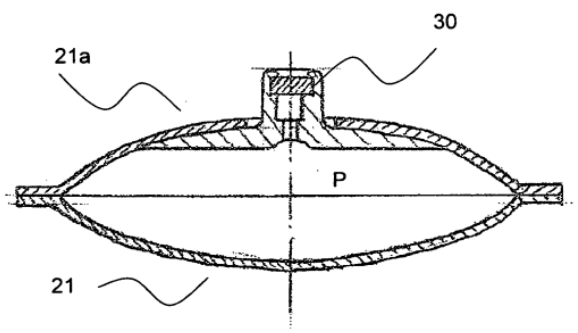


Figure 1

PATENT LAW – PROCEDURAL LAW

Revocation action dismissed; EP 231 maintained as granted (Article 65 UPCA)

Action admissible in spite of breach of a standstill clause

- **a breach of a standstill clause does not necessarily divest the breaching party of the right to bring an action but it may only give rise to liability for breach of contract**.

19. In the present case, the temporal restriction on the right to sue is not justified by any public interest, but rather, as acknowledged by the parties, is solely intended to provide them a cooling-off period to assess the possibility of a settlement, and thus, is driven by a private interest.

Claimant in revocation action cannot introduce new grounds of invalidity or introduce new documents considered novelty destroying or affecting inventive step in subsequent written acts (R. 44 RoP, R. 263 RoP)

- **Similarly, the claimant must specify in the statement of claim the facts that it considers necessary to prove in order to succeed in its claim, together with the relevant evidence.**
- **However, following the defence raised, the the claimant may need to allege new facts, insofar as they are considered capable of supporting the main facts already timely alleged and disputed by the defendant. Likewise, the need to produce new evidence may arise from the defendant's defence which disputes the facts alleged by the claimant or the probative value of the evidence already filed in Court.**

37. This is consistent with the principles set by the Court of Appeal (**decision issued on 21 November 2024, UPC CoA 456/2024**) according to which while the parties are required to set out their case as early as possible in the proceedings nevertheless specific new arguments may be admitted into the proceedings in consideration of specific circumstances of the case.

38. Applying these principles to the present case, it must be concluded that, as already stated by the judge-rapporteur in the forementioned order issued on 10 October 2024, the grounds for revocation based on 'Menot' and 'Lieberman' shall be excluded from consideration with regard to the patent as granted. These documents may be admitted to the proceedings only for the purpose of responding to the allegation contained in the defence to revocation and to the application to amend the patent.

39. Similarly, the invalidity challenges of the dependent claims filed by the claimants with their reply must be excluded from consideration as they were late filed. In this regard, the Court notes that the fact that an action has been filed by the defendant against the claimants based (also) on the infringement of the dependent claims does not constitute a justification of the late filing, as it did not prevent the claimants to challenge the validity of these claims in the current proceedings from the outset and, anyway, it does not cause the claimants for any harm as they can raise these challenges in the infringement action.

Person skilled in the art (Article 56 EPC)

- **may be identified – lacking any indication from the parties – in a generic technical expert who understands the technical meaning of these features,**

No added matter (Article 123(2) EPC)

- **the sentence in para. [0003] discloses a variant including only features A and C (and not B). Therefore, feature 1.5 of claim 1 – including features A and C – is supported by the description of the application as filed.**

Source: **Unified Patent Court**

UPC Court of First Instance,
Central Division Paris, 18 December 2024
(Catallozzi, Zhilova, Checcacci)
DECISION
of the Court of First Instance of the Unified Patent Court
Central division (Paris seat)
issued on 18 December 2024
in the revocation action No. ACT_589997/2023
UPC_CFI_454/2023
HEADNOTES:
The breach of a standstill clause does not divest the breaching party of the right to bring an action where the temporal restriction on the right to sue is not justified by any public interest, but it may only give rise to liability for breach of contract.
KEYWORDS:
competence of the Court.
CAKAIMANTS:
Tandem Diabetes Care, Inc. - 12400 High Bluff Drive, CA 92130, San Diego, USA
Tandem Diabetes Care Europe B.V. - Schiphol Boulevard 359, WTC Schiphol Airport, D-Tower 11th floor, 1118 BJ, Schiphol, Netherlands

both represented by Charlotte Garnitsch, Wim Maas and Pauline Springorum, Taylor Wessing N.V., Alexander Rubusch, Taylor Wessing Partnerschaftsgesellschaft mbB, and George Seezink, AOMB

DEFENDANT

Roche Diabetes Care GmbH - Sandhofer Strasse 116, 68305 Mannheim, Germany

represented by Christof Augenstein, Katharina Brandt and Robert Knaps, Kather Augenstein Rechtsanwälte PartGmbB, and Thomas Kronberger, Grünecker Patent- und Rechtsanwälte PartGmbB

PATENT AT ISSUE:

European patent n° **EP 2 196 231**

PANEL:

Panel 2

Paolo Catallozzi Presiding judge and judge-rapporteur

Tatyana Zhilova Legally qualified judge

Giorgio Checcacci Technically qualified judge

SUMMARY OF FACTS AND PARTIES' REQUESTS:

1. On 4 December 2023 Tandem Diabetes Care, Inc. and Tandem Diabetes Care Europe B.V. filed a revocation action against Roche Diabetes Care GmbH before this Central Division, registered as No. ACT_589997/2023 UPC_CFI_454308/2023, requesting that the patent at issue ('234) be revoked in its entirety, that the defendant be ordered to bear the legal costs of the proceedings and that the Court append an order for the enforcement to its decision, while declaring that the judgment is immediately enforceable.

2. The patent at issue was filed on 12 December 2008 and published on 27 February 2013 and does not claim any priority.

3. The patent relates to a system for ambulatory drug infusion. Its independent claim 1 reads as follows:

"*System for ambulatory drug infusion over an extended time period, the system comprising:*

a) an ambulatory infusion apparatus, the infusion apparatus comprising:

- a flexible container (20),

- a dosing unit in fluidic connection with the flexible container (20)

the system further comprising

b) a filling apparatus for the flexible container (20), the filling apparatus comprising a hollow support structure (5, 5', 105, 10, 10', 110) defining a container compartment (15, 15a, 15b), the container compartment (15, 15a, 15b) being adapted to receive, fully or in part, the flexible container (20), the support structure (5, 5', 105, 10, 10', 110) being adapted to limit an expansion of the flexible container (20) by contacting the flexible container (20) upon being filled, thus defining a maximum filling volume of the flexible container (20),

characterised in that the infusion apparatus further comprises an electronic controller unit configured to control operation of the dosing unit, and the flexible container (2) has a partly rigid container body and a top or cover made from a flexible foil sheet."

4. In the statement of claim the claimant argues that the patent is not valid because of added matter in claim 1, lack of novelty of claim 1 in view of WO 2007/077255 A2 ('Glejboel') and lack of inventive step of said claim 1, assuming as starting point U.S. 2002/0120236 ('Diaz') in combination with US 6,516,950 ('Robertson') or 'Glejboel' in combination with 'Diaz' and/or 'Robertson'.

5. On 22 January 2024 the defendant lodged a preliminary objection pursuant to **Rules 19 (1) (b)** and **48 of the Rules of Procedures ('RoP')** (registered as No. App_3514/2024) on the ground that the Courts currently have no jurisdiction to decide in this matter due to a standstill agreement between the parties according to which a party has to inform the other party of the intention to file a lawsuit 90 days before the lawsuit is filed. It assumes that the claimants have failed to do so.

6. By o**rder issued on 10 May 2024** the judge-rapporteur rejected the preliminary objection stating that the breach of a standstill agreement, even if established, does not constitute grounds for challenging the jurisdiction of the Unified Patent Court. This order was not appealed.

7. In the meanwhile, on 27 March 2024 the defendant had lodged the defence to revocation which included a conditional application to amend the patent based on 26 auxiliary requests. The defendant requested that: the action for revocation is dismissed; as an auxiliary measure, the patent in suit is amended and maintained on the basis of the amended claims filed herewith as one of Auxiliary Requests 1 to 26; the plaintiffs bear the legal costs.

8. With its reply to defence to revocation, filed on 28 May 2024, the claimants introduced in the proceedings two new prior art documents, EP 1 839 695 ('Menot') and US 2006/0100578 ('Lieberman') and argued that the patent at issue lacks novelty also in view on these documents. They also filed a lack of inventive step attack starting from 'Diaz' in combination with the new submitted 'Lieberman'. Lastly, they argued that also the dependent claims were invalid and that the auxiliary requests were not admissible and, anyway, did not overcome the issues regarding the validity of the patent.

9. On 28 June 2024 the defendant lodged its rejoinder to claimant's reply arguing that the action is inadmissible due to the standstill agreement between the parties and objecting to the introduction of new documents.

10. On the same day the defendant filed an application (registered as No. App_37868/2024) requesting, as a further auxiliary measure, that the patent be maintained on the basis on new amended claims (Auxiliary requests 27-30) as a direct reaction to the claimant's new submission.

11. After the closure of the written procedure an interim conference was held on 11 September 2024 in which the judge-rapporteur took several decisions and, in particular, stated that 'Menot' and 'Lieberman' shall be excluded from consideration for the purpose of assessing the soundness of the grounds for revocation of claim 1 of the patent as granted, the permission to the defendant to further amend the patent is denied and the grounds for revocation of the dependent claims filed in the reply to the defence to revocation shall be excluded from consideration and invited the parties to submit written

comments on the meanings of the terms "*container*", "*tank*" and "*tank-like*" used in the patent.
12. Both parties requested the panel to review, pursuant to **Rule 333 'RoP'** some of the decisions taken during the interim conference and the panel decided that the contested decisions to be addressed during the oral hearing.
13. Finally, the oral hearing was held on 6 November 2024.

GROUNDS FOR THE DECISION

Standstill agreement

14. In its rejoinder to claimants' reply, the defendant argues that the action is inadmissible due to the breach of the standstill agreement signed by the parties, according to which a party must inform the respective other party of the intention to file a lawsuit 90 days before the lawsuit is filed.
15. It contends that the circumstance regarding the existence of such a clause and its breach by the claimants had already been raised in the preliminary objection, and therefore, the introduction of the admissibility objection only in this written pleading (and not in the initial defence to revocation) cannot be considered untimely.
16. The Court finds that, regardless of any consideration as to the timeliness of the allegation, given that in the preliminary objection the facts were alleged to establish a lack of jurisdiction, whereas in the rejoinder they were alleged to establish the inadmissibility of the claim, a breach of a standstill clause does not necessarily divest the breaching party of the right to bring an action but it may only give rise to liability for breach of contract.
17. Indeed, it should be borne in mind that the principle of effective judicial protection is a general principle of EU law stemming from the constitutional traditions common to the Member States, which has been enshrined in Articles 6 and 13 of the ECHR and which has also been reaffirmed by Article 47 of the Charter of Fundamental Rights of the European Union (**see CJEU 16 July 2009, C-12/08, Mono Car Styling**) and while fundamental rights do not constitute unfettered prerogatives and may be restricted, the restrictions must correspond to objectives of general interest pursued by the measure in question and must not involve, with regard to the objectives pursued, a disproportionate and intolerable interference which infringes upon the very substance of the rights guaranteed (**see, CJEU 18 March 2010, C-317/08, Alassini and Others**).
18. These principles apply to restrictions imposed by legislative provisions and also to those stipulated by the parties, given that contractual freedom is not absolute and may be limited when it conflicts with other interests protected by the legal system.
19. In the present case, the temporal restriction on the right to sue is not justified by any public interest, but rather, as acknowledged by the parties, is solely intended to provide them a cooling-off period to assess the possibility of a settlement, and thus, is driven by a private interest.
20. It follows that the claim is admissible and the issue of the breach of the standstill clause is irrelevant to this determination.

Admissibility of late filed invalidity grounds and late filed prior art documents

21. As previously mentioned, the claimants introduced further invalidity attacks with its reply to defence to revocation, based on new filed documents ('Menot' and 'Lieberman'), arguing that these documents were identified from additional search for relevant prior art that was necessary to address the defendant's defence and auxiliary requests, and concerning also the dependent claims.
22. The claimants also filed invalidity challenges of the dependent claims, in addition to the added matter attack, justifying the late filing with the argument that the defendant had not asserted infringement of the dependent claims, nor were they ever addressed in any pre-suit discussions between the parties, but that the defendant had then asserted the infringement of the dependent claims 2, 3, 4 and 13 in its infringement action lodged before the Hamburg Local Division of the Unified Patent Court (No. ACT_10800/2024) and now combines claim 1 with several dependent claims for its submitted auxiliary requests.
23. By order issued pursuant to **Rule 105 'RoP'** on 10 October 2024 the judge-rapporteur stated that the grounds of invalidity not asserted in the statement for revocation or not relating to the amended version of the patent are not admissible in principle, included those of the dependent claims, and shall be disregarded as late filed. The panel agrees with the judge-rapporteur's statement and considers appropriate to give a more accurate reasoning on the issue.
24. **Rule 44 'RoP'** states that the statement for revocation shall contain *"... (e) one or more grounds for revocation, which shall as far as possible be supported by arguments of law, and where appropriate an explanation of the claimant's proposed claim construction; (f) an indication of the facts relied on; (g) the evidence relied on, where available, and an indication of any further evidence which will be offered in support ...*".
25. Similar requirements are requested in the statement of claim as **Rule 13 'RoP'** provides that this written pleading shall contain "*an indication of the facts relied on*" [lett. (l)], "*the evidence relied on*" [lett. (m)] and "*the reasons why the facts relied on constitute an infringement of the patent claims, including arguments of law and where appropriate an explanation of the proposed claim interpretation*" [lett. (n)].
26. In general, the parties are under an obligation to set out their full case as early as possible (**Preamble 'RoP', para. 7, last sentence**).
27. This legal framework introduces the so-called 'front loaded' procedural system whereby a claimant is required to concretely elaborate its arguments and evidence in its first written pleading (see, on this issue, **Paris CD, decision issued on 29 July 2024, UPC_CFI_263/2023**; **Brussels LD, order issued on 8 July 2024, UPC_CFI_376/2023**). The rationale behind these provisions is to ensure that the defendant is aware of the factual elements and grounds upon which the claim against him is based, as well as the evidence

available to the claimant, thereby enabling him to prepare an adequate defence, and, at the same time, to expedite the proceedings. This is one of the primary objectives of the Court, which would be undermined if the claimant were permitted to gradually introduce new factual circumstances, new legal arguments, or new evidence into the proceedings.

28. However, these provisions must also be interpreted in the light of the principle of proportionality, as set out in the **Preamble of the 'RoP'**, which requires that the parties should not be burdened with tasks that are unnecessary to achieve the stated objective. In this regard, it must be noted that **Rule 44 'RoP'** requires an "*indication*" of the facts relied on and this seems to support an interpretation of the relevant provisions contrary to an overly strict application of the 'front loaded' procedural system.

29. Furthermore, account must also be taken of the need, which is served by the principle of procedural efficiency, to avoid excessive and overly detailed allegations of facts and the production of multiple documents in relation to matters that can be presumed to be known to the opposing party and not to be disputed by them, provided that their allegation and evidence is preserved if challenged, thus considering the natural course of the procedural dynamics.

30. Moreover, an excessive and redundant allegation of facts and production of documents can also become an obstacle to the effective exercise of the right of defence, imposing on the opposing party a burdensome task of studying the claim and the evidence presented, and hindering the efficient functioning of the judicial response, by overburdening the Court with unnecessary activities.

31. Additionally, it can be argued that a document may be introduced into the proceedings at a later stage, if it was created or became available to the party during the proceedings, given the principle of fairness which protects a party that has acted in a diligent way.

32. It can therefore be stated that, in revocation actions, the claimant is required to specify in detail the grounds of invalidity that allegedly affect the contested patent, as well as the prior art documents relied upon to support any allegation of lack of novelty or inventive step. This defines the subject matter of the dispute and enables the defendant to understand the allegations made against it and to prepare an adequate defence, as well as allowing the Court to determine the scope of its jurisdiction in relation to the claim.

33. Consequently, the claimant cannot introduce new grounds of invalidity of the attacked patent or introduce new documents considered novelty destroying or affecting inventive step in subsequent written acts. This would result in a broadening or, in any case, a modification of the subject matter of the dispute, constituting an amendment of the case and falling within the scope of **Rule 263 'RoP'**, which may only be permitted by the Court upon specific request and after demonstrating that the requirements of that Rule have been met.

34. Similarly, the claimant must specify in the statement of claim the facts that it considers necessary to prove in order to succeed in its claim, together with the relevant evidence.

35. However, it should be noted that in certain situations, following the defence raised by the defendant, the claimant may need to allege new facts, insofar as they are considered capable of supporting the main facts already timely alleged and disputed by the defendant. In this case, the need to respond to the defendant's defence, the terms of which cannot be foreseen ex ante by the claimant, justifies the introduction of such new facts in the reply to defence to revocation.

36. Likewise, the need to produce new evidence may arise from the defendant's defence which disputes the facts alleged by the claimant or the probative value of the evidence already filed in Court.

37. This is consistent with the principles set by the Court of Appeal (**decision issued on 21 November 2024, UPC CoA 456/2024**) according to which while the parties are required to set out their case as early as possible in the proceedings nevertheless specific new arguments may be admitted into the proceedings in consideration of specific circumstances of the case.

38. Applying these principles to the present case, it must be concluded that, as already stated by the judge-rapporteur in the forementioned order issued on 10 October 2024, the grounds for revocation based on 'Menot' and 'Lieberman' shall be excluded from consideration with regard to the patent as granted. These documents may be admitted to the proceedings only for the purpose of responding to the allegation contained in the defence to revocation and to the application to amend the patent.

39. Similarly, the invalidity challenges of the dependent claims filed by the claimants with their reply must be excluded from consideration as they were late filed. In this regard, the Court notes that the fact that an action has been filed by the defendant against the claimants based (also) on the infringement of the dependent claims does not constitute a justification of the late filing, as it did not prevent the claimants to challenge the validity of these claims in the current proceedings from the outset and, anyway, it does not cause the claimants for any harm as they can raise these challenges in the infringement action.

40. Consequently, the order issued by the judge-rapporteur denying the permission to the defendant to further amend the patent must be confirmed, as the request was based on the assumption that the new invalidity attacks against claim 1 and the dependent claims filed by the claimants with their reply were admissible, which are not.

The patent at issue

41. The patent at issue contains 13 claims in which claim 1 is an independent claim and claims 2 to 13 are dependent on claim 1. As previously mentioned, the invention is related to a system for ambulatory drug infusion.

42. Ambulatory infusion apparatuses are known in the art for a variety of applications and, in particular, when

adapted for insulin administration form a basis for a state-of-the-art therapy of diabetes mellitus by Continuous Subcutaneous Insulin Infusion ('CSII'). Those devices are typically computer controlled micro dosing pumps which are adapted to be worn continuously and concealed from view, are of the syringe-driver type and comprise a typically cylindrical drug cartridge out of which insulin is forced into an infusion line by displacing a cartridge plunger in a controlled manner (see para. [0002]).

43. For a variety of technical as well as convenience and application-related reasons, recent systems are based on a different fluidic architecture and therefore a drug cartridge as known from stateof-the-art systems is less favourable and may therefore be replaced by a flexible container (para. [0003]).

44. Considering that patients are usually not particularly trained in the medical field, and in many cases, diabetes is accompanied by other diseases or handicaps that can impair operation, and that, accordingly, simple operation of the device is of great importance, in particular because the drug containers typically only hold the amount for a maximum of one week's use and therefore have to be filled and replaced frequently by patients themselves (para. [0005]), the patent in suit describes it as its overall objective to provide devices which enable a flexible container to be easily filled with a defined drug amount and at the same time prevent overfilling (para. [0009]).

45. As suggested by the claimants, and not objected by the defendant, claim 1 of the patent at issue, which is the only claim validly challenged, can be structured as follows:

> (1.1) System for ambulatory drug infusion over an extended time period, the system comprising:
> (1.2) a) an ambulatory infusion apparatus, the infusion apparatus comprising:
> (1.2.1) a flexible container (20),
> (1.2.2) a dosing unit in fluidic connection with the flexible container (20)
> (1.3) the system further comprising:
> b) a filling apparatus for the flexible container (20), the filling apparatus comprising
>> i. a hollow support structure (5, 5', 105, 10, 10', 110) defining a container compartment (15, 15a, 15b), (1.3.1) a cartomizer body dimensioned to hold a vaporizable substance
>> ii. the container compartment (15, 15a, 15b) being adapted to receive, fully or in part, the flexible container (20),
>> iii. the support structure (5, 5', 105, 10, 10', 110) being adapted to limit an expansion of the flexible container (20) by contacting the flexible container (20) upon being filled, thus defining a maximum filling volume of the flexible container (20),
>
> (1.4) characterized in that the infusion apparatus further comprises an electronic controller unit configured to control operation of the dosing unit, and
> (1.5) the flexible container (2) has a partly rigid container body and a top or cover made from a flexible foil sheet.

Added matter in feature 1.5.

46. The claimants argue that feature 1.5 contains an impermissible intermediate generalization. They note that the feature was not in the claims of the patent application but was added during the examination proceedings before the European Patent Office.

47. In particular, the claimants point out that feature 1.5 is mentioned only once in the patent description in para. [0003], last sentence, where it says that: "*In a further variant, the container body may be partly rigid and be made, for example tank-like and have a cover or top made from a flexible foil sheet*".

48. They assume that this disclosure consists of a combination of the three features: "*partly rigid*"; "*tank-like*"; and "*having a cover or top made from a flexible foil sheet*". They argue that excluding the "*tank-like*" feature, the remaining features have been isolated from their original context, and that a skilled person would not recognize their direct and unambiguous applicability to the general context of the patent.

49. The Court notes that the "*partly rigid*" container body is presented by the sentence in para. [0003] as the main feature of a variant of the system described therein, and the feature that follows is optionally added ("*for example*") for the container body. Thus, the sentence addresses a variant that must have a specific feature (a "*partly rigid*" container body) and may have, for example, the other feature (a container body being made "*tank-like*"").

50. It is evident from the reading of the sentence that feature 1.5 of the claim does not mention the specific feature consisting in a container body being made "*tank-like*". Therefore, the issue to be addressed is whether the sentence discloses (also) a system in which the container body is partly rigid (feature A), has a top or cover made from a flexible foil sheet (feature C) and is not tanklike (feature B), as this system is covered by feature 1.5.

51. In this regard, the issue must be addressed from the point of view of the person skilled in the art, who may be identified – lacking any indication from the parties – in a generic technical expert who understands the technical meaning of these features, and must take into account the entire specification as filed (description, claims and drawings), which relates to a container that is completely flexible, with the only exception of the variant mentioned in the sentence reported above, and the aim of the proposed invention, which is to control the exact volume of the container or better to avoid that the volume becomes excessive.

52. In the variant mentioned in that sentence, the container body is partly rigid; hence, feature A means that the container body has a rigid part and a flexible part. Then, introduced by the words "*and, for example*", feature B is added as a possible or suggested feature for the partly rigid container. Whether the other feature C ("*having a cover or top made from a flexible foil sheet*")

is required or not for the variant is of little interest, as this feature C is anyway present in claim 1 of the patent as granted.

53. Feature B is not used in any other parts of the application as originally filed. So, the description of the application cannot give any help in interpreting this feature B; therefore, the skilled person would consider its plain meaning in the context of this sentence only. The fact that feature C clearly refers to the flexible part of the container body does not authorize to associate feature B with the rigid part of the container body, as the expression "*tank-like*" does not imply in itself any rigidity. Rather, since feature B reports to "*tank*", i.e. to a word that is normally used to indicate a holder where a certain amount of a loose substance is stored for future use, the skilled person would intend "*tank-like*" as referring to the ability of the container body to hold an amount of medicament that is or can be larger than the amount that is delivered with a single use.

54. Thus, the suggested feature B can only be intended by the skilled person as independent from feature C, as the technical implications of these features B and C are not related one to the other. Indeed, if the container body is made tank-like, there is no compelling technical reason why a flexible part thereof should be made from a foil sheet; conversely, if any flexible part is made from a foil sheet, there is no compelling technical reason why any part of the container body should be made tank-like.

55. It follows that the sentence in para. [0003] discloses a variant including only features A and C (and not B).

56. Therefore, feature 1.5 of claim 1 – including features A and C – is supported by the description of the application as filed and **Article 123 (2) of the European Patent Convention** is not violated.

Lack of novelty in view of 'Glejboel'.

57. 'Glejboel' (D1) describes a medication delivery device for delivering a liquid medicament from a collapsible reservoir to the human body. The device employs a displacement pump where the displacement stroke volume can be adjusted (see para. [0001]).

58. The claimants argue that 'Glejboel' discloses all the features of claim 1 of the patent, while the defendant objects that at least feature group 1.3, and more particularly feature 1.3 iii, namely "*the support structure (5, 5', 105, 10, 10', 110) being adapted to limit an expansion of the flexible container (20) by contacting the flexible container (20) upon being filled, thus defining a maximum filling volume of the flexible container (20)*", is not disclosed.

59. The Court notes that Fig. 1 of 'Glejboel' is understood from the skilled reader in the way that the upper surface of the collapsible reservoir 7 needs to be sufficiently spaced from any possible cover surface (anyway, not shown in any drawing nor described in words), at least to leave the space for movement and operation of further elements such as the dosing spring 5 and the dosing wheel 6.

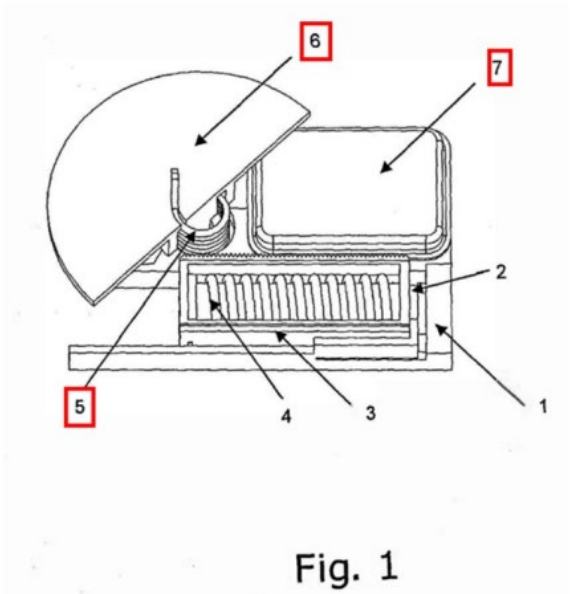


Fig. 1

60. The fact that the dosing spring 5 and the dosing wheel 6 are not represented in Figs. 4a, 4b and 5, and that different numbering is used in these figures for the collapsible reservoir (7 in Fig. 1, 304 in Fig. 4b, 401 in Fig. 5), does not mean that these figures relate to different embodiments where the dosing spring 5 and the dosing wheel 6 are not present. Indeed, Figs. 4a, 4b and 5 are focused to show specific aspects of the invention and do not include all elements of the device. However, they clearly show the same pin (unnumbered, pointed by a square here below) that supports the dosing spring 5 and the dosing wheel 6 visible in Fig. 1.

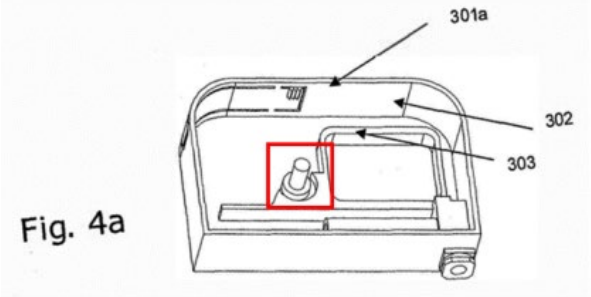


Fig. 4a

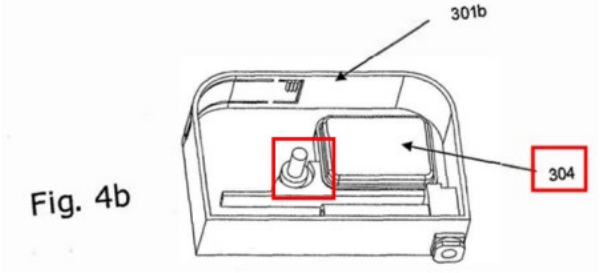


Fig. 4b

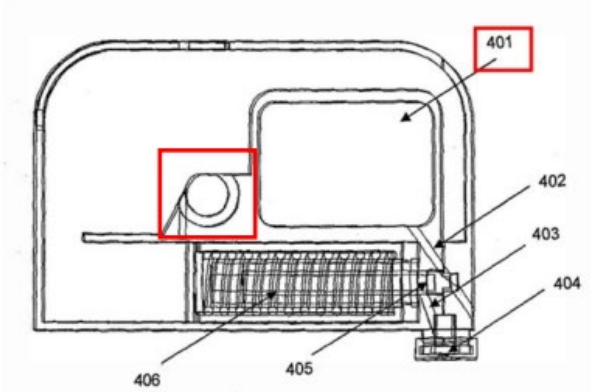


Fig. 5

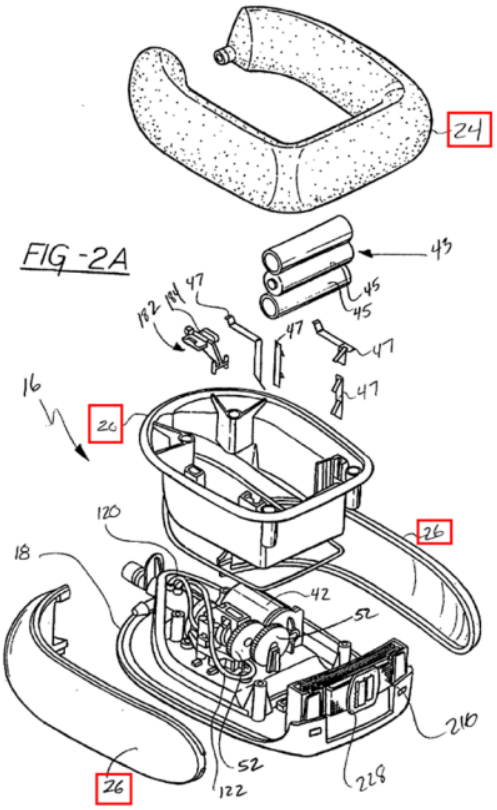
61. Moreover, the dosing spring 5 and the dosing wheel 6 are necessary elements for the operation of the system of 'Glejboel'.

62. Therefore, when the collapsible reservoir 7, 304, 401 expands upon filling, it could expand upwards (in the sense of the figures) but it could not reach any top cover. Therefore, the expansion of the collapsible reservoir of the device of 'Glejboel' is not limited by any support structure of the device.

63. The conclusion can only be that feature 1.3iii is not disclosed therein and thus claim 1 of the patent is novel over 'Glejboel'.

Lack of inventive step: a) 'Diaz' as a starting point and 'Robertson'

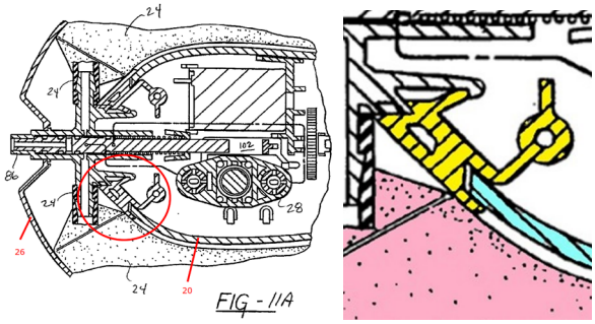
64. The Court agrees with the claimant that 'Diaz' (D2) may be considered as a suitable starting point to evaluate inventive step of claim 1 of the patent. Indeed, 'Diaz' relates to an integrated medication delivery system for delivering medication to a patient which is primarily used throughout the medical profession to deliver pain control medication and other medications intra-operatively, subcutaneously, and percutaneously to the patient after a surgical, or some other medical, procedures. 65. 'Diaz' discloses a medication delivery system, capable of delivering a medication from a flexible reservoir 24 to a patient. The system includes a base housing 16 that supports the flexible reservoir 24 for storing the medication and a pump assembly 28 for delivering the medication. 66. The general architecture of the system of Diaz can be appreciated from the following exploded view of figure 2A.



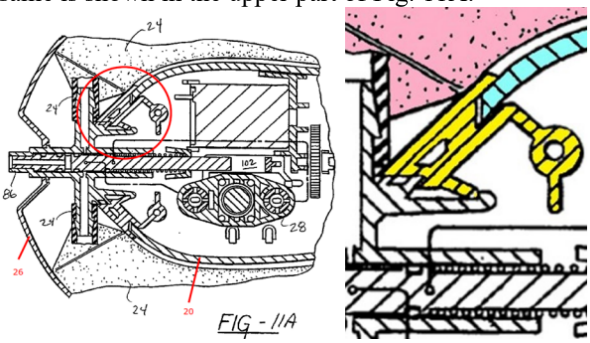
67. The claimants argue that the only difference between 'Diaz' and claim 1 of the patent at issue is that 'Diaz' does not disclose feature 1.5, but that starting from 'Diaz' the skilled person, looking for an alternative ambulatory system that allows filling of a flexible container with a defined drug amount while preventing overfilling, would inevitably look into 'Robertson' (D3) which serves to carry and preserve medication and discloses a flexible container carrier for a medicament.

68. The Court is the opinion that also feature 1.3iii is missing in 'Diaz'. Using the wording of feature 1.3iii with the references to the elements of 'Diaz', the issue is to establish whether in this latter document "*the support structure [20, 26] is adapted to limit an expansion of the flexible container [24] by contacting the flexible container [24] upon being filled, thus defining a maximum filling volume of the flexible container [24]*".

69. Given that 'Diaz' does not describe in words the individual features that constitute feature 1.3iii, the actual disclosure of Diaz can be better understood from its figures, in particular by referring to Fig. 11A (n.b.: Fig. 11A shows the rigid parts 20 and 26 without any reference number, so such reference numbers have been added here, for a better understanding). By enlarging the portion in the area of the red circle and then colouring, the actual content of the figure can be better appreciated.



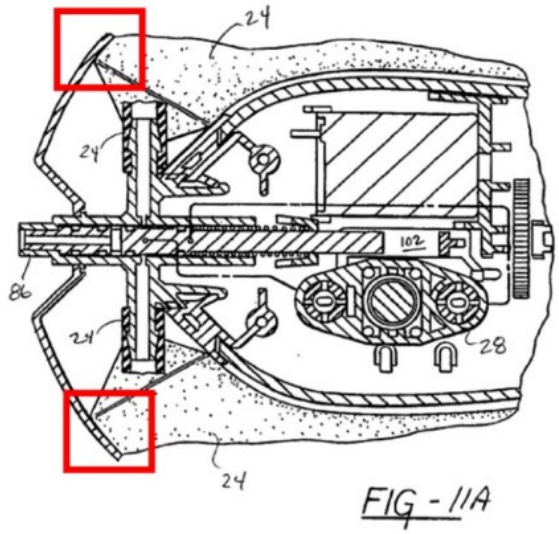
70. The colours only highlight what is already shown by the hatching. The part coloured in yellow appears to be an element that supports and holds the inner rigid wall 20, coloured in blue. The rigid wall 20 is not contacted by the medication reservoir 24, coloured in pink. The same is shown in the upper part of Fig. 11A.



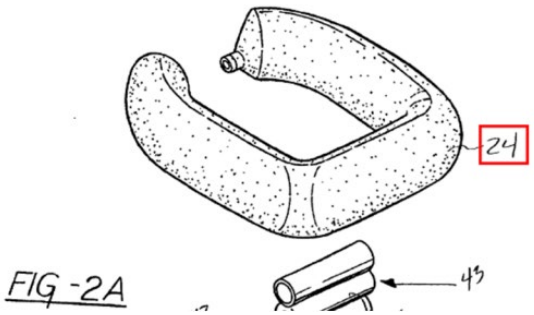
71. It is evident that Fig. 11A shows an empty gap between the medication reservoir 24 and the rigid structure 20, 26.

72. 'Diaz' does not specify whether the situation shown in Fig. 11A corresponds to the full condition of the flexible reservoir 24 or not. Thus, the gap shown in Fig. 11A cannot be taken as a positive disclosure of a system in which the expansion of the flexible reservoir 24 is not limited by the rigid structure 20, 26, but certainly – due to the gap – Fig. 11A does not provide a clear and unambiguous disclosure of a system in which the expansion of the flexible reservoir 24 is limited by the rigid structure 20, 26.

73. Besides, in Fig. 11A two areas are visible where the medication reservoir 24 contacts the rigid casing structure 26.



74. However, such contact in itself does not imply that the casing structure 26 limits the expansion of the medication reservoir 24 "*thus defining a maximum filling volume*" thereof. Rather, the maximum filling volume appears to be defined by the medication reservoir 24 itself. It should be noted that the medication reservoir 24 is said to be flexible (see, para. [0066] of 'Diaz'), not necessarily expandable. The skilled person – who, as said before, can be identified as a generic technical expert able to understand the technical meaning of the features described, both in the patent and in the prior art- knows that the word expandable implies a change (increase) of a volume, while flexible just implies a change of shape. Also, the already mentioned Fig. 2A does not suggest that the shape of reservoir 24 can change by expanding upon filling, rather it suggests that the shape of the reservoir 24 when filled is well defined.



75. Similarly to what previously stated in respect of Fig. 11A, the way the reservoir 24 is represented in Fig. 2A cannot be taken as a positive disclosure of a system in which the flexible reservoir 24 cannot expand upon filling because limited by the rigid parts 20, 26 that surround it. However, certainly Fig. 2A does not provide a clear and unambiguous disclosure of a system in which the expansion of the flexible reservoir 24 is limited by the rigid parts 20, 26.

76. Moreover, in 'Diaz', at para [0066], it is stated that "*the reservoir casing 26 at least partially surrounds the reservoir 24 to protect the medication that is to be delivered to the patient 12*." The skilled person understands that this protective function would be lost or at least jeopardized if the flexible reservoir 24 were allowed to expand so as to contact any of the rigid casings 20 or 26, since in that situation the rigid casings 20, 26 would exert a pressure against the flexible container 24. Also this consideration suggests that the gap visible in figure 11A and discussed above is intended to remain, even when the flexible reservoir 24 is completely filled.

77. In conclusion, it must be recognized that feature 1.3iii, in addition to feature 1.5, is not disclosed by 'Diaz'.

78. 'Robertson' does not provide any suggestions to modify the system of 'Diaz' to include those missing features.

79. Indeed, 'Robertson' relates to a container for solid medicaments, like pills. The container for the solid medicaments includes a rigid housing 12 closed by an upper thin elastic film 44.

80. First, it seems rather unlikely that the skilled person would have consulted 'Robertson' in order to improve in any respect the system of 'Diaz', as Robertson relates to a completely different system: a box for pills and not a delivery system for liquid medicaments.
81. Then, 'Robertson' does not disclose anything similar to feature 1.3iii. Thus, apart from any possible motivation to consult and to combine, the skilled person could have not received by 'Robertson' any suggestions to include in the system of 'Diaz' a feature that is not disclosed by 'Robertson' itself.
82. Therefore, the combination of 'Diaz' and 'Robertson' cannot affect the inventive step of claim 1 of the patent.

Lack of inventive step: b) 'Glejboel as a starting point and 'Diaz' and/or 'Robertson'

83. The previous analysis has shown that neither 'Glejboel', nor 'Diaz' nor 'Robertson' disclose feature 1.3iii.
84. Therefore, the conclusion can only be that this combination cannot affect the inventive step of claim 1 of the patent.

Conclusions

85. For these reasons, the grounds for invalidity raised by the claimant against the patent at issue and addressed by the panel are not well founded and any arguments of the parties which have not been specifically considered must be deemed absorbed.
86. Therefore, patent EP '231 shall be maintained as granted

Costs.

148. The costs of the Court and of the defendant shall be borne by the claimants, as the unsuccessful party.
149. The panel notes that during the interim conference, the value of the revocation action for the purpose of applying the scale of ceilings for recoverable costs was set at 1,000.00 euros and confirms this evaluation.

DECISION

The Court:
a) dismisses the revocation action filed by Tandem Diabetes Care, Inc. and Tandem Diabetes Care Europe B.V. against Roche Diabetes Care GmbH;
b) maintains the European patent EP n° 2 196 231 B1 as granted;
c) orders that the costs of the proceedings shall be borne by the claimants.
Issued on 18 December 2024.
Presiding judge and judge-rapporteur Paolo Catallozzi
Legally qualified judge Tatyana Zhilova
Technically qualified judge Giorgio Checcacci
Clerk Margaux Grondein
