Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

UPC Court of Appeal

UPC_CoA_768/2024
APL_64374/2024

Order

of the Court of Appeal of the Unified Patent Court
issued on 30 April 2025
concerning a request for provisional measures

HEADNOTES:

1. The interpretation of a patent claim is a matter of law. Therefore, the Court cannot leave the judicial task of interpreting the patent claim to an expert but has to construe the claim independently.
2. The skilled person is a notional entity that cannot be equated with any real person in the technical field of the invention. The decisive factor is not the individual knowledge and abilities of a person, but rather the general specialist knowledge that is customary in the relevant field of technology, as well as the average knowledge, experience, and abilities in this specialist field. It is for the Court, not the expert, to assess these circumstances.
3. In general, the risk of the continuation of the infringement arises from a prior infringement, if the infringer does not issue a cease-and-desist declaration with a sufficient penalty clause.
4. If one party is partially unsuccessful, the costs do not always have to be apportioned proportionately. In particular where a party's unsuccessful claim was relatively minor and did not cause further costs, its entire costs may be awarded against the other party.

KEYWORDS:

- Claim construction – expert opinion
- Person skilled in the art
- Continuation of infringement (Art. 62(1) UPCA)
- Cost decision if a party succeeds only in part (Art. 69(2) UPCA)

APPELLANT (AND APPLICANT IN THE PROCEEDINGS BEFORE THE COURT OF FIRST INSTANCE)

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RESPONDENT (AND DEFENDANT IN THE PROCEEDINGS BEFORE THE COURT OF FIRST INSTANCE)

EOFlow Co., Ltd., 302Ho, HUMAX VILLAGE, 216 – 13595, Hwangsaeul-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, Republic of Korea
(hereinafter EOFlow)

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LANGUAGE OF THE PROCEEDINGS

English

PATENT AT ISSUE

EP 4 201 327

PANEL AND DECIDING JUDGES

Panel 2
Rian Kalden, legally qualified judge and presiding judge,
Ingeborg Simonsson, legally qualified judge,
Patricia Rombach, legally qualified judge and judge-rapporteur,
Steven Richard Kitchen, technically qualified judge,
Udo Matter, technically qualified judge

IMPUGNED ORDER OF THE COURT OF FIRST INSTANCE

Milan Central Division, 22 November 2024, ORD_62486/2024, App_39640/2024, UPC_CFI_380/2024

ORAL HEARING

10 March 2025

SUMMARY OF FACTS

1. Insulet is the registered proprietor of the European patent with unitary effect 4 201 327 (hereinafter: patent at issue). The patent at issue, filed on 29 March 2013, claims priority from 30 March 2012 (US 2012618028). The granting of the patent at issue was published on 19 June 2024.

2. The patent at issue relates to fluid delivery devices for delivering therapeutic liquids to a patient, and more particularly, to an infusion pump for delivering therapeutic liquids to a patient. Its claim 1 reads as follows in the language of the proceedings under Art. 70 (1) EPC:

> A fluid delivery device comprising:
> a fluid reservoir (130);
> a transcutaneous access tool (172) fluidly coupled to the fluid reservoir (130); and
> a drive mechanism (150) for driving fluid from the reservoir (130), the drive mechanism comprising:

a drive wheel (156, 256);
a plunger (136) received in the reservoir (130); and
a leadscrew (152) extending from the plunger (136);
characterized in that the drive mechanism (150) further comprises:
a nut (154) threadably engaged with the leadscrew (152); and
a clutch mechanism (160) coupled to the drive wheel (156, 256), wherein the clutch mechanism (160) is configured to allow the nut (154) to pass through the clutch mechanism (160) when disengaged and is configured to grip the nut (156) when engaged such that the drive wheel (156, 256) rotates the nut (156) to advance the leadscrew (152) and the plunger (136) into the reservoir (130).

3. Insulet is a US based medical device company. Insulet is selling inter alia a disposable, wearable tubeless insulin management system which enables the automated dispense of insulin (a so-called insulin patch pump), in its current version of “Omnipod”, namely the “Omnipod 5”.

4. EOFlow is a manufacturer based in South Korea. It manufactures an insulin pump named “EOPatch” and “GlucoMen Day Pump” (hereinafter `attacked embodiment´). EOFlow ships the attacked embodiment to the company A. Menarini Diagnostics s.r.l in Italy (hereinafter Menarini), the exclusive European distributor of the attacked embodiment.

5. On 21 June 2024 Insulet sent EOFlow a warning letter based on the patent at issue and asked EOFlow to sign a cease-and-desist declaration until 1 July 2024. EOFlow´s South Korean counsel asked for a time extension to answer until 15 July 2024.

6. On 3 July 2024, Insulet filed an application for provisional measures before the Milan Central Division against EOFlow. In summary, Insulet requested without hearing EOFlow (ex parte) an injunction concerning infringement actions in the territories of the Member States of the Unified Patent Court based on claim 1 as granted as well as the declaration of origin and distribution channels, the quantities delivered, received or ordered as well as the price obtained, the identification of all parties involved in the production or distribution, and payment of the costs of the proceedings. Furthermore, Insulet requested that the Court ordered periodic penalties in case of non-compliance with the order of the Court.

7. Insulet filed also an application for provisional measures against Menarini before the Milan Local Division.

8. By order issued on 8 July 2024 the Milan Central Division denied the ex-parte application and set the hearing for 6 September 2024.

9. Insulet amended the claims in its submission of 27 August 2024 and 26 September 2024 with 4 auxiliary requests. On 26 August 2024, EOFlow filed a request for joinder of the proceedings regarding Menarini and EOFlow. On 28 August 2024, the Milan Central Division issued an order postponing the hearing already set and making the postponement subject to a more thorough evaluation of EOFlow´s request for a joint discussion, on which Insulet was asked to express its opinion.

10. By the impugned order, after a hearing on 16 October 2024, the Milan Central Division rejected the application for a preliminary injunction against EOFlow as well as the "ancillary" requests.

11. The Milan Central Division held that the subject matter of claim 1 of the patent at issue as granted appears to be lacking novelty in view of the prior art US 2009/0124994 A1 (hereinafter US`994). Hence, the Court of First Instance (hereinafter: CFI) considered it more likely than not that the patent at issue is invalid. The CFI held that auxiliary requests in proceedings for provisional measures are not admissible.

12. By order issued on 22 November 2024 (ORD_56587/2024, ACT_40442/2024, UPC_CFI_400/2024) the Milan Local Division rejected the application for a provisional injunction against Menarini as well.

13. Insuled appealed the order of the Milan Central Division (impugned order) as well as the order of the Milan Local Division.

14. The Court of Appeal heard both cases together (R. 302.3 RoP). During the hearing, settlement discussions were held between Insulet, Menarini and EOFlow. The parties were given the opportunity to notify the Court within a specified period if the settlement discussions were successful. While a settlement was reached between Insulet and Menarini, the settlement discussions between Insulet and EOFlow were unsuccessful.

REQUESTS OF THE PARTIES

15. In summary, Insulet requests that the Court of Appeal:
    - I. set aside the impugned order,
    - II. grant provisional measures to the extent requested by Insulet in the first instance (including the auxiliary requests),
    - III. grant leave to change its claims under the auxiliary requests and also to other related ancillary claims,
      order EOFlow to pay periodic penalties of up to € 250,000 or another amount as the Court may order, to the Unified Patent Court, for each violation of, or non-compliance with, the order(s) plus up to € 100,000 for each day, or part of a day counting as an entire day, that the violation or non-compliance continues, or another amount as determined by the Court.
    - IV. order that the above orders are effective and enforceable immediately,
    - V. order EOFlow to pay the costs of the proceedings, or in the alternative, EOFlow bears reasonable and proportionate legal costs and other expenses incurred by Insulet in these proceedings (interim award of costs), up to the applicable ceiling, or in the amount as the Court may order,
    - VI. set the value in this dispute at € 2,500,000.

16. EOFLow requests:

    A. that the Court of Appeal
        - I. reject the appeal,
        - II. order Insulet to pay the costs of the appeal proceedings,
        - III. order Insulet to pay to EOFlow € 100,000 as interim costs for the appeal proceedings.

    B. in the alternative to A., refer the case back to the CFI,

C. in the alternative to A. and B., i.e. if the Court should neither reject the appeal nor refer the case back, allow EOFLow to continue the alleged infringing activities subject to provision of security by EOFlow, the amount of which to be determined by the Court.

D. in the alternative to C., apply to any provisional injunction ordered against EOFlow the proviso that

I. the territories of Austria, Bulgaria, Denmark, Estonia, Finland, France, Germany, Latvia, Lithunia, Luxembourg, Malta, Portugal and Slovenia are excluded from the geographical scope of this provisional injunction; and

II. allow EOFlow to continue – if the Court deems appropriate subject to provision of security by EOFlow, the amount of which to be determined by the Court – to supply Menarini with the attacked embodiments to ensure that Menarini may continue to supply the attacked embodiments to public and private hospitals and health care providers under tenders awarded to EOFlow before the service of the application for provisional measures; or

E. in the alternative to D.,

I. allow EOFlow to continue – if the Court deems appropriate subject to provision of security by EOFlow, the amount of which to be determined by the Court – to supply Menarini with the attacked embodiments to ensure that Menarini may continue to supply the attacked embodiment to patients to whom the attacked embodiment was prescribed prior to the date of service of the application for provisional measures for at least six months of the date of the decision of the Court; and

II. allow EOFlow to continue – if the Court deems appropriate subject to provision of security by EOFlow, the amount of which to be determined by the Court – to supply Menarini with the attacked embodiments to ensure that Menarini may continue to supply the attacked embodiment to patients who have been prescribed the attacked embodiment before the date of service of the application for provisional measures and have been certified by a diabetologist to be unable to use an insulin pump different from the attacked embodiment indefinitely;

F. in the alternative,
in any event where the Court orders a provisional injunction, order Insulet to provide a security for the enforcement of a provisional injunction and/or other provisional measure, the amount to be determined by the Court, whereas the security should not fall below EUR 2,500,000.

PARTIES' SUBMISSIONS

17. Insulet submits, summarised and insofar as relevant, as follows

- Claim 1 is directed to a fluid delivery device in its assembled state.
- EOFlow and the Central Division ignore that the states/couplings mentioned in claim 1 must be realized at the same time.
- A threaded engagement of the nut with the leadscrew is also required when the nut passes through the clutch mechanism in its disengaged state.
- It should be noted that the skilled person distinguishes between a "clutch" and a "coupling". A coupling does not have a disengaged state.
- The Central Division did not understand the teaching of US´994 correctly.
  - The Central Division referred to Figure 4 of US'994 and simply alleged that the feature "the clutch mechanism (160) is configured to allow the nut (154) to pass through the clutch mechanism (160) when disengaged" is disclosed without providing any reasoning. The exploded view of Figure 4 does

not provide a disclosure that the shaft (32) should be configured to pass through the one-way clutch when the fluid delivery device is in its mounted state.

- In particular, the shaft (32) cannot be axially moved according to the teaching of US´994 at all, and US´994 is completely silent on any filling process. In addition, the Central Division incorrectly assumed that US´994 discloses the concept of moving the leadscrew (42) in an axial/longitudinal direction without any rotation, although only a rotation of the leadscrew (42) is disclosed (see e.g. claim 1) which should result in a longitudinal movement due to its engagement with the threads (80) of the keyhole element (72).
- A longitudinal movement of the shaft (32) is not possible, because in the mounted state of the drug delivery device, the shaft (32) is (fixedly) supported by a pair of base supports (70) and would thus result in a misalignment of the wheel relative to the driving mechanism shown in Figures 1 to 3, in particular relative to the piezoelectric bender (12).
- The Central Division also incorrectly assumed that US´994 does not disclose a rotation of the leadscrew (42).
- A pure longitudinal movement of the leadscrew (42) without any rotation would be blocked by the threads (80) of the keyhole element (72).
- The keyhole element (72) is necessary to transmit the rotation into a longitudinal movement of the leadscrew (42).
- Even when assuming that the keyhole element (72) must be disregarded in the embodiment of Figure 4, there is no disclosure that the rotation of the leadscrew (42) should be prohibited when the shaft (32) is rotated by the one-way clutch. And even if the snap-in connection could transmit rotational forces, this would result in a rotation of the plunger within the reservoir. This, however, is not acceptable, because a rotation of the plunger would result in an unpredictable/undefined drug delivery.
- The non-working disclosure of Figure 4 has to be disregarded.

- The weighing of interests is in favour of Insulet. It is very difficult to switch from one solution to another in the field of practice, both in terms of technical implementation and in terms of the necessary approval procedures. Once patients and hospitals have decided in favour of EOFlow´s product, Insulet´s market is initially blocked in this respect. Insulet is therefore threatened with a permanent loss of market share.
- Insulet expects to lose approximately half of its customers if infringement is not stopped immediately. Menarini has only recently had the chance to access the EU market, and it was announced that it would enter the market in 17 EU countries shortly.
- A large-scale production of the infringing embodiment by EOFlow is possible. A massive ramp-up of sales of the infringing embodiment by EOFlow/Menarini will likely result in price erosion.
- Insulet had R&D costs amounting to ca. $ 1 billion.
- Insulet and EOFlow are direct competitors on a dual product market for patch pumps.
- Insulet provides patch pumps in all UPC Contracting Member States (CMS) in which EOFlow/Menarini are currently selling the infringing embodiment. Thus, it is possible for patients of EOFlow/Menarini to directly switch to Insulet´s product. Furthermore, alternative insulin therapies are available.
- The US proceedings, where a jury found that EOFlow misappropriated certain of Insulet´s trade secrets, confirm that the infringing embodiment was developed by the deliberate use of Insulet´s technology.

18. EOFlow defends the impugned order and submits, summarised and insofar as relevant, as follows

- Claim 1 is not limited to any assembled state of the claimed device and not to any filling activity either. Claim 1 is not limited to a solution in which the nut can pass through the clutch when the reservoir is filled, since in the alternative embodiment of the patent at issue the plunger is already retracted, i.e. the nut has already passed through the clutch well before filling of the reservoir even starts.
- There is no basis to require that all features of claim 1 must be realized at the same time.
- The drive mechanism has nothing to do with the filling process at all, since the focus of the claim is on driving fluid from the reservoir.
- Claim 1 does not specify any requirement as to when the nut and the leadscrew should be threadably engaged.
- The CFI correctly applied the understanding that only the internal threaded part can be considered as the nut, not the part that has no internal threads.
- The skilled person understands that “pass through” of the nut-portion results in an alignment of the nut-portion with the gripping zone of the clutch mechanism. It is beneficial for security and stability of the clutch mechanism and for a stable transfer of the torque from the drive wheel to the nut and the lead screw if the clutch grips this threaded nut portion.
- The transcutaneous access tool is solely the tool that has the technical function to pass the fluid into the patient. A permanent coupling of the transcutaneous access tool to the reservoir is not required.
- The Central Division did understand the teaching of US´994 correctly.
  - US´994 discloses a clutch mechanism which is configured to allow the nut to pass through the clutch mechanism when disengaged. Upon assembly of the pump and drive mechanism, the threaded nut portion and part of the shaft pass through the clutch mechanism as the lead screw is snapped-in to the plunger (piston, 44).
  - Insulet does not provide any explanation as to why the shaft of US´994 would or could be fixed to the base supports, yet at the same time be free to rotate.
  - During assembly the shaft (32) with nut (41) will pass into supports (70) and through clutch (28), thus anticipating the claim feature that the clutch mechanism is configured to allow the nut to pass through the clutch mechanism when disengaged.
  - A longitudinal movement of the shaft does not result in a misalignment of the wheel (24) relative to the driving mechanism shown in Figures 1 to 3, in particular relative to the piezoelectric bender, because US´994 discloses that an extension (26) coupling the piezoelectric bender (12) and the wheel (24) via a pin (29) is fitted into a slot (31).
- All arguments presented by Insulet´s representative are attorney opinion. Such attorney opinion cannot possibly hold sway in light of the assessment of the teaching of US´994 as provided by EOFlow´s party expert.
- Starting from US´994 the subject matter of claim 1 would lack inventive step. In addition, the subject matter of claim 1 would neither be novel nor inventive over WO´504.
- The patent at issue is likely not infringed either.

- There is no necessity for granting provisional measures.
  - When weighing up the interests of the parties to the dispute, the consequences for EOFlow in case of a provisional injunction are significantly more severe than for Insulet if provisional measures are refused. Insulet has not shown any grounds on which basis any harm to Insulet would be expected, let alone severe or even irreparable harm.
  - Only the damage expected until the possible date of an issuance of the decision on the merits if Insulet had started the main proceedings on the date of filing the application for provisional measures may be taken into account.
  - Insulet is not threatened with a significant loss of market share as a result of the sale of the attacked embodiment. There is also no risk of price erosion.
  - It is uncontested by Insulet that there are less than [redacted] patients in Europe who are currently served by the distributor Menarini with the attacked embodiment, and it is equally uncontested that these sales already started in 2023, i.e. before the patent at issue was even granted. Menarini is not partaking in any further public tenders and the attacked embodiments are only distributed via such tenders and not freely via a pharmacy.
  - EOFlow is in no position to flood the market with attacked embodiments – neither in terms of production capacities nor in terms of finances.
  - In general, harm cannot lie in the fall of stock prices or the interim loss of market capitalization.
  - Moreover, the health-related interests of EOFlow´s patients speak against the ordering of provisional measures. The brunt of the burden of a provisional injunction would have to be borne by the patients who are already served and who decided for the attacked embodiment for very specific health reasons – be it for skin irritations caused by the adhesives of other products or the mere fact that these patients regard the attacked embodiment to inflict less pain.
  - For a large number of Contracting Member States (CMS), there is also no need to grant an injunction. This is the case in Bulgaria, Estonia, Latvia, Lithuania, Malta, Portugal and Slovenia, where the Omnipod 5 is not offered by Insulet, so there is no risk of market share loss or price erosion. The same applies to Austria, Denmark, Germany, Finland and France, as Menarini does not offer the attacked embodiment in these countries.
- There is no legal basis for the requests regarding the rendering of the accounts.
- This Court is not the appropriate forum to decide upon an alleged trade secret misappropriation or even take it into consideration.

GROUNDS FOR THE ORDER

19. The Appeal against the order of the Milan Central Division is admissible and well-founded.

A. Provisional injunction

20. The main application for a provisional injunction is successful.

I. Subject matter of claim 1, 2 and 3

1. The Patent and its technical background

21. The patent at issue relates to a fluid delivery device for delivering therapeutic liquids to a patient, and more particularly, to an infusion pump (para. 1).

22. According to the description of the patent at issue, ambulatory infusion pumps have been used in the state of the art to deliver insulin to a patient. These ambulatory infusion pumps have the ability to offer sophisticated fluid delivery profiles, including variable basal rates and bolus requirements. The ability to carefully control drug delivery can result in better efficacy of the drug and therapy and less toxicity to the patient (para. 2).

23. Some infusion pumps have been designed to be relatively small, low cost, light-weight, and easy-to-use. These pumps include insertion mechanisms for causing a transcutaneous access tool, such as a needle and/or soft cannula, to be inserted into the patient. Although such pumps are effective and provide significant advantages over other insulin pumps, the design of the insertion mechanism may be improved, for example, to reduce the size of the pump, to improve the comfort to the user, and/or to incorporate continuous glucose monitoring (CGM). These pumps also include fluid driving mechanisms for driving fluid from the reservoir through the transcutaneous access tool. The fluid driving mechanisms may also be improved to facilitate assembly and use of the pump (para. 4), in particular to facilitate filling a reservoir and engagement of a drive mechanism for driving fluid out of the reservoir (para. 8, colon 3 line 58 - colon 4 line 3, para. 20, colon 7 lines 13-17).

24. Against this background, the problem underlying the invention relates to improving the fluid delivery device such that filling its reservoir is simple, while changing the device into a state for delivering fluid to a patient is efficient and reliable.

2. Feature breakdown of claim 1

25. This objective is achieved by a device according to claim 1 with the following features:

1	A fluid delivery device comprising:
2	a fluid reservoir (130);
3	a transcutaneous access tool (172) fluidly coupled to the fluid reservoir (130); and
4	a drive mechanism (150) for driving fluid from the reservoir (130), the drive mechanism comprising:
4.1	a drive wheel (156, 256);
4.2	a plunger (136) received in the reservoir (130); and
4.3	a leadscrew (152) extending from the plunger (136): characterized in that the drive mechanism (150) further comprises:
4.4	a nut (154) threadably engaged with the leadscrew (152); and
4.5	a clutch mechanism (160) coupled to the drive wheel (156; 256),
4.5.1	wherein the clutch mechanism (160) is configured to allow the nut (154) to pass through the clutch mechanism (160) when disengaged and
4.5.2	is configured to grip the nut (154, *corrected by the Court*) when engaged such that the drive wheel (156; 256) rotates the nut (154, *corrected by the Court*) to advance the leadscrew (152) and the plunger (136) into the reservoir (130).

26. The core of the invention is that the fluid delivery device includes a clutch mechanism to facilitate filling a reservoir and engagement of a drive mechanism for driving fluid out of the reservoir (para. 8, colon 3 line 58 - colon 4 line 3; para. 20, colon 7 lines 13-17).

27. Figure 11 is a top perspective view of a fluid driving mechanism of an embodiment of the invention with a clutch mechanism in a disengaged position prior to filling. It comprises a drive wheel (156, feature 4.1), a plunger (136) received in the reservoir (130) (feature 4.2), and a leadscrew (152) extending from the plunger (136) (feature 4.3).

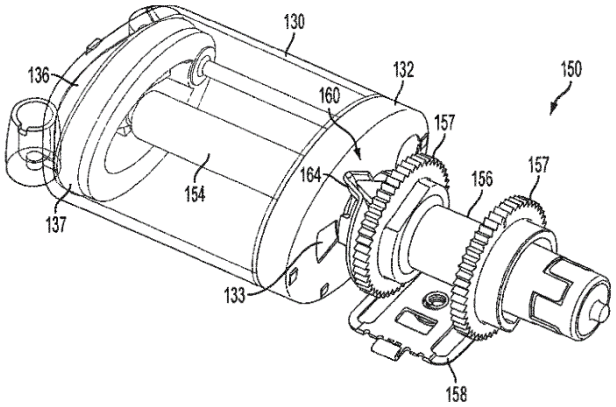


FIG. 11

28. Figure 12 is a cross-sectional view of the fluid driving mechanism shown in Figure 11.

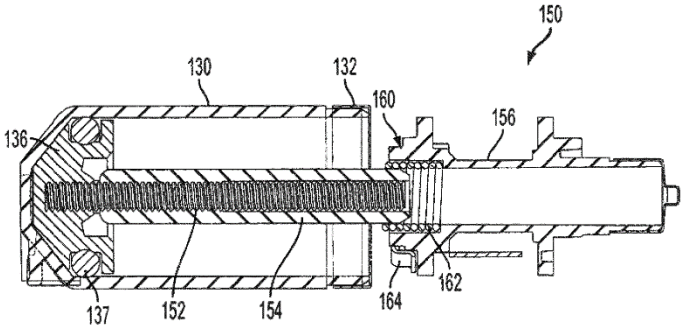


FIG. 12

29. The fluid drive mechanism (150) includes with the leadscrew (152) a first threaded member in the form of an elongated shaft with external threads extending from a plunger (136) received in the reservoir (130) (see para. 20 lines 17-21). A second threaded member a nut (154) threadably engages the leadscrew (152) (feature 4.4) and may be driven by a drive wheel (156) via a clutch mechanism (160) (see para. 20 lines 24-28), which is coupled to the drive wheel (feature 4.5).

30. When the reservoir (130) is empty (Fig. 11 and 12), the plunger (136) is positioned at one end of the reservoir (130) such that the plunger (136) is extended and the clutch mechanism (160) is disengaged (para. 21 lines 29-32). In certain embodiments, the reservoir (130) may be filled with fluid, particularly insulin, by opening an inlet port to the reservoir (130) and pumping in the insulin under sufficient

hydraulic pressure to retract the plunger within the reservoir (130). Thus, when filling the reservoir (130) the clutch mechanism (150) remains disengaged, and the plunger (136) moves to the opposite (retracted) end of the reservoir (130). This is shown in Figure 13 (see para. 21 lines 32-42).

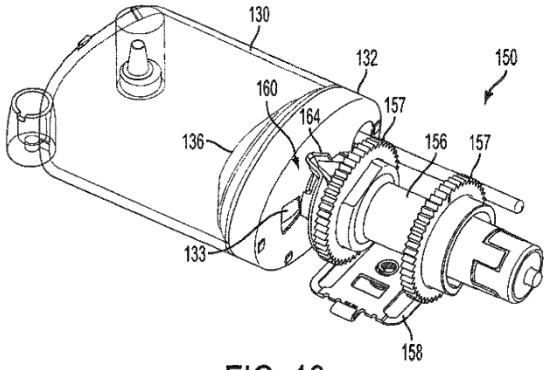


FIG. 13

31. The clutch mechanism (160) may then be engaged such that rotation of the drive wheel (156) causes the clutch mechanism (160) to rotate the tube nut (154) which causes the leadscrew (152) to advance the plunger into the reservoir (130) to deliver the fluid from the reservoir (130).

32. In alternative embodiments the reservoir (130) may be filled when the plunger (136) is already retracted (colon 7, lines 48-49).

33. Figure 14 is a top perspective view of an illustrated embodiment of the fluid driving mechanism with the clutch mechanism being released to the engaged position (col. 3, lines 10-13).

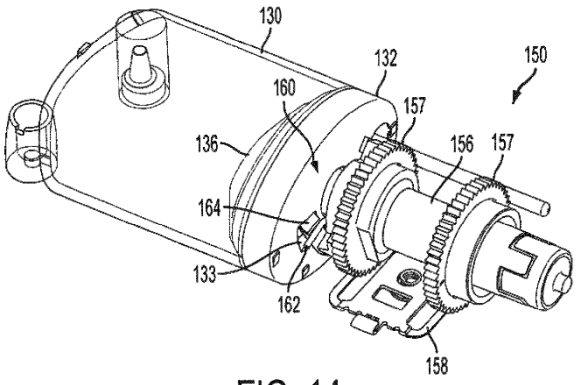


FIG. 14

34. By using a clutch mechanism, the engagement between the leadscrew and the nut occurs at assembly, and thus no rotation is needed for the nut to engage the leadscrew by operation of the device. This reduces the number of fluid path prime pulses to prime the pump and assures a full and proper priming of the fluid path before placement on the body. The clutch mechanism also enables the changing of thread pitch for other drug applications without a need to redesign the tilt nut used in a fluid driving mechanism in other existing pumps. The components of the clutch mechanism are also more easily inspected than the tilt nut assembly (para. 25).

3. *Claim construction*

35. The Court bases its decision on the following technical meaning of the features from the point of view, as at the priority date, of the person skilled in the art, who is an engineer (e.g. master´s degree in mechanical engineering), possessing several years of experience in the development of medical technology products such as insulin pumps. This is undisputed by the parties and rightly held by the Court of First Instance.

36. EOFlow relies on the opinion of EOFlow´s party expert regarding both the interpretation of the patent and the understanding of US '994 by a person skilled in the art. EOFlow advances that this opinion should be followed because Insulet has not provided an expert opinion of its own. The Court of Appeal does not agree.

37. The interpretation of a patent claim is a matter of law. Therefore, the Court cannot leave the judicial task of interpreting the patent claim to an expert but has to construe the claim independently. It is true that the understanding of the person skilled in the art of the terms used in the patent claim in the context of the patent claim as a whole and considering the description and drawings, is the basis for claim construction. But this does not mean that the Court must follow a party's expert´s opinion where the other party does not rely on an expert opinion. The skilled person is a notional entity that cannot be equated with any real person in the technical field of the invention. The decisive factor is not the individual knowledge and abilities of a person, but rather the general specialist knowledge that is customary in the relevant field of technology, as well as the average knowledge, experience, and abilities in this specialist field. It is for the Court, not the expert, to assess these circumstances.

38. However, if these circumstances concern facts that can be proven, the Court shall consider the expert opinions submitted by the parties with respect to such facts.

Feature 1 and assembled state

39. Claim features must always be interpreted in the light of the claim as a whole (UPC Court of Appeal, 13 May 2024 UPC_CoA_1/2024 para. 29 - Hanshow). The determination of the technical meaning of features from the point of view of the person skilled in the art can, if necessary, concentrate on the features in dispute between the parties. Even then, however, the overall context must not be lost sight of, since interpreting individual features only serves the purpose of determining the solely relevant meaning of the patent claim as whole.

40. The Court of Appeal does not agree with the observation of the Central Division that the patent at issue does not appear to be limited to the assembled state. The skilled person understands that claim 1 is a product claim relating to a fluid delivery device, and thus to an assembled product, which is designed to deliver liquids. Thus, it must be in an assembled state.

41. This is confirmed by the wordings of feature 3 (coupled), feature (4.2) (received), feature 4.3 (extending) and feature 4.5 (coupled). These wordings describe an assembled state. The Court does not agree with

EOFlow that the contrary follows from the fact that the claim language uses a broad "comprising" instead of possible, more limiting wording.

Feature 4.4

Permanent engagement

42. That the fluid delivery device is limited to an assembled state also follows from feature 4.4 according to which the fluid delivery device comprises a nut threadably engaged with the leadscrew.

43. Contrary to EOFlow´s opinion, this requires a permanent engagement. This applies also to the disengaged state of the clutch mechanism according to feature 4.5.1 ("wherein the clutch mechanism (160) is configured to allow the nut (154) to pass through the clutch mechanism (160) when disengaged"). There is no indication in the claim or description to suggest that the engagement can be abandoned while the clutch is in a disengaged state.

44. This makes sense. According to the description, the use of the clutch mechanism according to claim 1 has the advantage that the nut and leadscrew may be permanently engaged. Para. 25 reads: "By using a clutch mechanism, the engagement between the leadscrew and the nut occurs *at assembly* (emphasis by the Court), and thus no rotation is needed for the nut to engage the leadscrew by operation of the device. This reduces the number of fluid path prime pulses to prime the pump and assures a full proper priming of the fluid path before placement on the body." Thus, feature 4.5.1 guarantees that such a retraction is possible, although the nut and the leadscrew are permanently threadably engaged, by allowing the nut to pass through the clutch mechanism.

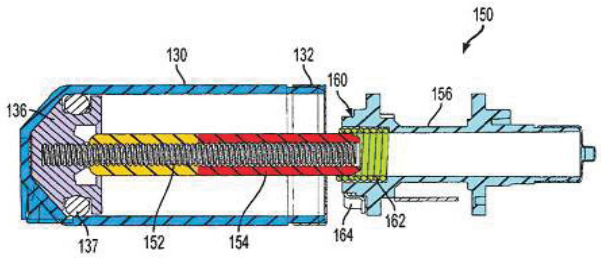
Nut

45. The Milan Central Division rightly held, and the parties do not dispute, that the skilled person understands a nut to be a hollow body with a thread on its inner surface. According to EOFlow, only the portion with the internal threads makes up the nut, nothing else. The Court of Appeal does not agree. As long as the nut is threadably engaged with the leadscrew, the nut may be fully threaded or only partially threaded. This means that also the part which is not threaded is part of the nut.

46. Claim 1 does not contain specifications of the extension of the thread. Nor does the description. Paragraph 20 (lines 24-27) mentions that a second threaded member in the form of an elongated shaft such as a tube nut (154) with internal threads threadably engages the leadscrew (152) without any limitation or distinction between a non-threaded portion and a threaded portion. From a functional perspective, it only matters that the internal thread of the nut engages the thread of the lead screw such that the plunger can be advanced within the reservoir (wherein the rotation of the nut is transmitted into a longitudinal movement of the leadscrew). The engagement of the nut with the leadscrew is also possible if only a part of the nut is threaded. The description shows an embodiment where the fluid drive mechanism (150) includes a first threaded member in the form of an elongated shaft, such as a threaded drive rod or leadscrew (152), with external threads extending from the plunger (136) received in the reservoir (130). A second threaded member in the form of an elongated shaft such as a tube nut (154) with internal threads, threadably engages the leadscrew (152) (para. 20). As can be seen from figure 12 (as coloured by EOFlow), in the illustrated embodiment, the nut is an elongated tube nut in which one

part of the nut has an internal thread (left yellow section of the nut 154) and the other part is only a tube or cylinder without any thread.

A.



47. That the engagement between nut and leadscrew is also possible by a partially threaded nut is also confirmed by EOFlow´s party expert. He explains (HRM4 para. 27) that the threaded part in figure 16 (not shown) “has a greater number of turns (length of the nut-portion) than is relevant for simply providing a secure threaded engagement between the screw and the nut.”

48. Indeed the advancement of the leadscrew is only performed by the threaded part. Contrary to EOFlow’s opinion, however, this does not justify artificially dissecting the one single component into two parts.

Features 4.5, 4.5.1. and 4.5.2

49. According to feature 4.5.1 and 4.5.2 the clutch mechanism is configured to have an engaged and a disengaged state. It follows that feature 4.5 requires a switchable clutch which can switch between a disengaged and an engaged state. This follows from the fact that in its disengaged position (”when disengaged”) it allows the nut (154) to pass through the clutch mechanism (feature 4.5.1), and in its engaged position, it grips the nut (feature 4.5.2). The disengaged state facilitates filling a reservoir (which requires the plunger to be retracted) and in the engaged state it provides a driving mechanism for driving fluid out of the reservoir (see para 8, colon 4, lines 1-3), The wording in feature 4.5.1 that the clutch ”allows” the nut to pass through the clutch mechanism shows that the clutch mechanism is configured in such a way that a disengagement is necessary to allow the nut (154) to pass through the clutch mechanism (feature 4.5.1). The Court agrees with Insulet that in order to return to the other (engaged) state an active gripping is required.

50. Feature 4.5.1 relates to a device in an assembled state (see feature 1), whereby the nut and the leadscrew are threadably engaged (see feature 4.4). This is also clear from para 25, colon 8, lines 41-44, where it is stated that by using a clutch mechanism, the engagement between the leadscrew and the nut occurs at assembly and thus no rotation is needed for the nut to engage the leadscrew by operation of the device. In the assembled state the container needs to be filled and feature 4.5.1 allows that to take place, without interfering with the engagement between nut and leadscrew. The nut together with the threadably engaged leadscrew slidably passes the clutch, thereby retracting the plunger and allowing the container to be filled.

51. Contrary to EOFlow´s opinion, the description in the above cited paragraph 21 of the patent at issue does not lead to a different interpretation. It discloses two alternatives of the retraction of the plunger in an assembled device: either the hydraulic pressure of the fluid retracts the plunger or the plunger is already

retracted before filling. This must not be understood – as the CFI obviously but wrongly did - that it is sufficient that the nut passes through the clutch mechanism when assembling the fluid delivery device.

52. EOFlow argues that the skilled person understands that “pass through” of the nut-portion results in an alignment of the nut-portion with the gripping zone of the clutch mechanism, such that the gripping should occur in the zone where nut and screw are threadably connected, in order to provide a secure and stable transfer of the torque.

53. The Court of Appeal does not agree. Such a restriction cannot be inferred from the patent claim.

54. From a functional perspective, it is not necessary that there is an alignment of the threaded nut-portion with the gripping zone of the clutch mechanism. EOFlow refers without success to the statement of the party expert in his first report (HRM 4 para. 33), which reads: ”it appears that there is an important technical significance to the ”tube nut”’s nut-portion having adequate length to pass through and beyond the drive-wheel-side of the clutch spring 162, such that the threaded nut-portion is fully aligned with the whole gripping zone of the clutch spring 162.” In this regard, the party expert refers to his comment (HRM 4 para. 28), according to which “fully aligning the nut-portion with the complete gripping zone of the clutch spring 162” would be ”beneficial for some required security or stability of the clutch mechanism to provide for a stable transfer [of] the torque from the drive wheel to the ”tube nut” and to the leadscrew”. Thus, according to the party expert, the alignment of the threaded nut portion with the complete gripping zone is only advantageous but not a requirement.

Feature 3

55. According to feature 3, the fluid delivery device comprises a transcutaneous access tool (172) fluidly coupled to the fluid reservoir.

Transcutaneous access tool

56. It is clear from the wording of feature 3 that the transcutaneous access tool is configured to penetrate the patient´s skin and to provide a coupling between the reservoir and the body of a person or an animal, which allows the fluid to be delivered from the reservoir to the body (see para. 10, lines 14-18). The skilled person understands that this requires a needle or the like to first pierce the skin and expects the needle to be subsequently retrieved, leaving behind a cannula or the like for the actual fluid delivery (see also para. 8, colon 3 lines 48-53 which reads ”A fluid delivery device, consistent with embodiments of the present disclosure, may be used to deliver a therapeutic fluid (e.g. a liquid medicine) to a patient via a transcutaneous access tool, such as a needle/trocar and/or a cannula” [emphasis by the Court]).

57. The wording “fluidly coupled” does not require that there is a permanent fluid communication between the transcutaneous access tool and the reservoir. Rather, it is sufficient to have a coupling that allows such fluid exchange when the device is in use.

II. Validity

58. It is not more likely than not that claim 1 of the patent at issue is invalid.

1. Novelty over US 2009/0124994 A1 (in the following: "US´994", Exhibit HRM 8)

59. It is not more likely than not that US´994 discloses all features of claim 1 of the patent at issue.

Description of US´994

60. The invention according to US´994 is generally related to miniature drug delivery pumps, and in particular to a miniature drug delivery pump with a piezoelectric drive system having a unidirectional clutch (para. 1). The invention provides a drug delivery pump which uses a piezoelectric drive system to advance a small syringe piston to deliver a liquid drug and a method thereof. According to the description of US´994 this invention has a cost and a size advantage compared to traditional pumps and is a very compact and potentially disposable pump device design (para. 3 and 14).

61. The specification of the patent application US`994 describes a drive system and a method for dispensing a liquid drug from a container having a piston. The drive system comprises a leadscrew having a rotational axis, a shaft extending along the rotational axis and configured to rotate the lead screw about the rotational axis, and a piezoelectric bender configured to produce reciprocating lateral motion adjacent to the rotational axis. A clutch is coupled to the shaft and configured to rotate about the rotational axis. The drive system also includes a wheel mounted to the clutch and operably connected to the piezoelectric bender, wherein the wheel is arranged to convert the reciprocating lateral motion about the rotational axis which turns the clutch bi-directionally, and wherein the clutch in only one direction turns the shaft which advances the leadscrew (para. 4, 5).

62. In all the embodiments, the shaft (32) is a hollow tube having a center cavity, which is represented by a dashed line that is indicated by reference number (33) (p. 2, colon 2, lines 8-10; fig. 5).

63. Figure 4 shows an exploded view of an embodiment of a miniature drug delivery pump, generally indicated by reference number (40). In all embodiments, the unidirectional rotational motion of the shaft (32) is used to advance a leadscrew (42) from the cavity (33) of the shaft. In the illustrated embodiment shown in figure 4, a nut portion (41) is provided at the open end of the cavity (33) of the shaft (32). The threads (not shown) of the nut portion (41) engage the threads of the leadscrew (42) and cause the movement of the leadscrew (42) upon rotation of the shaft (32). Movement of the leadscrew (42) advances the plunger or piston (44) to dispense a liquid drug from a drug container (46). As shown, the drug container (46) is accommodated in the cradle (48) of a base (50) of the delivery pump (40). In one embodiment, the leadscrew (42) has a snap-in connection (49) to the piston (44) of the drug container (46) (para. 22).

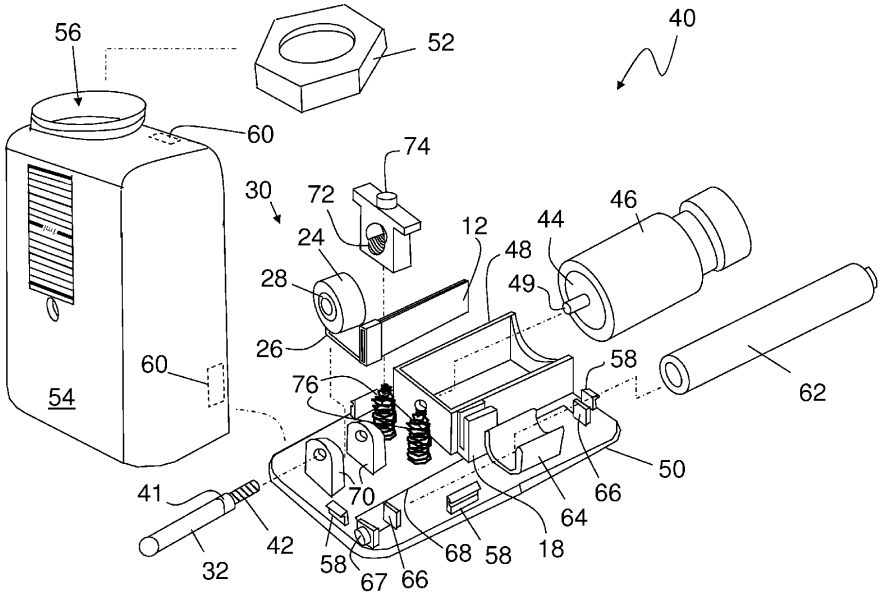


FIG. 4

Sufficiently clear teaching of US´994 concerning the embodiment shown in Figure 4

64. Insulet claims that Figure 4 does not disclose a functional embodiment because the shaft (32) and the leadscrew (42) rotate together. It is true, that - like the Milan Central Division rightly held - there are two alternative possible mechanisms to convert a rotational motion into a translational motion. In the first one the screw is not rotating and advanced by rotating the nut (shaft), which cannot move in the axial direction. In the second one the screw is rotating in the non-rotating nut (shaft), which again cannot move in the axial direction (CFI: “rotate inside the nut”). Thus, it is not possible to advance the screw if both the nut (shaft) and the threadably engaged screw are rotating together. In Figure 5, the rotating shaft (32) does not have an internal thread, but a detent portion (84) that engages a slot (86) in the screw (42), so that the screw (42) is rotated by the shaft (32) and can simultaneously move axially within the shaft (32).

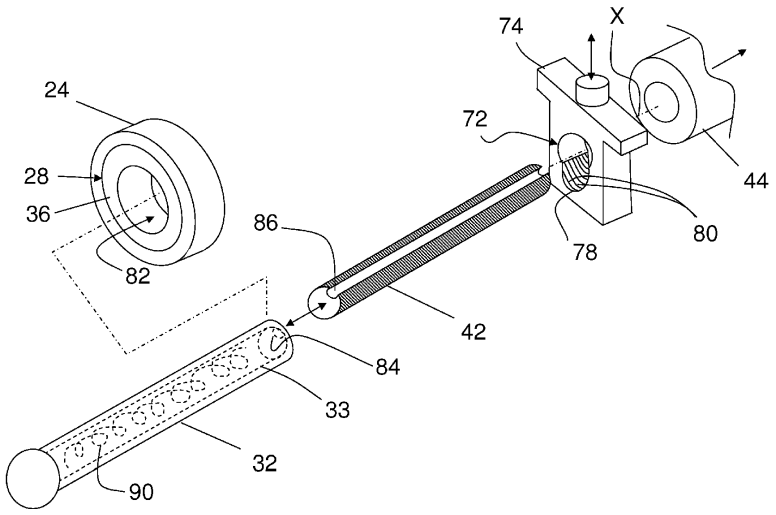


FIG. 5

65. In this embodiment, the “nut” with internal threads (80), which converts the rotational movement of the screw (42) into a translational movement, is the keyhole (72) of the release button (74).

66. The Court cannot see at this point that Insulet´s opinion is correct, that in the embodiment of Figure 4 the shaft (32) and the leadscrew (42) rotate together. The statement in paragraph 22 of US´994 that the unidirectional rotational motion of the shaft (32) is used to advance the leadscrew (42) from the cavity (33) of the shaft (32) does not imply that the shaft (32) and the leadscrew (42) rotate together. On the contrary, the skilled person will understand that the rotational motion of only the shaft (32) causes the advancing of the leadscrew. Nothing else follows from claim 1 of US´994. It is true that claim 1 requires a shaft extending to the rotational axis and configured to rotate the lead screw about the rotational axis. The person skilled in the art would understand that Figure 4 and its description in paragraph 22 does not disclose an embodiment according to claim 1 of US´994.

67. Against this background, the Milan Central Division rightly held that the shaft (32) is only supported by the pair of base supports (70) (see para. 27 lines 35-36) but not fixed to it. Of course, the base supports (70) do not hinder the rotation of the shaft (32), but prevents that it moves in the axial direction.

68. It is true that a pure longitudinal movement of the leadscrew (42) without any rotation would be blocked by the threads (80) of the keyhole element (72) shown in Figure 4. The skilled person would understand that the keyhole element (72) is not part of the embodiment shown in figure 4, but that the keyhole element (72) relates only to the embodiment shown in Figure 5, where the screw (42) is slidably accommodated in the shaft (32) and is rotating together with the shaft (32). US´994 describes the release button (74) with the keyhole element (72) only in connection with an embodiment where the drug container (46) is replaceable (“Accordingly, in this embodiment where the drug container 46 is replaceable, pressing down on the release button 74 disengages the threads 80 with the threads of the lead screw 42 such that the lead screw 42 retracts back into the shaft 32 upon inserting a new drug cartridge into the delivery pump 40”, para. 27 lines 44-49). By contrast, Figure 4 only relates to a “non-replaceable drug cartridge embodiment” (see para. 28 lines 57-60: “In this embodiment, the lead screw 42 is slidably accommodated in the cavity 33 of the shaft 32, wherein the nut portion 41 (FIG 4) of the previous non-replaceable drug cartridge embodiment is not provided”).

69. In view of the above, arguments raised by Insulet based on the presumption that the skilled person would consider the embodiment of figure 4 to be unworkable, do not require further discussion.

Disclosure of features 1 to 4.2

70. US´994 directly and unambiguously discloses features 1 to 4.2.

Disclosure of feature 4.3

71. The Court of Appeal is unable to recognize feature 4.3. Due to the snap-in connection (49) in US´994, the leadscrew (42) does not extend from the plunger (44). US'994 does not disclose a direct connection between the piston and the leadscrew.

Disclosure of feature 4.4

72. As shown above, in the embodiment of Figure 4 the nut portion (41) of the nut (shaft 32) is threadably engaged with the leadscrew (42).

No disclosure of features 4.5 and 4.5.1

73. As follows from the Court of Appeal's interpretation of feature 1, it is not sufficient that upon assembly of the pump and drive mechanism, the nut and the shaft pass through the clutch mechanism. This must also be possible after assembly. This is not true for the embodiment disclosed in US´994 and therefore it does not disclose feature 4.5.1. Since it does not show a clutch mechanism, which can switch between a disengaged and engaged state in an assembled fluid delivery device, feature 4.5 is not disclosed either.

2. Novelty over WO 2010/055504 A1 (hereinafter "WO´504", Exhibit HRM 9)

74. WO´504 also does not anticipate patent claim 1 of the patent at issue in a manner detrimental to novelty.

75. WO´504 relates to a fluid delivery device that include a two-part skin-securable unit having a reusable part and a disposable part (para. 2). It discusses the first and second generation portable insulin pumps and their drawbacks. The third generation skin-securable devices were, among other, devised to avoid the cost of disposing expensive components every 2-3 days. These devices include two parts: (1) a reusable part containing the electronics, at least a portion of the driving mechanism and other relatively expensive components, and (2) a disposable part containing the reservoir (para. 7 lines 14-18).

76. According to WO´504, a fourth generation infusion device has been devised as a dispensing unit that can be disconnected from and reconnected to a skin-securable cradle unit and can be operated by buttons located on the reusable part (WO´504 para. 10 lines 2-4).

77. WO´504 describes that a typical pumping mechanism of third and fourth generation two-part skin-securable devices may be a "syringe-like" or "piston-type" pumping mechanism. Here, a plunger slides

within a reservoir to draw fluid outwardly. The plunger may be pushed forward by a rotating drive screw (plunger rod) that freely articulates within the plunger. Linear motion is achieved by rotation of the drive screw relative to a nut. The nut is rigidly fixed to the housing or chassis (insert) of the disposable part. Rotating the drive screw within the non-rotating nut causes linear motion of the drive screw relative to the nut. The drive screw is also used as a plunger rod to backwardly slide the plunger during reservoir filling. After filling, the disposable part that contains the reservoir and outlet port is connected to the reusable part concomitantly with engagement of the drive screw with the gear of the reusable part (para. 12).

78. WO´504 criticises that the major limitation of a freely-articulation rotation drive screw is inaccuracy in drug delivery caused mainly due to plunger wobbling during forward motion within the reservoir. Plunger wobbling is caused by rotation of the distal end of the drive screw at the articulation point within the plunger (para. 13).

79. According to the summary of WO´504, devices and means for engaging various components contained within such devices are disclosed therein. Embodiments of the devices are directed to delivering therapeutic fluid into the body of a patient. Such devices may include a pumping mechanism having a reservoir and a plunger that may be positioned within the reservoir (para. 14 lines 11-15).

80. Some device embodiments may include a drive nut with internal threads and external teeth. The drive nut may be capable of engagement to, and in some embodiments disengagement from, the drive screw based on engagement between the internal threads of the drive nut and external threads on the drive screw. Some embodiments may also have a drive nut that comprises two parts, namely a first section and a second section (e.g., a split-nut). Some embodiments of the drive nut have an "open" position and at least two closed positions. In one closed position, the two parts of the drive nut may be locked together but still maintain relative space between each other (i.e., form a slit there between) that can further be closed. In this position, the drive nut and drive screw are said to be "disengaged." In another closed position, the two parts of the drive nut are seated against each other. In this position, the drive nut and the drive screw are said to be "engaged" (para. 15).

81. Embodiments of the drive nut may have two basic operational modes – disengaged and engaged. In the disengaged mode, the two parts (i.e., the first section and second section) of the drive nut are locked together but there is still a space between them (i.e., the slit is open), whereby the drive screw can freely slide backwards and forwards within and relative to the drive nut, according to some embodiments. In the engaged mode, the two parts of the drive nut are seated against each other (i.e., the slit is closed). In this position, the drive nut´s internal threads are engaged with the drive screw threads such that upon rotation of the drive nut, the drive screw is linearly displaced. More specifically, because the drive screw is unable to rotate based on its rigid connection with the plunger, the rotational movement of the drive nut is converted to linear movement of the drive screw (para. 16, p. 6 – p. 7 line 3).

82. Figure 3 shows a two-part fluid dispensing unit (10) having a reusable part (RP 100) and a disposable part (DP 200) (para. 62 lines 20-22). The pumping mechanism of unit (10) may be a “piston-type” pump that includes a plunger (250) that may move within the reservoir (220) (para. 62 lines 27-28). In some embodiments, the DP 200 contains the reservoir (220), the plunger (250) (…), a drive screw (112) having

a proximal end (113) (e.g., a conical tip) receivable within the rotating sleeve (114) (also referred to as "receiving portion" or "receiving component") and a distal end (not shown) connected to the plunger (250), and a drive nut (500) coupled to the drive screw (112) (page 18 lines 4-8).

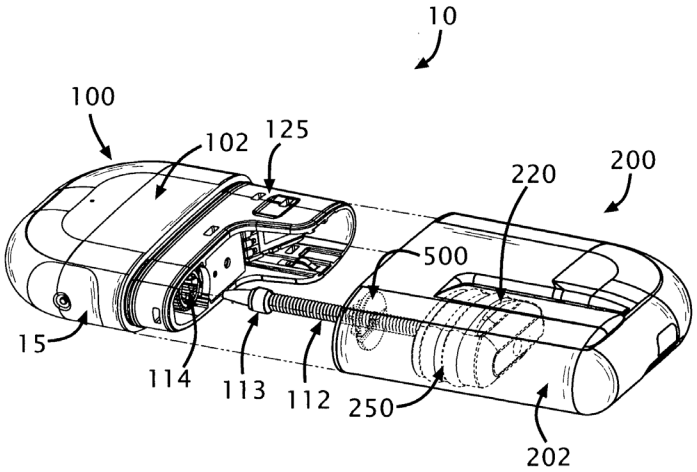


FIG. 3

83. As shown in Figure 4a and described above, in the disengaged position, when the reusable part (RP 100) and the disposable part (DP 200) are disconnected, the inner thread of the drive nut (500) is not engaged with the threads of the drive screw (112).

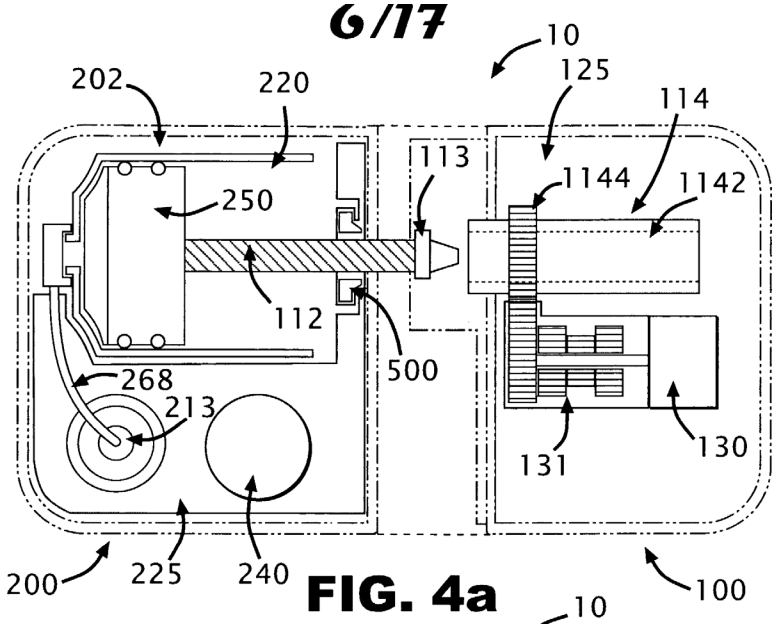


FIG. 4a

84. On the other hand, as shown in Figure 4b and described above, when the reusable part (RP 100) and the disposable part (DP 200) are connected, the proximal end (113) of the drive screw (112) enters the rotating sleeve (114), and the drive nut (500) is placed within rotating sleeve (114). The engagement of the drive nut (500) with the rotating sleeve (114) forces internal threads (507) of the drive nut (500) to be engaged with external threads on the drive screw (112).

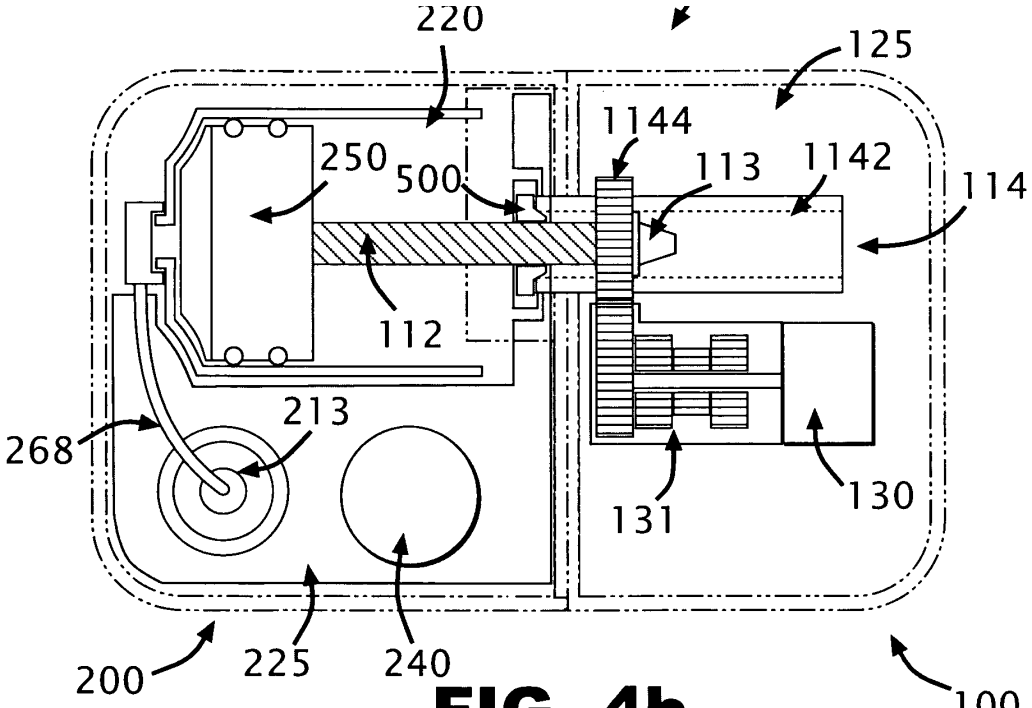


FIG. 4b

85. During the filling process, the drive nut (500) is in a disengaged position, according to some embodiments. In this position, the drive screw (112) can freely slide back and forth within the drive nut (500). During the filling process, a user may pull the push-pull rod (70) and drive screw (112) backward until drawing from the vial (60) a desired volume of fluid into the reservoir (220) (page 24 lines 9-13).

Disclosure of the features when the reusable and disposable parts are connected

Features 1 to 4.4

86. When the reusable and disposable parts are connected, features 1 to 4.4 are disclosed.

Features 4.5 and 4.5.1

87. In this stage feature 4.5.1 is not disclosed. The minimal relative longitudinal movement of split nut (500) and sleeve (114) when the external teeth (514) of the split nut (500) come into contact with the inner teeth of the sleeve (114) does not mean that the split nut "passes through" the clutch mechanism (114, 118), when *disengaged*. Rather, the nut is received in the rotating sleeve to transmit the power of the motor (130) to the drive nut. This requires that the rotating sleeve *engages* the nut.

88. A clutch mechanism whereby the nut and leadscrew remain threadably engaged and can be retracted together in that engaged state by switching a clutch into a disengaged state is not disclosed in WO'504. In order to retract the plunger, WO'504 discloses other mechanisms. In par. 21 of WO'504 it is described that this is done by the drive screw – as the skilled person will understand by reverse rotation of the drive nut, which retracts the drive screw and therewith the plunger: "The drive screw may also be used to

displace the plunger backward within the reservoir to draw in fluid and fill the reservoir when the drive nut is in a disengaged position". Another mechanism described in WO'504 is that the nut consists of different parts that may be 'opened', as a result of which the threaded engagement between the drive screw and nut becomes disengaged and the drive screw can slide freely (backwards) in the drive nut. This is described in par. 16, cited above.

Disclosure of the features when the reusable and disposable parts are disconnected

Feature 1

89. Feature 1 is not disclosed in the disconnected state of the reusable and disposable part of the embodiment shown in Figure 4. The fluid delivery device is not assembled.

No disclosure of feature 4.4

90. In case of the disconnection of the reusable and disposable part WO´504 does also not disclose a nut which is threadably engaged with the leadscrew in the sense of feature 4.4. As stated in the context with claim construction, feature 4.4 requires a permanent engagement of nut and leadscrew, even in the disengaged state according to feature 4.5.1.

No disclosure of features 4.5, 4.5.1 and 4.5.2

91. Furthermore feature 4.5, 4.5.1 and 4.5.2 are not disclosed. Because the nut is not engaged with the leadscrew, there is no possibility to rotate the nut to advance the leadscrew and the plunger into the reservoir, as already mentioned. A clutch mechanism, which can switch between an engaged and disengaged state is missing altogether.

3. Inventive step

92. It is not more likely than not that the subject-matter of claim 1 is obvious to the person skilled in the art.

Inventive step based on US´994

93. EOFlow argues that the only necessary adaption to the pre-known device to adopt the device to a fully assembled state and apply a "pass through while/when/during filling" approach, is to accept that the plunger in its initial state is extended and the leadscrew and nut need to travel backwards, passing through the clutch mechanism during filling.

94. The Court of Appeal cannot see in US´994 a pointer leading the person skilled in the art in this direction. In both variants the drug container is put in the fluid delivery device in a pre-filled state. The skilled person understands that the piston is then already in a retracted position and there is no need to retract the piston. Thus, it is not necessary to move the shaft (32) with the threadably engaged leadscrew (42) through the clutch mechanism when disengaged.

Inventive step based on WO´504

95. A different assessment does not arise with regard to WO´504 either. As already mentioned, in order to retract the plunger, WO'504 discloses other mechanisms. EOFlow has not convincingly established that there was a pointer for the skilled person to amend the embodiment of WO'504 to include a switchable clutch that allows the nut to pass through the clutch mechanism when disengaged according to features 4.5 and 4.5.1.

4. Infringement

96. It is more likely than not that the attacked embodiments infringe claim 1 of the patent at issue.

Features 1 to 2 and 4 to 4.5

97. Realization of features 1 to 2 and 4 to 4.5 is rightly not in dispute between the parties.

Feature 3

98. The attacked embodiment also makes use of feature 3. As stated in the context of claim construction, feature 3 does not require that there is a permanent fluid communication between the transcutaneous access tool and the reservoir. Rather, it is sufficient to have a coupling that allows such fluid exchange when the device is in use.

Features 4.5.1 and 4.5.2

99. The attacked embodiments realize features 4.5.1 and 4.5.2 [redacted]

III. Prerequisites of provisional measures and balance of interests

100. Under Art. 62 UPCA and R. 211.1 RoP, the Court may grant provisional measures intended to prevent any imminent infringement, to prohibit, on a provisional basis and subject, where appropriate, to a recurring penalty payment, the continuation of the alleged infringement or to make such continuation subject to the lodging of guarantees intended to ensure the compensation of the right holder.

Continuation of infringement

101. EOFlow ships the attacked embodiment to Menarini in Italy. The fact that Menarini has entered into a settlement with Insulet does not mean that there is no risk of patent infringement with regard to EOFlow. In general, the risk of the continuation of the infringement arises from a prior infringement, if the infringer does not issue a cease-and-desist declaration with a sufficient penalty clause. EOFlow has not issued a cease and desist declaration at Insulet's request.

Necessity of provisional measures and balance of interests

102. Pursuant to Art. 62(2) UPCA and R. 211.3 RoP, the Court shall have the discretion to weigh up the interests of the parties and, in particular, to take into account the potential harm for either of the parties resulting from the granting or the refusal of the injunction. The Court must in addition consider the time factor. More specifically, the Court must assess whether it is possible to await proceedings on the merits, or whether provisional measures are necessary (UPC Court of Appeal, order of 24 February 2025, UPC_CoA_540/2024, APL_52692/2024, Biolitec v Light Guide et al, para. 19).

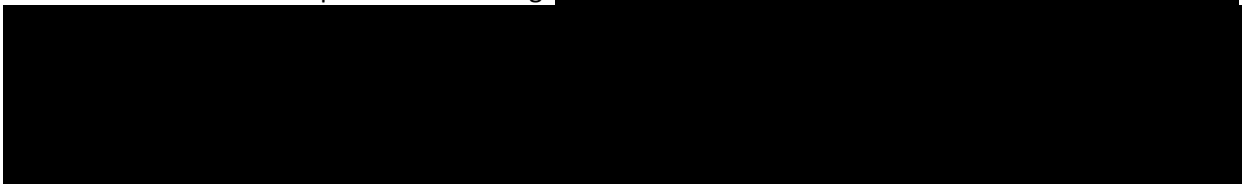
103. Provisional measures will be necessary, for instance, where any delay would cause irreparable harm to the patent holder. Irreparable harm is, however, not a necessary condition for the ordering of provisional measures (UPC Court of Appeal, order of 25 September 2024 – UPC_Co_182/2024, APL_21143/2024, para. 237 – Mammut v Ortovox; order of 24 February 2025, UPC_CoA_540/2024, APL_52692/2024, Biolitec v Light Guide et al, para. 21).

104. The necessity of provisional measures may also follow from the fact that there is direct competition between the attacked embodiment and the product of the patent holder (see UPC Court of Appeal, Biolitec v Light Guide et al, para. 26). In those cases granting provisional measures may be justified if they are necessary in order to maintain the status quo that existed immediately prior to the alleged infringement until the decision of the Court on the merits (UPC Court of Appeal, Mammut v Ortovox, para. 238 et seq; Biolitec v LightGuide et als, para. 28). The necessity for provisional measures may arise in a move from a market situation where only one product is available to one where there are two such competing products. Such a move can be expected to lead not just to price pressure but to a permanent price erosion (see UPC Court of Appeal, order of 3 March 2025, UPC_CoA_523/2024, APL_51115/2024, Sumi-Syngenta, para. 93).

105. This is such a situation. Typical insulin-delivery systems can be divided into MDI therapy and CSI therapy. MDI (multiple daily injection) requires the use of insulin pens, whereas CSI (continuous subcutaneous insulin infusion) therapy comprises tethered pumps (having a tube) or modern tubeless patch pumps. Insulet and EOFlow both offer tubeless patch pumps. Unlike other delivery mechanisms such as insulin pens, rather than relying on multiple, painful injections, patch pumps can achieve steady insulin levels by delivering small doses of insulin to a patient´s body over a period of days. Moreover, patch pumps are also less expensive than tethered pumps and are disposable, which means patients, young and old, do not need to worry, if they are broken or lost. Because of these advantages, which are important for the physicians who decide on the prescription, it is not important in this context that there are competitors offering tethered insulin pumps or insulin pens on the market.

106. The fact that there are other competitors offering tubeless patch pumps like Roche is also not relevant. It is sufficient if a price drop only affects products according to the patented solution.

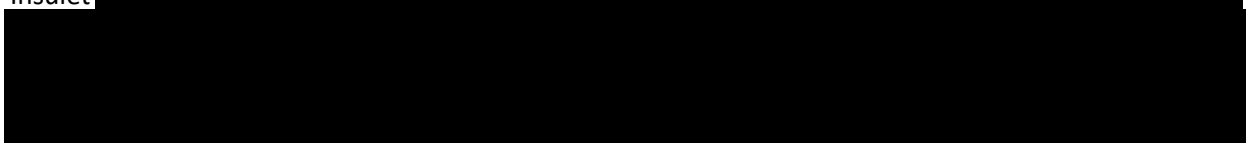
107. There is also evidence of price undercutting. [redacted]



108. Furthermore, it is very difficult to switch from one solution to another in this field of practice, both in terms of technical implementation and in terms of the necessary approval procedures. Once patients and hospitals have decided in favour of the attacked embodiment, Insulet´s market access is initially blocked in this respect. As EOFlow itself submits, prescriptions for insulin patch pumps generally last four years. Since the attacked embodiments have to be disposed after a use of up to 3.5 days, the damage is substantial, it would not be reasonable for Insulet to await proceedings on the merits.

109. When weighing up the interests, it must be taken into account that a decision in the proceedings on the merits is to be expected around December 2025. The damage incurred up to that point justifies the issuing of a provisional order. Insulet was not required to file the main action at the same time as the application for provisional injunction. According to the Rules of Procedure, it is also possible for the applicant to start proceedings on the merits only after a provisional injunction has been issued (see R. 213 RoP). The reason for this is that applications for interim measures are usually decided within a very short period of time. Conversely, this means that in cases where proceedings for interim measures take a relatively long time, the applicant may have grounds for initiating main proceedings. If he fails to do so, this must be taken into account to his disadvantage when weighing up the interests involved. It is true, that Insulet must have been aware that the preliminary injunction proceedings would take longer than usual by 28 August 2024, when the originally scheduled hearing date was postponed due to the rejoinder motion. Given that numerous pleadings have been exchanged later and that the same is true for the parallel proceedings against Menarini, it cannot be assumed that Insulet had time to prepare an action for the proceedings on the merits before the closure of the oral hearing. It is not objectionable that Insulet then also waited for the Central Division´s decision which was to be expected soon.

110. The extension of EOFlow´s market share is not excluded due to the fact that Menarini has settled with Insulet [redacted]



Furthermore, since EOflow has not issued a cease-and-desist declaration, it cannot be ruled out in particular that EOFlow itself distributes the contested embodiments [redacted].

111. It is true that the distribution of the attacked embodiment started in 2023, i.e., before the patent at issue was even granted (19 June 2024). It is also true that in a case, where the patented product was already marketed by the infringer before the grant of the patent, necessity may be denied because the

requested provisional measures would change the status quo of the market established years before the grant of the patent (UPC CoA Biolitec v Lightguide et al. para. 27).

112. However, in the present case there is no such established market, because the distribution of the attacked embodiments by Menarini and EOFlow was limited in time and space. Sales of the attacked embodiments in Germany were already discontinued in the beginning of May 2023. On 27 February 2023, the Düsseldorf Regional Court granted a preliminary injunction concerning the distribution of attacked embodiments in Germany against BERLIN-CHEMIE AG, a Division of Menarini which was responsible for the exclusive distribution of the attacked embodiments, based on the German part of EP 1 874 390. BERLIN-CHEMIE AG acknowledged the injunction with letter 2 May 2023. On 15 April 2024, the Düsseldorf Regional Court granted an injunction against EOFlow regarding the distribution of attacked embodiments in Germany based on the same patent.

113. Menarini also provided a cease-and-desist declaration based on the German part of EP 1 874 390, which prevents it from continuing to offer and market the attacked embodiments in Germany. Furthermore, Menarini agreed not to offer and sell the attacked embodiments based on the aforementioned patent in France (and UK).

114. On 4 October 2023, the United States District Court for the District Massachusetts granted Insulet´s request for a preliminary injunction, finding that there was “strong evidence of misappropriation” because EOFlow hired former Insulet employees who retained “Insulets confidential documents” that “fall within the statutory definition of trade secret”. The resulting preliminary injunction was issued on 6 October 2023, and enjoined EOFlow “from manufacturing, marketing, or selling any product that was designed, developed, or manufactured, in whole or in part, using or relying on the Trade Secrets of Insulet” (see HRM 6 page 3-4) in Europe, among other places. The District Court amended the injunction on 24 October 2023, adding limited carveouts for certain patient populations in South Korea, the European Union and the United Arab Emirates. Menarini informed its customers in a letter dated 13 November 2023 (PS 15) that it stopped selling the attacked embodiment due to the US proceedings.

115. The United States Court of Appeals for the Federal Circuit reversed the grant of the preliminary injunction on 17 June 2024.

116. As mentioned above, [redacted]

117. The number of patients buying the attacked embodiments to date, as stated by EOFlow, does not justify the assumption of a small market loss because these patients make repeat purchases of the attacked embodiments. In addition, this number is not meaningful due to the long supply interruptions. Insulet is justifiably concerned that the prevalence of infringing embodiments will increase now that the U.S. court has lifted the preliminary injunction.

118. Moreover, it is not the number of patients previously supplied that is relevant, but rather the number of patients who will be newly supplied with the attacked embodiments until a decision is issued in the main proceedings. According to the submissions of EOFlow, its current production capacity allows the production of [redacted] units per year, which is only sufficient to annually supply a maximum of [redacted] patients. Although this number of patients is small compared to the number of patients Insulet supplies (more than 100,000), Insulet should not be forced to accept that EOFlow will increase its market share and continue to expand its production capacity based on the profits generated by infringing the patent at issue.

119. The Court assumes in favour of EOflow that it is a small company that manufactures and distributes a single product - the attacked embodiment. Therefore, any interruption of sales is a serious interruption of business and is considered critical by EOflow's creditors. However, given that the likelihood that the patent is valid and infringed by the challenged embodiments is not remote, Insulet's interests prevail.

Patient´s interests

120. The interests of the patients supplied by Menarini also do not tip the balance against the issuance of provisional measures. The alleged benefits of the attacked embodiments over the Omnipod 5 (longer battery life lasting 3.5 days instead of 3 days, gentler adhesive which avoids skin irritations and allergic reactions, shorter cannula where the needle works with a different insertion angle making the insertion less painful for the patient) lead to mere inconveniences in a situation where the attacked embodiments are not available any more.

121. Menarini´s patients have the opportunity to switch to tethered pumps (having a tube) or other tubeless patch pumps. This also applies to countries where Insulet allegedly does not deliver. It cannot be inferred from EOFlow´s submissions that there are countries in which only the attacked embodiments are offered.

122. That the patient needs to be re-examined to determine a suitable substitute and that this would at least take several months could be a fact that speaks in favour of allowing Menarini to deliver patients for several months. However, since Menarini has reached a settlement with Insulet, this does not justify allowing EOFlow patent infringing actions.

123. For the same reasons, the sanctions imposed on Menarini by Italian public procurement law do not justify a different assessment here.

The territorial scope of the order

124. As a rule, injunctions will cover the territory of those CMS for which the patent has effect, unless certain circumstances justify an exception (Art. 34 UPCA, CoA Sumi v Syngenta para. 103).

125. It is true that the attacked embodiments are not offered anymore in Germany. However, this does not justify excluding Germany from the preliminary injunction more than the fact that EOFlow was ordered to cease and desist offering the attacked embodiments on the basis of a different patent.

126. The same applies to other countries in which the attacked embodiments were not offered.

127. The Court also sees no reason to limit the scope of the injunction to countries where Insulet offers the Omnipod.

Security pursuant to Art. 62 (1) UPCA

128. Under the circumstances of the case, the Court of Appeal sees no reason to make the continuation of the infringement conditional upon lodging of security intended to ensure compensation for Insulet. Insulet's damages are difficult to quantify, which means its interests would only be partially protected by such security.

B. Communication of information pursuant to Art. 67 UPCA

129. The application for information is partially successful.

130. Communication of information pursuant to Art. 67 UPCA may also be ordered in the framework of provisional measures, always provided there is an urgent interest, and such measures are proportionate (see CoA, order of 14 February 2025, UPC_CoA_382/2024, APL_39664/2024, Abbott vs Sibio et al, para. 160-164).

131. In view thereof, the Court of Appeal is of the opinion that Insulet has a sufficient and urgent interest to obtain the requested information with respect to the origin and distribution channels of the attacked embodiments in the CMS in which the patent is in force. This information will allow Insulet to take appropriate action to prevent any further infringement within UPC territory.

132. Insulet has not sufficiently indicated why it has an urgent interest to obtain the requested information in relation to the quantity and the price obtained for the attacked embodiments. This information is primarily relevant in relation to the calculation of damages. Insulet has not substantiated that this information is relevant prior to a decision on the merits being rendered. This request shall therefore be denied.

C. Penalty Payment

133. The Court´s decisions and orders may provide for periodic penalty payments payable to the Court in the event that a party fails to comply with the terms of the order or an earlier order (R. 354.3 RoP). The Court considers a penalty payment of up to € 250,000 for each violation of the cease-and-desist order, and a penalty payment of up to € 100,000 for each day EOFlow fails to comply with the information order, to be reasonable.

D. Security for Enforcement

134. EOFlow´s request for a security for enforcement shall be rejected. If the Court does not, of its own motion, see reasons to order the rendering of security for enforcement of provisional measures, the defendant can still bring forward arguments and facts to support the view that the outcome may be different once the action on the merits is tried, and/or that there will be an undue burden in enforcing an order for compensation of injuries caused by the provisional measures, if those measures are revoked. The burden of proof generally rests on the defendant (see UPC CoA, Sumi v Syngenta, para. 114). The Court fails to see at this point that the outcome in the main proceedings will be different or there is an undue burden in enforcing an order for compensation of injuries caused by the provisional measures.

E. Costs

135. Since this order ends the action, the Court of Appeal shall render a cost decision. Pursuant to Art. 69(1) UPCA, reasonable and proportionate legal costs and other expenses incurred by the successful party shall, as a general rule, be borne by the unsuccessful party, unless equity requires otherwise. Pursuant to Art. 69(2) UPCA, where a party succeeds only in part or in exceptional circumstances, the Court may order that the costs be apportioned equitably or that the parties bear their own costs. If one party is partially unsuccessful, the costs do not always have to be apportioned proportionately. In particular, where a party's unsuccessful claim was relatively minor and did not cause further costs, its entire costs may be awarded against the other party.

136. This is the case here. The request regarding information in relation to the quantity and the price obtained for the attacked embodiments was in relation to the successful claims relatively minor and caused no further costs.

ORDER

The Court of Appeal

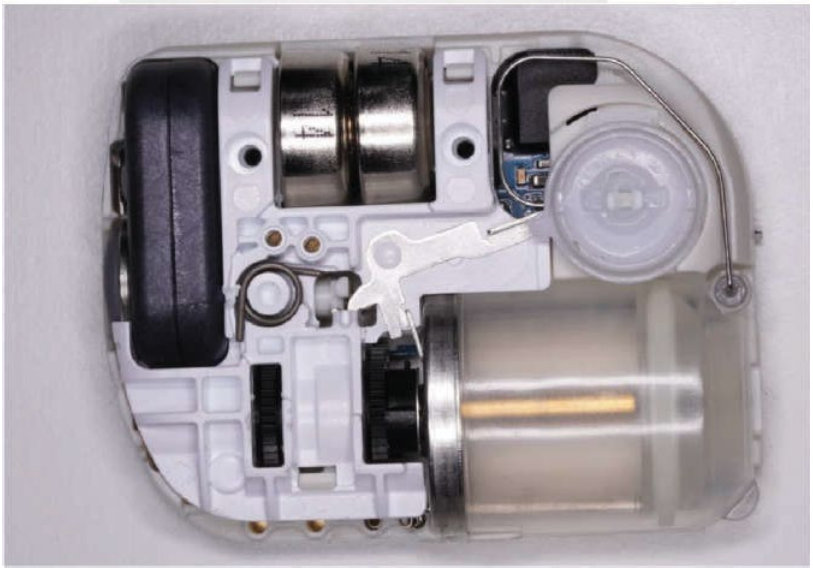
I. sets aside the impugned order;

II. orders EOFlow

1. to refrain from making, offering, placing on the market, using or possessing for the purposes mentioned, or importing or storing the product for those purposes in the territories of the Republic of Austria, the Kingdom of Belgium, the Republic of Bulgaria, the Kingdom of Denmark, the Republic of Estonia, the Republic of Finland, the French Republic, the Federal Republic of Germany, the Italian Republic, the Republic of Latvia, the Republic of Lithuania, the Grand Duchy of Luxembourg, the Republic of Malta, the Kingdom of the Netherlands, the Portuguese Republic, the Republic of Slovenia and/or the Kingdom of Sweden

   a fluid delivery device comprising: a fluid reservoir;
   a transcutaneous access tool fluidly coupled to the fluid reservoir; and a drive mechanism for driving fluid from the reservoir, the drive mechanism comprising: a drive wheel; a plunger received in the reservoir; and a leadscrew extending from the plunger;

characterized in that the drive mechanism further comprises: a nut threadably engaged with the leadscrew; and a clutch mechanism coupled to the drive wheel, wherein the clutch mechanism is configured to allow the nut to pass through the clutch mechanism when disengaged and is configured to grip the nut when engaged such that the drive wheel rotates the nut to advance the leadscrew and the plunger into the reservoir, such as the insulin pumps shown in the pictures below, inter alia offered under the tradenames “EOPatch” and/or “GlucoMen Day Pump”



2. to provide counsel for Insulet, within 4 weeks after service of the order rendered in this matter, with a written statement, substantiated with appropriate documentation of:
    a. the origin and distribution channels of the infringing devices referred to under II. 1 in the UPC Contracting Member States (including the full names and addresses of the legal entities that are involved);
    b. the identity of any party involved in the production or distribution of the devices referred to under II.1, in the UPC Contracting Member States (including the full names and addresses of the legal entities that are involved);

III. if EOFlow fails to comply with the order I.1 the Court provides for periodic penalty payments payable to the Court of up to € 250,000 for each individual violation, and if it fails to comply with the order II.2, the Court provides for periodic penalty payments payable to the Court up to € 100,000 for each day that the violation continues, a part of a day counting as an entire day;

IV. declares the order to be immediately enforceable;

V. rejects any further requests made by Insulet or EOFlow;

VI. orders EOFlow to bear the reasonable and proportionate legal costs and other expenses incurred by Insulet both at first instance and on appeal;

VII. sets the value in dispute at € 2,500,000.00.

Issued on 30 April 2025

Rian Kalden

Date: 2025.04.30 22:00:55 +02'00'

Rian Kalden, legally qualified judge and presiding judge,

Digitally signed by Åsa Ingeborg Simonsson
Date: 2025.04.30 16:29:39 +02'00'

Ingeborg Simonsson, legally qualified judge,

Patricia Ursula Rombach

Digitally signed by Patricia Ursula Rombach
Date: 2025.04.30 16:14:49 +02'00'

Patricia Rombach, legally qualified judge and judge-rapporteur

STEVEN RICHARD KITCHEN

Digitally signed by STEVEN RICHARD KITCHEN
Date: 2025.04.30 17:45:50 +02'00'

Steven Richard Kitchen, technically qualified judge,

Udo Matter

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Datum: 2025.04.30 18:49:47 +02'00'

Udo Matter, technically qualified judge

Anna Monika Ławrynowicz-Drewek

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Date: 2025.04.30 21:47:34 +02'00'

Anna Lawrynowicz-Drewek, Clerk, Registry of the Court of Appeal