Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Milan Local Division

COURT OF FIRST INSTANCE OF THE UNIFIED PATENT COURT

UPC CFI NO. 400/2024
APP. NO. 40442/2024

Order no. 56587/2024
issued on 22 November 2024

Headnotes:

1. In proceedings for provisional measures, the Applicant is required to provide cumulatively reasonable evidence to satisfy the Court with a sufficient degree of certainty that: (i) the Applicant is entitled to initiate proceedings under Art. 47 UPCA; (ii) the patent is valid; (iii) its rights are being infringed or that such infringement is imminent (Rule 211.2 RoP). Additionally, the balance of interests must be in favour of the Applicant (Rule 211.3. RoP). Therefore, the absence of any one of these requirements is sufficient to warrant dismissal of the application.

2. Auxiliary requests to amend the patent pursuant to Rule 30.2 RoP are inadmissible in proceedings for provisional measures. This is consistent with the required expediency of the procedure, which demands both the imminence of prejudice and the necessity to uphold the adversarial principle and the right of defence.

3. The auxiliary request to amend the patent is expressly admitted only in the defence to a counterclaim for revocation (Rule 30.2 RoP) or in the defence to revocation (Rule 50.2 RoP) and it may therefore be lodged only in the main proceedings, before the court with jurisdiction to issue a final decision on the validity of the patent.

4. The phrase “amend its case” in Rule 263.2 RoP refers to any modification of the case by the introduction of a new claim or the substitution of the original claim (“change its claim”). This is therefore a different instrument from the application to amend the patent, which is governed by Rule 30.2 RoP. In proceedings for provisional measures, the former is inadmissible if it constitutes an attempt to introduce a request to amend the patent.

Keywords:
Claim interpretation, provisional measures, auxiliary request to amend the patent, Rule 30.2 RoP, claim limitation, Rule 263.3 RoP.

APPLICANT
INSULET CORPORATION
100 Nagog Park - MA 01720 - Acton - United States of America

DEFENDANT
A. MENARINI DIAGNOSTICS S.R.L.
via dei Sette Santi 3 - 50131 - Florence - Italy

PATENT AT ISSUE
EP4201327

DECIDING JUDGE
Panel of the Local Division in Milan

Pierluigi Perrotti	presiding judge
Aliza Zana	judge rapporteur
Anna-Lena Klein	legally qualified judge
Uwe Schwengelbeck	technically qualified judge

LANGUAGE OF PROCEEDINGS
English

SUBJECT
Rule 209.1 RoP - Application for provisional measures

Procedural history

Insulet Corporation (hereinafter "Insulet") is an US company specialising in medical devices, headquartered in Acton, Massachusetts, with offices in the U.S., U.K., France, Germany, Netherlands, Canada, China, Mexico, Australia, and the U.A.E.
Insulet has developed a closed loop, cloud-connected insulin delivery system known as the Omnipod 5 that is a disposable, wearable, tubeless insulin management system for the automated delivery of insulin (a so-called insulin patch pump).
The Applicant's products are available in 25 countries, with services accessible worldwide.

Menarini Diagnostics s.r.l. (hereinafter "Menarini"), belonging to the Menarini Group, is a leading international pharmaceutical company.
It is the exclusive European distributor of the EOPatch patch-insulin pump, developed and manufactured by the South Korean company Eoflow, which the Defendant markets in Europe under the trade name GlucoMen Day Pump (hereinafter also "attacked embodiment").

On 8 July 2024, Insulet filed an application for provisional measures against the Defendant for infringement of the European bundle patent EP 4 201 327 CO (hereinafter “EP 327” or “patent at issue”).
Insulet asserted that the Defendant infringes its EP 327 rights through the offering and sale of pumps marketed under the names EOPatch / GlucoMen Day Pump.
The Applicant requested a provisional injunction, accompanied by a penalty, as well as ancillary measures including a declaration of origin and distribution channels, identification of all parties involved, delivery up of the devices to a bailiff and payment of the costs of the proceedings.
With regard to urgency, Insulet argued that during the time required for the outcome of the proceedings on the merits, the Defendant’s continued commercial activities in the Contracting Member States would, in a short period, have a distorting effect on the market This would lead to significant loss of revenue and market share that would be irrevocable, causing irreparable harm.
Insulet declared the value of the case to be 2,500,000 EUR.

Considering that the requirements for issuing an order without hearing the Defendant were not met, the Court, by order of 15 July 2024, scheduled a hearing for 15 October 2024, and established deadlines for the parties to submit their responses.

On 6 August 2024, Menarini lodged its objections, raising multiple validity attacks, and concluded that, based on the criteria defined by the case law of the Court of Appeal, it is more likely than not that the patent is invalid. In particular, the Defendant argued that: (i) the patent at issue was invalid, as it was anticipated in a novelty-destroying manner by US 2009/0124994 and lacked inventive step; (ii) its device did not infringe the patent at issue; (iii) there was no urgency; (iv) the injunction should have not been granted on the basis of a proper balance of interests, emphasising also the need to protect the health of patients which would have been seriously jeopardised if such an injunction were imposed.
In addition, the Defendant requested confidentiality for certain information contained in its reply.

Regarding the request under Rule 262A RoP, after consulting with Insulet, the judge-rapporteur granted confidentiality by an order of 4 September 2024, which was not appealed.

On 26 August 2024, Insulet lodged its reply, reaffirming that the patent at issue was valid even in light of the prior art submitted by the Defendant. Additionally, Insulet filed four auxiliary requests to amend the patent.

On 16 September 2024 Menarini lodged its rejoinder, objecting to the admissibility of the auxiliary requests on the grounds that they were filed in breach of Rule 263 RoP and Articles 84 and 123 EPC. Furthermore, it was argued that the auxiliary requests were not patentable.
Menarini renewed its request for confidentiality regarding certain information in its rejoinder. Following consultation with Insulet, the judge-rapporteur granted confidentiality by order of 1 September 2024.

Meanwhile, on 16 September 2024 Eoflow - the developer and manufacturer of the patch-insulin pump *EOPatch* as specified above - lodged an application to intervene pursuant to Rule 313 RoP in support of the Defendant's request to dismiss the application for provisional measures.
Eoflow noted that it was the Defendant in a parallel proceeding before the Milan Central Division, initiated by the same Applicant, Insulet Corporation.
After consulting the parties, the Court dismissed the application by order dated 1 October 2024.

On 30 September 2024, Insulet lodged an application pursuant to Rule 363.3 RoP, unconditionally limiting its claim to the auxiliary requests previously submitted. The Applicant also requested permission to amend its legal claim as filed in the initial application for provisional measures dated 8 July 2024 (as further clarified in its reply dated 26 August 2024).

The judge-rapporteur invited the Defendant to provide comments on Insulet's latest application.

Menarini objected that provisional measures cannot be granted on the basis of amended claims, arguing that an application under Rule 263.3. RoP is only applicable in main proceedings. The Defendant further contended that the claim combination in the new main request lacked novelty or, at the very least, inventive step in view of US 994.

Lastly, on 14 October 2024 Menarini filed an application to inform the panel of the revocation action brought by Eoflow before the Milan Central Division.

The oral hearing was held on 15 October 2024 before the panel.

Order sought by the parties
On 8 July 2024 Applicant requested the following:
I. The Defendant is ordered:
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 Member States of the Unified Patent Court[1] a fluid delivery device (….) (infringement of claim 1 of EP 4 201 327 C0)[2];

[1] i.e. 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.

[2] such as the following insulin pumps labelled as *EOPatch* / *GlucoMen Day Pump*: (..) in particular,
- if the nut (156) is a tube nut, (infringement of claim 2 of EP 4 201 327 C0)
- if the clutch mechanism includes a spring that grips the tube nut when released, (infringement of claim 3 of EP 4 201 327 C0)
- if the clutch mechanism further includes a spring latch configured to hold the clutch spring in a disengaged position and configured to release the clutch spring such that the clutch spring moves to an engaged position, (infringement of claim 4 of EP 4 201 327 C0);

2. to provide counsel for Applicant, within 4 weeks after service of the order rendered in this matter, with a written statement, substantiated with appropriate documentation of:
- the origin and distribution channels of the infringing devices referred to under I.1.(…);
- the quantities delivered, received or ordered, as well as the price obtained for the devices referred to under I. 1. (…);
- the identity of any party involved in the production or distribution of the devices referred to under I. 1. (…);
II. Defendant is ordered to deliver up to a bailiff appointed by Applicant, at its own expense, any device mentioned under I. 1. in stock and / or otherwise held, owned, or in the direct or indirect possession of the Defendant (…) within one week after service of the order to be rendered in this matter, and to provide Applicant's counsel with proper evidence of the full and timely compliance with this order within 10 days after the delivery to the bailiff;
III. For each individual infringement of the orders under I.1., I.2. and II. above, Defendant shall pay periodic penalties of up to EUR 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 EUR 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 this Court;
IV. The above orders are effective and enforceable immediately;
V. Defendant is ordered to pay the costs of the proceedings, respective, Defendant bears reasonable and proportionate legal costs and other expenses incurred by Applicant in these proceedings (interim award of costs), up to the applicable ceiling, or in the amount as the Court may order;
VI. The amount in dispute is set at EUR 2,500,000.
The Applicant requested that the interim measures are granted without hearing the Defendant.

On 26 August 2024 Insulet requested the following:
I. The Defendant is ordered,
1. ("Main Request" infringement of claim 1 of EP 4 201 327 C0)
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 Member States of the Unified Patent Court[3] as requested (..) such as the insulin pumps shown in the pictures below, inter alia offered under the tradenames *EOPatch* and/or *GlucoMen Day Pump*;

in the alternative to I.1 ("Auxiliary Request 1", infringement of the combination of claim 1, 2 and 3 of EP 4 201 327 C0)
2. 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 Member States of the Unified Patent Court[4] (..) a fluid delivery device comprising (..) such as the insulin pumps shown in the pictures in I.1 above, inter alia offered under the tradenames *EOPatch* and/or *GlucoMen Day Pump*;

[3] See footnote n. 1.
[4] See footnote n. 1.

in the alternative to I.1 and I.2 (“Auxiliary Request 2”, infringement of the combination of claim 1, 2, 3 and 4 of EP 4 201 327 C0)
3. 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 Member States of the Unified Patent Court[5] (…) a fluid delivery device comprising (..)such as the insulin pumps shown in the pictures in I.1 above, inter alia offered under the tradenames *EOPatch* and/or *GlucoMen Day Pump*;

in the alternative to I.1, I.2 and I.3 (“Auxiliary Request 3” (infringement of the combination of claims 1 to 3 with additional features from the specification of EP 4 201 327 C0)

4. 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 Member States of the Unified Patent Court (..)[6] a fluid delivery device comprising (..) such as the insulin pumps shown in the pictures in I.1 above, inter alia offered under the tradenames *EOPatch* and/or *GlucoMen Day Pump*;

in the alternative to I.1 - I.4 (“Auxiliary Request 4” (infringement of the combination of claims 1 to 3 with additional features from the specifications of EP 4 201 327 C0)
5. 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 Member States of the Unified Patent Court[7] a fluid delivery device comprising (..) such as the insulin pumps shown in the pictures in I.1 above, inter alia offered (infringement of the combination of claims 1 to 3 with additional features from the specification of EP 4 201 327 C0) under the tradenames *EOPatch* and/or *GlucoMen Day Pump*;

in addition, for all Requests I.1 - I.5 above, Insulet repeated the requests from II to VII, specified on 8 July 2024 and requested to dismiss Defendant’s motions in the Objection to the Application for provisional measures according to items II. – XIII

Following a request for leave to amend the claims lodged by the Applicant, the Applicant requested that the Court:
(unconditionally limiting the claim pursuant to Rule 263.3 RoP to former Auxiliary Request 1, which the Applicant now asserts as New Main Request)
grant leave to change Applicant’s claim filed in the Application for provisional measures dated 8 July 2024, and as further specified in the Reply dated 26 August 2024, so that Applicant’s unconditional claim reads as follows (amendments to original claim no. I.1. underlined):
The Defendant is ordered,

[5] See footnote n. 1.
[6] See footnote n. 1.
[7] See footnote n. 1

(New Main Request - infringement of the combination of claim 1, 2 and 3 of EP 4 201 327 C0)
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 Member States of the Unified Patent Court[8] 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 tube nut threadably engaged with the leadscrew, and a clutch mechanism coupled to the drive wheel,
wherein the clutch mechanism is configured to allow the tube nut to pass through the clutch mechanism when disengaged and is configured to grip the tube nut when engaged such that the drive wheel rotates the tube nut to advance the leadscrew and the plunger into the reservoir, wherein the clutch mechanism includes a clutch spring that grips the tube nut when released;

As regards the ancillary claims, the Applicant referred to the requests made in the Reply dated 26 August 2024 (item II. VII.). These ancillary claims are maintained.

In the alternative, in case the Court did not allow the application for leave to change the claim according to R. 263.3 RoP, the Applicant requested that the Court shall decide the case based on claim 1 of the patent in suit as granted and as set forth in item I.1. of the original Application as well as in the Reply.

On 7 August 2024 the Defendant, requested that the Court:
I. dismiss the Application for Preliminary Measures;
II. in the alternative to I., allow the alleged infringement to continue subject to provision of security by Defendant, the amount of which to be determined by the Court;
III. in the further alternative to I. and II., to only order a preliminary injunction against Defendant with the proviso that
1. the territories of Austria, Bulgaria, Denmark, Estonia, Finland, France, Germany, Latvia, Lithuania, Luxembourg, Malta, Portugal and Slovenia are excluded from the geographical scope of this preliminary injunction; and
2. the Defendant may continue to supply the Attacked Embodiment to public and private hospitals and health care providers under tenders awarded to Defendant before the service of the Application for Provisional Measures; or
3. in the alternative to III.2.
a) the Defendant 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

[8] See footnote n. 1

b) the Defendant is allowed to 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 not be able to use an insulin pump different
from the Attacked Embodiment indefinitely;
IV. in any event where the Court orders a preliminary injunction, order Applicant to provide a security by for the enforcement of a preliminary 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;
V. in the event that the Application for Provisional Measures is dismissed or withdrawn, order Applicant to pay the costs of the proceedings;
VI. order Applicant to provide security for costs in the amount of EUR 200,000 before 1 October 2024
VII. the portions of this Objection that are highlighted in grey to be "Confidential Information".

On 9 October 2024 the Defendant requested that the Court:
I. reject the Application to Change Claim;
II. in the alternative, dismiss the Application for Provisional Measures also in the version of the new main request contained in the Application to Change Claim.

GROUNDS FOR THE ORDER

1. Requirements for provisional measures

Regarding preliminary injunctions, the Applicant is required to provide reasonable evidence to satisfy the Court with a sufficient degree of certainty that:

a. the Applicant is entitled to initiate proceedings under Art. 47 UPCA;
b. the patent is valid;
c. its rights are being infringed or that such infringement is imminent (Rule 211.2 RoP).

Additionally, urgency and the balance of interests are considered when granting a preliminary injunction. The balance of interests must be in favour of the Applicant (Rules 209.2(b), 211.2 and 211.3 RoP).
These requirements are cumulative (see Lisbon Local division, UPC CFI no. 317/2024, order of 15 October 2024)
Therefore, the absence of even one of these requirements is sufficient to warrant the dismissal of the application.
In the present case, the Court finds that there is an insufficient degree of certainty that the patent is valid for the reasons outlined hereinafter.

2. The patent at issue as granted

2.1. Claims, description and features

EP 327, titled "*fluid delivery device with transcutaneous access tool, insertion mechanism and blood glucose monitoring for use therewith"*, is based on a divisional application within the patent

family of PCT application WO 2013/149186 A1 and was applied for in English on 29 March 2013, claiming priority from US 2012261618028 P of 30 March 2012.
The patent application was published on 28 June 2013 and was granted without opposition on 19 June 2024.
The unitary effect was registered on 23 June 2024, with identical claims for all Member States of the Unified Patent Court (UPC), and it remains in force (exhibit PS 6).

EP 327 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 (cf. patent at issue, paragraph [0001]).
The patent at issue reads "*a fluid delivery device for delivering therapeutic liquids to a patient*" and it contains the following claims:
1. a fluid delivery 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. 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 (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).
In addition, dependent claims 2 to 5**,** directed to advantageous features of the invention, are configured as follows:
2. the fluid delivery of the claim 1, wherein the nut (156) is a tube nut;
3. the fluid delivery device of the claim 2, wherein the clutch mechanism (180) includes a clutch spring (162) that grips the tube nut when released;
4. the fluid delivery device of the claim 3, wherein the clutch mechanism (160) further includes a spring latch (164) configured to hold the clutch spring (162) in a disengaged position and configured to release the clutch spring (162) moves to an engaged position;
5. the fluid delivery device of claim 4, wherein the spring latch (164) is configured to release the clutch spring (162) in response to movement of the drive wheel (156, 256).

Figures 12 and 16 of the Patent are as follows:

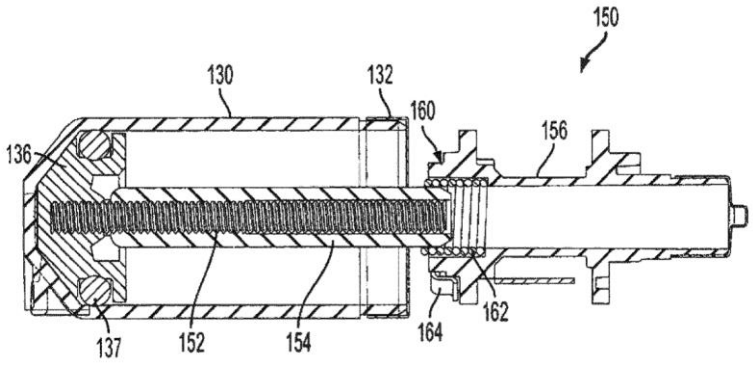


FIG. 12

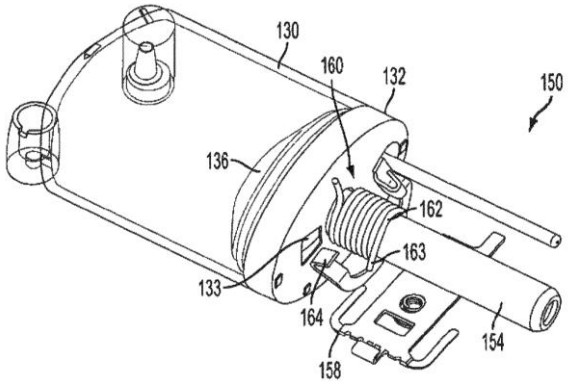


FIG. 16

In particular, the description of the patent contains, inter alias, the following:
[0020] Referring to FIGS. 11-16, the fluid drive mechanism 150 according to the present invention uses a clutch mechanism 160 to facilitate filling of the reservoir 130 and engagement of the fluid drive mechanism 150 for driving fluid out of the reservoir 130. 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 a plunger 136 received in the reservoir 130 and sealed with an o-ring 137 against the inside surface of the reservoir 130. The leadscrew 152 and plunger 136 may be an inseparable, insert-molded assembly. 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 and may be driven by a drive wheel 156 via a clutch mechanism 160.
[0022] In the illustrated embodiment, the clutch mechanism 160 includes a clutch spring 162 (e.g., a helical torsion spring) located in a counterbore at one end of the drive wheel 156, adjacent the reservoir 130. The inside diameter of the clutch spring 162 is larger than the outside diameter of the tube nut 154 when the clutch spring 162 is loaded, thereby disengaging the clutch spring 162 from the tube nut 154 and allowing the tube nut 154 to pass through the centre aperture of the spring 162 and into the elongated bore of the drive wheel 156 (…)

[0023] (…) When the clutch spring 162 is engaged, the drive wheel 156 contacts an end 163 of the clutch spring 162 to create a thrust on the clutch spring 162 that causes the clutch spring 162 to rotate the tube nut 154. The fluid drive mechanism 150 may also use other clutch mechanisms capable of allowing the tube nut 154 or other type of nut or threaded member to pass through the clutch mechanism and then being activated to engage the nut or threaded member.
[0025] 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 fluid driving mechanisms in other existing pumps. The components of the clutch mechanism are also more easily inspected than the tilt nut assembly.

2.2. Technical background of the invention

According to the description of the patent at issue, fluid delivery devices have numerous uses such as delivering a liquid medicine or other therapeutic fluid to a patient subcutaneously. In a patient with diabetes mellitus, for example, ambulatory infusion pumps have been used to deliver insulin to a patient. The ability to carefully control drug delivery can result in better efficacy of the drug and therapy and less toxicity to the patient. (cf. patent at issue, paragraph [0002]). Although prior art pumps are effective and provide several advantages, the fluid driving mechanism may also be improved to facilitate assembly and use of the pump (see. patent at issue, paragraph [0004]).
In view of this, the problem underlying the patent at issue is to provide a fluid delivery device where the filling of the fluid reservoir is simple and changing the device into a state for delivering fluid to a patient is efficient and reliable (cf. patent at issue, paragraph [0008]).
In addition, by using the claimed clutch mechanism, the results achieved are (para [0025]):
- to reduce 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.
- to change the thread pitch for other drug applications without a need to redesign the tilt nut used in fluid driving mechanisms in other existing pumps;
- to inspect the clutch mechanisms themselves more easily than the swing nut assembly.

The person skilled in the art may be defined as an engineer (e.g. bachelor's degree in mechanical engineering) possessing several years of experience in the development of medical technology products such as insulin pumps.

2.3. Claim construction

2.3.1. General considerations

The claim interpretation is made by the Court in accordance with:
- art. 69 EPC and the Protocol on its interpretation;
- UPC case law, and in particular the following decisions.

"*According to Art. 69 EPC in conjunction with the Protocol on its interpretation, the patent claim is not only the starting point, but the definitive basis for determining the protective scope of a*

European patent. The interpretation of a patent claim does not depend solely on its exact wording in the linguistic sense. Rather, the description and the drawings must always be taken into account as explanatory aids for the interpretation of the patent claim and not only be used to clarify any ambiguities in the patent claim. However, this does not mean that the patent claim serves only as a guideline and that its scope may extend to what, from a consideration of the description and drawings, the patent proprietor has contemplated" (Düsseldorf Local Division, UPC CFI no. 463/2023, order 30 April 2024; UPC CoA no. 335/2023, order 26 February 2024; Düsseldorf Local Division UPC CFI no. 452/2023, order 9 April 2024).
"*Claim construction is a task that has always to be performed and not just in case of ambiguities*" (Court of Appeal, UPC CoA no. 335/2023, order 26 February 2024).
"*The interpretation of the claim is the common basis on which both the validity issue and the infringement issues are to be decided*" (Court of Appeal, UPC CoA no. 335/2023, order 26 February 2024; Düsseldorf Local Division, UPC CFI no. 7/2023, decision 3 July 2024).
"*The interpretation of the patent is therefore not only mandatory for the Court, but also for the parties, who must submit their views on their proposed interpretation*" (Düsseldorf Local Division, UPC CFI no. 166/2024, order 6 September 2024).

2.3.2. The case at hand

Firstly, the parties presented arguments regarding the meaning of certain words, which the Court deems should be interpreted as follows in the light of the above-mentioned principles.
In particular, the following words and terms are disputed.

(i) "Device" (see Feature 1)

Insulet asserts that claim 1 does not refer to a general device but to a fluid delivery device "*in its mounted/assembled state*".
Menarini responded that "*comprising*" is a generic and broad term, and is broader in scope compared to the term "including". It does not refer to any state of assembly: the claim language does not contain any such limitation (see paras. [0033] and [0025], where it is specified that the components of the clutch mechanism are "*also more easily inspected than the tilt nut assembly*").
The Court observed that the patent does not appear to be limited to the assembled state. Claim 1 encompasses two filling techniques:
- the first technique involves moving the plunger during the filling process (para. 0012, col. 7, 29-47);
- the second technique requires that the reservoir be filled when the plunger is already retracted (EP 002, 7, 48-49).

Therefore, claim 1 encompasses this capability during assembly, after assembly, during filling, or at any other moment (see exhibit BB 50, Defendant, p. 6 para. 34).

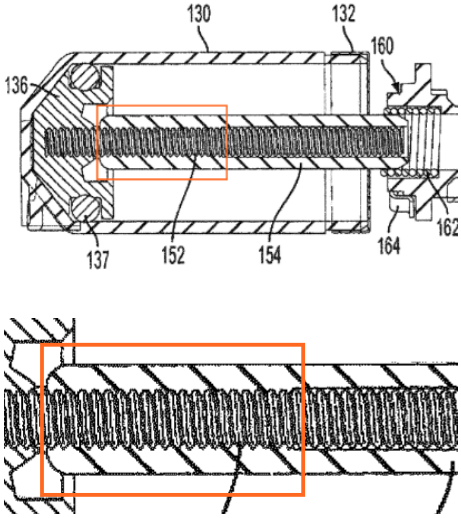
(ii) "Nut" (see Feature 4.3).

The Applicant considers that:
- the term "nut" does not require a continuous internal thread and that the patent at issue does not address the extension of the internal thread;

- this feature requires that the leadscrew and the nut must always be threadably engaged.

The Defendant argues that:
- the term “nut” is defined neither in the claim language nor in the specification;
  the patent at issue considers “nut” in its general sense when describing “first threaded member having external threads (i.e. the screw) and a “second threaded member having internal threads (the nut) (para. [0020]). Thus, the “nut” is described as a part that has an internal thread (the screw) that could be engaged with external threads (of the lead screw);
- the term “nut” is functionally limited to the portion with the internal thread and thereby contributing to the engagement with the leadscrew. This interpretation is made taking into account:
- the description in para. [0020] of the patent at issue;
- the fact that “nut” and “tube nut” are not standardized terms;
- the fact that the patent specification has its own dictionary;
- the fact that the nut does not require a continuous internal thread.

The Court agrees with the Defendant’s assertion that, in general, the skilled person understands a nut to be a hollow body with a thread on its inner surface.
According to an embodiment/example shown in Figure 12, the nut (154) is an elongated tube nut in which one part of the nut has an internal thread (left part of nut 154; see marked section enlargements of Fig. 12 below) and the other elongated part is only a tube or cylinder without any thread (right part of nut 154).



Therefore, the “tube nut” is described as having an elongated shaft (see para. [0020]).
In particular, fig. 12 describes the tube nut as comprising a portion with internal threads and shaft-like portion without any threads;
The term “nut” does not refer to any particular contouring of the external surface;
This feature does not require that the leadscrew and the nut must always be threadably engaged (see fig. 12). The feature does not require a continuous internal thread and the patent at issue does not mention the extension of the internal thread.

The term “nut” seems to be functionally limited to the portion with the internal thread and thereby contributing to the engagement with the leadscrew.

(iii) “The engagement” (see Feature 4.4)
The Applicant specifies that this feature requires that the leadscrew and the nut must always be threadably engaged.
The Defendant argues that this feature does not require that the leadscrew and the “nut must always be threadably engaged” (see fig. 12). Such an engagement of the leadscrew and nut is technically only necessary in the context of feature 4.5.2, but not in respect of feature 4.5.1.
The Court agrees with the Defendant, pointing out that the language of the claim does not refer to such a requirement, nor is it technically necessary, either in feature 4.4 or in feature 4.5.1. Furthermore, fig. 12 displays only a preferred embodiment and cannot be used to restrict the scope of protection of the patent.

(iv) “a clutch mechanism” (see Feature 4.5)
According to the Applicant, the clutch mechanism requires activation in the form of a “gripping actuation”, in accordance with para. [0022].
According to the Defendant, the patent at issue relates to switchable clutches, clearly referring to a clutch that can switch between a “disengaged clutch” state (feature 4.5.1) and an “engaged clutch” state (feature 4.5.2). The limitation proposed by the Applicant (based on para. [0022] is unnecessary for the general technical function of the clutch mechanism of features as described in para. [0008].
The Court notes that the word “clutch” refers to a device for connecting rotating shafts. The clutch can be used to engage and disengage rotating shafts. The clutch spring (162) shown as an example in fig. 12 transmits rotational motion of the drive wheel to the nut when engaged.

(v) “to pass through” (see Feature 4.5.1)
The Applicant specifies that this feature requires the nut to be surrounded by the clutch mechanism (see fig. 22).
The Defendant notes that “pass through” is not further defined in the patent at issue. Figure 12 teaches the person skilled in the art that “pass through” does not require the nut to entirely pass through the clutch mechanism.
The Court notes that in feature 4.5.1, the phrase to “allow the nut (154) to pass through the clutch mechanism (160)” does not necessarily mean that the (elongated) nut or its internal thread has to pass entirely through the clutch mechanism. Furthermore, it is not necessary for the clutch mechanism to grip the part of the elongated nut that has a thread (see patent at issue fig. 12 and fig. 16, and the length of the parts/components of the device).

(vi) *“to grip”* (see Feature 4.5.2)
The Applicant contends that the clutch mechanism requires activation through a “gripping actuation”, as described in para. [0022] EP 327;

The Defendant argues that Feature 4.5.2 must be interpreted such that "to grip" represents a technical effect and not an "activity".
The Court observes that the word "grip" means "to hold something firmly", preventing relative motion and ensuring a stable grip: the forces involved ensure that the clutch nut and the tube nut reach equilibrium and remain stationary. That is the sole technical meaning of the feature "grip", as made clear by the technical sense of Feature 4.5.2: the grip must occur "such that" the drive wheel rotates the nut. There is further explanation of the how the grip the shall occur.
Therefore, claim Feature 4.5.1 must be interpreted in connection with claim Features 4, 4.1 to 4.5 and 4.5.2. These features relate specifically to the arrangement of components of the nut (154) with respect to the clutch mechanism (160).
In particular, Features 4, 4.1 and 4.2. teach a drive mechanism (150) for driving fluid from the reservoir (130) of the fluid delivery device comprises a drive mechanism, a drive wheel (156; 256), and a plunger (136) received in the reservoir (130).
Features 4.3 and 4.4 claim a leadscrew (152) that extends from the plunger (136) and a nut (154) threadably engaged with the leadscrew (152).
Features 4.5, 4.5.1 and 4.5.2 teach that a clutch mechanism (160) is coupled to the drive wheel (156; 256). The clutch mechanism (160) is configured to allow the nut (154) to pass through the clutch mechanism (160) when disengaged (feature 4.5.1). According to Feature 4.5.2, the clutch mechanism 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).
These features teach the skilled person, that the drive wheel (156) can rotate the nut, as the clutch mechanism is coupled to the drive wheel and the clutch mechanism engages the nut (cf. patent at issue, Fig. 12 and Fig. 16). This means that the clutch mechanism may initially be disengaged and thus not grip the nut so that the nut can pass through the clutch mechanism without rotation of the drive wheel (see Feature 4.5.1).
Fig. 12 shows an embodiment in which the reservoir (130) is not filled with fluid. In Fig. 16, the device is shown with a plunger (136) in a position associated with a filled reservoir (130). Fig. 16 displays a removed drive wheel (156) and shows details of the clutch mechanism (160) (cf. patent at issue, para. [0020]).

3. Validity of the patent at issue

3.1. General consideration

As specified above in point 2, the Court observes that:

- for an injunction to be granted, *inter alia*, the patent must demonstrate "sufficient certainty" of validity, pursuant to Art. 62.4 and Rule 211.2 RoP;
- the requirement of "sufficient certainty" is fulfilled if the Court considers it to be more likely than not that the patent at issue is valid (UPC CoA no. 335/2023, order 26 February 2024);
- the fact that the Applicant has decided to file auxiliary requests does not in itself give rise to any doubts regarding validity. Instead, such auxiliary requests are indicative of legal caution (Dusseldorf Local Division, UPC CFI no. 463/2023, order 30 April 2024).

The Defendant has discharged its burden of proving a lack of certainty regarding the validity of the patent as follows.

3.2. Novelty

The Defendant objected that the patent at issue lacks novelty over US 994, which describes a "*miniature drug delivery pump with a piezoelectric drive system*" (Exhibit BB02).

US 994 was filed on 8 November 2007 and published on 14 May 2009, and thus is prior art pursuant to Art. 54.2 EPC.

It pertains to the same technology as the patent at issue, disclosing a miniature drug delivery pump that is capable of being held on the skin of a patient by means of adhesives and to be concealed under patient's clothing (para. [0025])

US 994 was not available to the patent examiner at the EPO.

Firstly, the Court recalls at the outset that it is common knowledge that the conversion of a rotational movement into a translational movement, or vice-versa, can be achieved by means of a screw and a nut. The art provides two examples of screw mechanisms in which, respectively:

1) the screw is not rotating and advanced by rotating the nut;
2) the screw is slidably accommodated in a cavity of a shaft.

US 994 discloses and describes examples of both: a rotating nut advancing the screw in fig. 4 (exploded view); the screw is slidably accommodated in the cavity of the shaft in fig. 5.

That being said, according to the Defendant, the embodiment illustrated in Figure 4 appears, at this stage, to destroy the novelty of EP 327.

Indeed, US 994 discloses all Features claimed in EP 327 and in particular:

✓ (Feature 1) a fluid delivery device (delivery pump 40, see fig. 4);

✓ (Feature 2) a fluid reservoir of the pump (fig. 4) represented by a liquid drug container (46); (see para. [0022]: "(...) *to dispense liquid drug from a drug contain*er (46)");

✓ (Feature 3) an administration set (98) described as "*a transcutaneous access tool, fluidly coupled to the fluid reservoir"* (drug container (46), as shown in fig. 6, see para. [0030]). The drug container (46) includes an injection site (94) which is used to connect a spike or other suitable type of connector (96) of an administration set (98) to the delivery pump (40). The spike or other suitable type of connector (96) is connected to a fluid conduit (100) […]

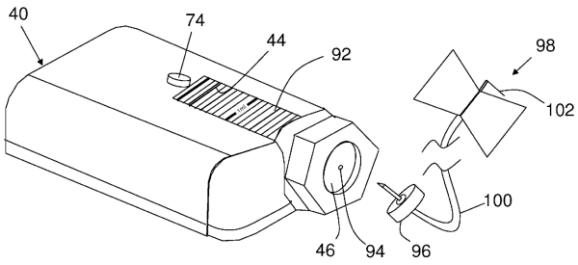


FIG. 6

✓ (Feature 4) "*a drive mechanism of the pump in the form of a screw mechanism having rotating nut* (fig. 4) *for driving fluid from the reservoir*"

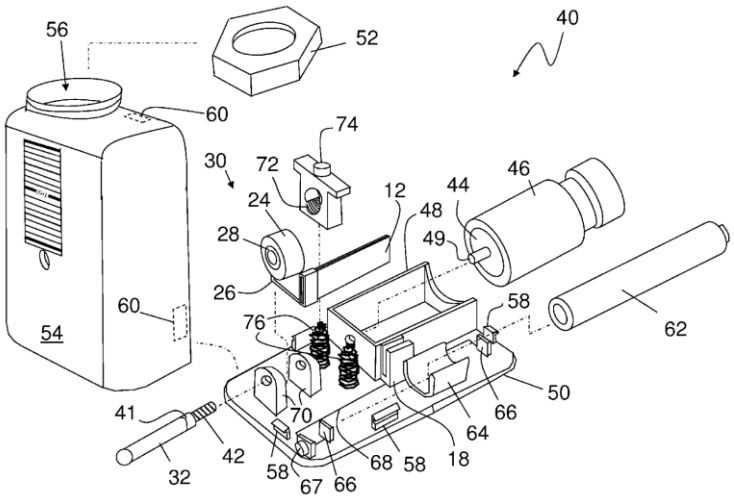


FIG. 4

and the drive mechanism comprises:
- a drive wheel (24);
- a lead screw (42) extending from a plunger or piston (44);
- a plunger (44);
- an (elongated) nut (41);
- a clutch (28) coupled to a drive wheel (24).

✓ (Feature 4.1.) a drive wheel (fig. 1 and 4,) driven by a piezoelectric bender (12) (para. [0018]) and transmitting movement to the shaft (32) via a clutch (28) (para. [0021].

✓ (Feature 4.2.) "a plunger (44) received in the reservoir (46) (see fig. 4) of the pump (see fig. 4 and para. [0022]).

✓ (Feature 4.3) "a leadscrew extending from the plunger".
The connection between lead screw (42) and plunger is realized via snap fit (49) (see fig. 4 and 6).

✓ (Feature 4.4.) "a nut threadably engaged with the leadscrew".
Fig. 4 discloses a tube shaft (32) with a threaded nut portion (41) engaged with a leadscrew (42). "The thread (not shown) of the nut portion 41 engage the threads of the lead screw 42 and cause the movement of the leadscrew" (see par. [0022])
The Court underlines that the aforementioned elongated nut (41) with a shaft (32) and threads represents a tube nut similar to the tube nut of the patent at issue.

✓ (Feature 4.5) a clutch mechanism coupled to the drive wheel (24, see fig. 4) which serves as a drive wheel of the device;

✓ (Feature 4.5.1) "The clutch mechanism is also configured to allow the nut to pass through the clutch mechanism when disengaged".
The exploded view of fig. 4 shows the clutch mechanism (clutch 28) configured to allow the nut (nut portion 41) with its shaft (shaft 32) to pass through the clutch mechanism when disengaged (cfr. fig. 4, paras. [0021], [0022]: […] "*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 lead screw 42 and cause the movement of the lead screw 42 upon rotation*

of the shaft 32. Movement of the lead screw 42 advances a plunger or piston 44 to dispense a liquid drug from a drug container 46)".
Thus, feature 4.5.1 is also already shown in the device known from the prior art according to US 994.

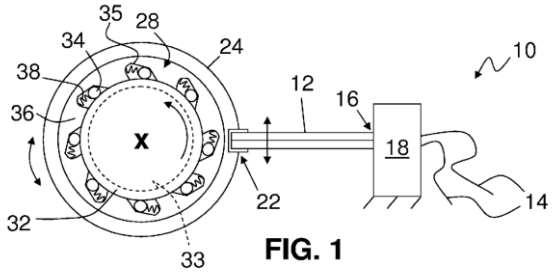


FIG. 1

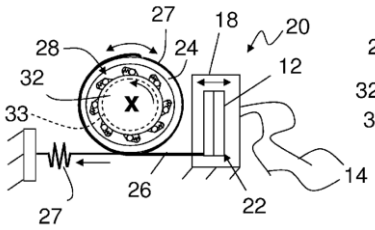


FIG. 2

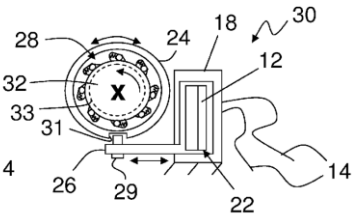


FIG. 3

✓ (Feature 4.5.2) The clutch mechanism is configured to grip the shaft (32) with the nut portion (41) when clutch rollers (34) are blocked between the shaft (32) and clutch (36), thus locking shaft (32) with nut portion (41) and clutch (28) together. In this engaged status a rotation of the drive wheel (24) causes a rotation of the shaft (32), pushing out the lead screw (42) and thereby the plunger (44) into the reservoir (46) (see Figs. 1 - 5 and para. [0022]: *Movement of the lead screw 42 advances a plunger or piston 44 to dispense a liquid drug from a drug container 46*).
In other words:
- the wheel (24) transmits movement via the clutch (28) on the shaft (32) with nut portion (41);
- the rotation on the shaft (32) with nut portion (41) causes the movement of the lead screw;
- the lead screw advances with the plunger (44) into the reservoir (46).

The Applicant contests that EP 327 is anticipated in a novelty-destroying manner by US 994, asserting that it fails to disclose:
(i) 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". In US 994, the shaft (32) does not move in axial-longitudinal direction, instead the shaft is fixedly supported by a pair of base supports (70). It remains in the same position and thus does not "pass through" the clutch mechanism as required by Feature 4.5.1.
(ii) Feature 4.4.: "a nut (154) threadably engaged with the leadscrew (152)". According to the embodiment of figure US 994, the leadscrew is slidably accommodated in the cavity (33) of the

shaft (para. [0028]). The shaft rotates together with the leadscrew (42) but does not transmit a longitudinal/axial force to the leadscrew (42) over a threaded engagement.
(iii) Feature 4.5.2: “wherein the clutch mechanism (160) 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)”.
The Applicant specifies that US 994 does not disclose any longitudinal movement of the shaft (32) (see para. [0027] of US 994). During the operation, the shaft (32) does not move in a longitudinal direction either.
The skilled person in the art would recognize the technical problems associated with the working embodiment depicted in figure 4. They would disregard the threaded engagement in view of the error and resolve this technically incorrect disclosure by interpreting the design of the shaft (32) and the leadscrew (42) such that the leadscrew (42) is slidably accommodated within the shaft (32) but with a fixed rotational relationship between these parties (similar to the embodiment shown in figure 5).
Assuming that the shaft has threaded engagement with the leadscrew (42) over the nut portion, allowing the shaft to rotate relative to the leadscrew, is not a reasonable interpretation for the following reasons:
- it would be in contradiction with the disclosure in US 994 that the shaft (32) and leadscrew (42) both rotate (para. [0004]):
- if the leadscrew were to move longitudinally without any rotation, this longitudinal movement would be blocked by the thread (80) of the keyhole (72);
- the use of the verb “retract back” in paragraph [0027] instead of “rotate back” would not make sense.

By contrast, following the interpretation suggested by the Defendant, the Court notes that, at first glance, the inclusion of a release button (74) with the thread (78) in the base might seem incompatible with the explanations provided in paragraph [0022].
However, this apparent inconsistency is resolved in the description of US 994 (see para. [0028], last sentence, in conjunction with figs. 4 and 5). Accordingly, the configuration featuring a release button (74) and a thread (78) in contact with lead screw (42) corresponds to a different embodiment in which there is no thread provided inside the shaft (32) of the nut Instead a spring (90) is provided that pushes the lead screw (42) into engagement with thread (78), thereby also pushing the piston further into drug container (44).

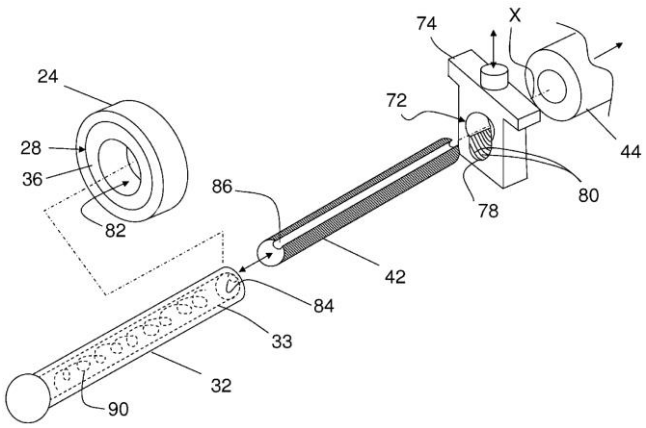


FIG. 5

As a result, a person skilled in the art would identify two distinct embodiments in Fig. 4 based on the information in para. [0028]., This interpretation does not conflict with the description in para. [0022] concerning Fig. 4 of US 994. Therefore, US 994 does not appear to contain any errors, nor are the embodiments "unworkable".
Indeed:

- US 994 discloses different versions of the drug delivery pump, as the patent at issue describes examples of both: rotating nut (fig. 4), rotating screw (fig. 5);
- fig. 4 of US 994 discloses use of rotating nut (para. [0022]);
- fig. 5 of US 994 discloses use of a rotating screw that does not provide for an internal threaded nut. Instead the shaft comprises an internal protrusion (84) aligned with a corresponding "linear slot" (86) foreseen in lead screw (42) so that when both parts are connected the protrusion (849 runs in the slot (86). The translational movement of the lead screw (42) is achieved by means of the threads (80) inside of the keyhole (72);
- fig. 4 of US 994 does not contain any errors, nor are the embodiments unworkable;
- the screw mechanism implements the well-known solution of a rotating nut (shaft 32, performing the nut function), fully functioning without the thread (80) of the keyhole (72). The person skilled in the art understands that the keyhole (72) is relevant only for the screw mechanism of the rotating screw as displayed in fig. 5 but not in fig. 4;
- fig. 4 of the US 994 discloses the feature 4.4., i.e. a nut threadably engaged with a leadscrew; regarding this point, the Applicant attempts to create an "unworkable embodiment";
- fig. 4 of US 994 discloses a clutch mechanism which is configured to allow the nut to pass through the clutch mechanism when disengaged;
- fig. 4 of US 944 discloses feature 4.5.2.

3.4. Conclusion

As a result, the subject matter of claim 1 as granted appears to be lacking novelty, in view of the prior art US 994 (Defendant's exhibit BB02).
In the light of the foregoing, the Court considers it more likely than not that the patent at issue is invalid (UPC CoA no. 335/2023, order 26 February 2024).

4. Auxiliary requests

As previously indicated, on 26 August 2024 Insulet filed four auxiliary requests to amend the patent.

4.1. Admissibility

The Applicant argued the admissibility of the auxiliary requests, taking into account the following points:

- the Court is also competent to decide on the validity of the patent at issue;
- the Court's competences are further reinforced by the appointment of a technically qualified judge to the panel;
- the auxiliary requests only represent an expression of legal caution (see Dusseldorf Local Division, UPC CFI no. 463/2023, order 30 April 2024) and are admissible at any stage of the proceedings.

The Defendant responded that:

- provisional measures can only be granted on the basis of the granted version of the patent;
- UPC case law establishes that provisional measures shall not be ordered based on the patent amendments, possibly only with the exception of extraordinary circumstances (Dusseldorf Local Division, UPC CFI no. 463/2023, order 30 April 2024; Munich Local Division, UPC CFI no. 17/2023, 10 October 2024);
- The Applicant did not file an application for leave to change its claims under Rule 263 RoP;
- The Applicant did not explain in its reply as to "why such change or amendment was not included in the original pleading";
- the new request was not filed within the correct workflow;
- an application to amend the patent may be only filed in accordance with Rule 30 RoP and Rule 50 RoP, which govern defences to a counterclaim for revocation;
- the auxiliary requests lacks clarity (Art. 84 EPC) and extends the protection it confers.

The Court determines the admissibility of the auxiliary requests taking into account the following:
(i) the principles of proportionality, flexibility, fairness and equity, having regard to the legitimate interests of all parties, as set out in the Preamble of the RoP;
(ii) Art. 138 EPC and ff., Rules 30.2. and 50.2. RoP; in particular, Art. 138.3 EPC states that "*In proceedings before the competent court or authority relating to the validity of the European patent, the proprietor of the patent shall have the right to limit the patent by amending the claims. The patent as thus limited shall form the basis for the proceeding*".
(iii) the case law of the UPC on patent amendments.
In particular, reference should be made to the following UPC case law.
"*A request (to amend the patent) would be inadmissible in preliminary injunction proceedings. The legal framework of the UPCA and the RoP for provisional measures does not expressly allow for such a possibility, in contrast to rule 30 RoP, which applies to actions on the merits. Furthermore, an analogous application of rule 30 RoP is not admissible. An auxiliary request to amend a patent claim in provisional measures is incompatible with the nature of such proceedings which are: summary proceedings; not on the merits; likelihood of the judgement on validity and infringement; urgency. Additionally, these proceedings require the lodging of a main case in which*

the outcome may differ. Therefore, the provisional nature of such action is inconsistent with the contemplated request" (Lisbon Local Division UPC CFI no. 317/2024, order 15 October 2024); "*The expression 'amend its case' contained in rule 263 RoP [...] seems to be interpreted in connection of the previous expression 'change its claim', as they constitute a hendiadys which relates to any modification to the case by the means of the introduction of a new claim or the replacement of the original one ('change its claim'), as the expressed reference to a counterclaim seems to evoke, or of the submission of new or different grounds of the claim ('amend its case'). It follows that the request to replace the original application to amend the patent with a new set of amendments appears to be outside the scope of said rule 263 RoP, as it does not pertain to a claim.*" (Paris Central Division, UPC CFI no. 255/2023, order 27 February 2024).

The Court follows the previous case law of the UPC and therefore holds that the auxiliary requests in the proceedings for provisional measures are not admissible prior to the main proceedings.
In addition, it is noted that:

- Rule 30 and 50 RoP must be interpreted in close connection with Art. 138 EPC ("*in proceedings before the competent court or authority relating to the validity of the European patent, the proprietor of the patent shall have the right to limit the patent by amending the claims. The patent as thus limited shall form basis for the proceedings").*
- within the UPC system, the amendment of the patent is expressly admitted only in the defence to the counterclaim for revocation (Rule 30.2 RoP) or in the defence to revocation (Rule 50.2 RoP) and it may therefore be lodged only in the main proceedings before the court having jurisdiction to give a final decision on the validity of the patent;
- where the Court is not competent to decide on the validity of the patent, the proprietor of the patent has no right to limit the patent;
- this interpretation is consistent with the need for expediency in provisional measures proceedings, which requires an imminent risk of harm while simultaneously respecting the principles of adversarial proceedings and the right of defence;
- provisional measures are instrumental to the main proceedings and do not produce *res iudicata* effects that may derive only from final decisions on the merits after the exhaustion of appeal rights or after the expiry of time limits for appeal - even regarding patent amendments;
- third parties other than litigants must have clarity and certainty regarding the scope of protection conferred by the patent;
- the specific application provided for in Rule 30.2 RoP is distinct and different from the amendment of legal claims under Rule 263.3 RoP, which may be introduced in any proceedings but does not pertain to amendments to the claims of the patent.

Accordingly, the auxiliary requests filed on 26 August 2024 by Insulet are dismissed.

5. Application pursuant to Rule 263.3 RoP

As previously stated, on 30 September 2024, Insulet lodged an application pursuant to Rule 263.3. RoP, specifying that it was unconditionally limiting its claim to the former auxiliary request. The

Applicant requested permission to amend its claim as initially filed in the application for provisional measures dated 8 July 2024 (as further specified in its reply dated 26 August 2024).
The Defendant objected that provisional measures cannot be granted on the basis of an amended claims application under Rule 263.3 RoP, arguing that this rule applies exclusively to the main proceedings on the merits, taking into account the following points:

(i) the Defendant's right to defend itself effectively;
(ii) unlike in main proceedings, there is no general principle in proceedings for provisional measures that imposes unconditional limitations preventing a claimant from reintroducing parts of a claim later again in the proceedings on the merits;
(iii) a limitation of the claim under Rule 263.3 RoP is only permissible if Defendant has no legitimate interest in a decision in respect of the original claim, whereas in the case at hand such an interest exists;
(iv) The Applicant did not follow the correct workflow;
(v) the need to file the application for provisional measures in a timely manner;
(vi) the combination of claims in the new main request lacks novelty or, at the very least, inventive step in view of US 994.

The Court recalls the UPC case law and, in particular, the following decision.
"*A request to replace the original application to amend the patent with a new set of amendments is not governed by rule 263 RoP but falls under rule 50.2 RoP and pursuant to rule 30.2 RoP such a subsequent request requires the permission of the Court (rule 263 RoP, rule 30 RoP, rule 50 RoP). The expression* "amend its case" *contained in rule 263 RoP, and to which the Defendant has referred to, seems to be interpreted in connection of the previous expression "*change its claim"*, as they constitute a hendiadys which relates to any modification to the case by the means of the introduction of a new claim or the replacement of the original one (*"change its claim"*), as the expressed reference to a counterclaim seems to evoke, or of the submission of new or different grounds of the claim (*"*amend its case*"*). It follows that the request to replace the original application to amend the patent with a new set of amendments appears to be outside the scope of said rule 263 RoP, as it does not pertain to a claim* (see Paris Central Division UPC CFI no. 412/2023, order of 9 February 2024).

The Court fully agrees with the above interpretation: the phrase "*amend its case*" under Rule 263.2 RoP refers to any modification to the case by introducing a new claim or replacing the original one ("*change its claim*"), even in the context of provisional measures (see Court Of Appeal, UPC CoA no. 182/2024, Order of 25 September 2024). Therefore, the "*claim limitation*" pursuant to Rule 263.3. RoP constitutes a formally distinct type of request.
In the present case, this is an attempt to use a different instrument to introduce a request for the amendment of the patent - governed by Rule 30.2 RoP – into these proceedings. Such a request is itself inadmissible in proceedings for provisional measures, as already stated in paragraph 4 above.
In conclusion, application under Rule 263.3 RoP is inadmissible and is therefore dismissed.

6. Security for costs

6.1. General considerations

An order for security of costs requires a substantiated presentation of facts concerning the financial situation of the opposing party which give rise to a legitimate concern about a risk of insolvency or indicate a lack of sufficient assets (see, *inter alia*, Munich Local Division, UPC CFI no. 514/2023, order of 23 April 2024; Nordic-Baltic Regional Division, UPC CFI no. 380/2023, order of 20 August 2024).

6.2. The case at hand

The Defendant seeks security for costs in the amount of EUR 200,000.

In particular, Menarini argued that there is a significant risk that, in the likely event that Defendant is successful in these proceedings, it will be unable to adequately enforce its claim for the reimbursement of costs. Insulet is a US company under the laws of Delaware. The United States of America is not a party to any international treaty that would allow for the enforcement of a decision regarding the reimbursement of the Defendant's costs - neither with the Italian Republic - where the Defendant has its registered office - nor with the European Union, nor with the Court itself.

The application is admissible under Art. 69.4 UPCA and Rule 158 RoP, but is unfounded as the requirements of Rule 158 RoP are not met.

The Defendant has failed to allege or prove circumstances that would indicate an alarming financial situation on the part of the Applicant. Security for costs is not primarily intended to protect against the difficulties of enforcing a cost decision abroad. Furthermore, the Defendant has provided no evidence that the Applicants would be unwilling to pay substantial interim costs without significant enforcement efforts. The mere fact that enforcing a cost claim outside the territory of the UPC is practically burdensome is not sufficient (see Dusseldorf Local Division, UPC CFI no. 165/2024, order 6 September 2024).

In the light of this consideration, the request is dismissed.

7. Interim award of costs

The Defendant requested the Court to order the Applicant to pay the costs of the proceedings, in the event that the application for provisional measures is dismissed or withdrawn (see point V. of its requests dated 6 August 2024).

The Defendant may claim interim costs based on an analogy with Rule 211.1(d) RoP.

The value of the case - set at EUR 2,500,000 by the Applicant - is not disputed.

The calculation of the Defendant's preliminary legal expenses, amounting to EUR 117,465.00 (see Exhibit BB47 of the Defendant, i.e. the invoices for these proceedings received from its legal representatives for the work conducted in this case up to 31 July 2024) is undisputed between the parties and cannot be the subject of any objection by the Court (see Local Division Düsseldorf, UPC CFI no. 452/2023, order of 9 April 2024).

This amount is therefore settled as interim costs.

8. Order to file action on the merits

According to the clear wording of Rule 213.1 RoP, as long as the Court has not granted any provisional measures, there is no need to take such measure.

ORDER

1. the application for provisional measures is dismissed;
2. the Applicant is ordered, subject to the final decision on the allocation of costs, to pay an amount of EUR 117,465.00 as an interim award of costs;
3. in all other respects, the Defendant's requests are dismissed;
4. the value in dispute is set at EUR 2,500,000.

Milan, 22 November 2024

Pierluigi Perrotti, presiding judge

Pierluigi Perrotti
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Alima Zana, judge-rapporteur

Alima ZANA
Firmato digitalmente da Alima ZANA
Data: 2024.11.22 08:59:41 +01'00'

Anna-Lena Klein, legally qualified judge

ANNA-LENA KLEIN
Firmato digitalmente da ANNA-LENA KLEIN
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Uwe Schwengelbeck, technically qualified judge

Uwe Schwengelbeck
Digitally signed by Uwe Schwengelbeck
Date: 2024.11.22 09:26:54 +01'00'

Sub-Registry

FERRETTI MADDALENA
MINISTERO DELLA GIUSTIZIA
22.11.2024 08:35:43 UTC

Information about appeal

An appeal to this order may be brought in accordance with Art. 73 UPCA and R. 220.1 RoP within 15 calendar days of the notification of this order.