

UPC_CFI_597/2024
Decision by default on the revocation action
Decision on the infringement action
Decision on the costs of the Preliminary Injunction Proceedings
of the Court of First Instance of the Unified Patent Court
delivered on 22/07/2025

HEADNOTES:

- Rule 355.2 RoP requires that, before issuing a decision by default against a defendant based on a procedural violation or failure to defend, the Court must verify that the case file contains sufficient, precise and consistent evidence to enable the judgment to be issued. A decision by default cannot be issued against the defendant based solely on a procedural violation or failure to defend.
- A patent has its own lexicon. However, patent terms should be interpreted following a straightforward reading of the claims and drawings, without looking, result-oriented, for a way out of a possible infringement. Thus, the terms of the patent must be interpreted according to their principal functional meaning, bearing in mind the language used in the patent itself.
- Pursuant to Article 1(3) of the decision of the Administrative Committee of 24 March 2023, the cap applies in each instance of the court proceedings, regardless of the number of parties or patents involved. Consequently, when considering patent infringement, where both an infringing manufacturer and an infringing distributor are involved in two separate but parallel proceedings concerning the same patent and the same act of infringement, a unitary approach is warranted. The cap established in Article 1(3) would be otherwise violated.

KEYWORDS: decision by default, patent lexicon, double litigation.

PARTIES:

CLAIMANT IN THE REVOCATION PROCEEDINGS AND DEFENDANT TO THE COUNTERCLAIM FOR INFRINGEMENT

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DEFENDANT IN THE REVOCATION PROCEEDINGS AND CLAIMANT IN THE INFRINGEMENT PROCEEDINGS

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PATENT AT ISSUE

<i>Patent no.</i>	<i>Proprietor/s</i>
EP4201327	Insulet Corporation

COMPOSITION OF PANEL – FULL PANEL

Presiding judge and judge rapporteur	Andrea Postiglione
Legally qualified judge	Anna-Lena Klein
Technically qualified judge	Uwe Schwengelbeck

LANGUAGE OF PROCEEDINGS: English

SUBJECT-MATTER OF THE PROCEEDINGS: revocation action – counterclaim for infringement –
Procedure for costs

SUMMARY OF FACTS

EOFLOW Co. Ltd. (hereinafter: EOFLOW) is a medical device developer and manufacturer based in South Korea, manufacturing the ‘EOPatch’ insulin pump, which is marketed in Europe under the trade name ‘GlucoMen Day Pump’.

INSULET Co. (hereinafter referred to as INSULET) is also a medical device company, based in the United States. The applicant sells, inter alia, ‘Omnipod5’, a disposable, wearable, tubeless insulin management system that allows automatic insulin delivery.

INSULET is the proprietor of European patent EP4201327 (with unitary effect: EP4201327C0; hereinafter “EP’327”), which is based on a divisional application in the patent family of PCT application WO 2013/149186 A1 (filed 29 March 2013, priority date: 30 March 2012). The grant of the patent was published on 19 June 2024. The unitary effect of the patent was recorded in the Register for Unitary Patent Protection on 23 June 2024.

On 14 October 2024, EOFLOW requested that this Court:

- revoke European patent 4 201 327 (EP’327), and to
- order Defendant to pay the costs of the proceedings or, in the alternative, that Defendant bear reasonable and proportionate legal costs and other expenses incurred by Claimant in these proceedings (interim award of costs), up to the applicable ceiling, or in the amount as the Court may order;

The claimant set the amount in dispute at EUR 2,500,000.

The grounds of revocation are:

- lack of patentability pursuant to Article 138 (1), lit. a) of the European Patent Convention (EPC) and Article 65 (2) of the Agreement on a Unified Patent Court (UPCA),
- lack of novelty as to independent Claim 1 and to dependent claims 2 to 5 (Art. 138 (1), lit. a) EPC over the prior art documents US 2009/01224994A1 (ROE) and WO 2010/055504A1 (YODFAT) and Art. 54 EPC), and to some extent US 2005/0238507A1 (Dilanni)
- lack of inventive step as to independent Claim 1 and dependent claims 2 to 5, Art. 138 (1), lit. a) EPC and Art. 56 EPC.

The revocation action was brought by EOFLOW consequent to INSULET's application to this Court, in July 2024, for a preliminary injunction to prevent the marketing of the EOPatch pump.

In fact, on 3 July 2024, INSULET filed for an *ex parte* preliminary injunction before this Milan CD, followed by a second *ex parte* request before the UPC Milan LD against the main distributor of the pump, requesting that the Courts order EOFLOW to cease manufacturing, offering, placing on the market, using, or possessing the fluid delivery device 'EOPatch'.

This court (Milan CD) rejected the preliminary injunction (PI) request on 22 November 2024, and the CoA overturned the decision of this Court of First Instance on 30 April 2025 (CoA_768_24/APL_64374/24), issuing the preliminary injunctions requested in July 2024.

On 10 December 2024, INSULET lodged in these proceedings a Defence to Revocation with a conditional application to amend the patent and counterclaim for infringement. Defendant requested that the Court uphold the patent or, on an auxiliary basis, uphold it based on one or more of the auxiliary requests submitted to the Court, and order the Claimant to bear the cost of proceedings.

INSULET also lodged a counterclaim for infringement, with the following request:

- I. The Counter-Defendant is ordered, 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 in which the Unified Patent Court Agreement was in force on June 19, 2024 (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 (sic), 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; wherein 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; (infringement of claim 1 of EP 4 201 327 C0) such as the insulin pump labelled as "EOPatch" / "GlucoMen Day Pump".

INSULET filed the same requests based on each auxiliary request (I2-I11).

Furthermore, INSULET requested:

I.12 to provide the Counter-Claimant within 30 days from service of the decision on the merits with complete information on the extent to which [EOFLOW] has committed the acts referred to in I.1 above, on an auxiliary basis the acts referred to [in] one of Petitions I.2 to I.11 above, since June 19, 2024 stating, structured by each month of a calendar year,

a) the origin and distribution channels of the infringing products;

b) the quantities produced, manufactured, delivered, received or ordered as well as the prices obtained for the infringing products;

c) the identity of any third person involved in the production or distribution of the infringing products;

d) the number and dates of the products offered;

e) the advertising carried out, broken down by advertising media, its distribution, the distribution period, and the distribution area; including evidence of these advertising activities;

f) the prime costs broken down by the individual cost factors and the profit generated, whereby

– I.12 (sic) to recall the products referred to in Petition I.1 above, on an auxiliary basis the products referred to [in] one of Petitions I.2 to I.11 above, which have been put on the market, from commercial customers, with reference to the infringing condition of the products determined by the Court and with the binding undertaking to refund any fees and to bear any necessary packaging and transport costs as well as customs and storage costs associated with the return and to take back the products;

I.13 to remove the products referred to in Petition I.1 above, on an auxiliary basis the products referred to [in] one of Petitions I.2 to I.11, from the channels of commerce, with reference to the infringing condition of the products determined by the Court and with the binding promise to refund any fees and to bear necessary packaging and transport costs as well as customs and storage costs associated with the removal and to take back the products;

I.14 to provide products referred to in Petition I.1 above, on an auxiliary basis the products referred to [in] one of Petitions I.2 to I.11, that are in their direct or indirect possession or ownership to a bailiff to be appointed by the Claimant for the purpose of destruction and to bear the costs associated with the destruction;

- II. For each individual infringement of the orders under I.1 to I.14 above, Counter-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 noncompliance 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.
- III. Counter-Defendant is obliged to compensate the Counter-Claimant for all damages which it has suffered since June 19, 2024 and will suffer as a result of the acts referred to in Petition I.1 above, on an auxiliary basis the acts referred to [in] one of Petitions I.2 to I.10 above.
- IV. The Counter-Defendant is ordered to pay preliminary damages of EUR 400,000.00 to the Counter-Claimant within three weeks from the date of service of the decision.

- V. The Counter-Defendant is ordered to pay the costs of the proceedings.
- VI. It is ordered that Counter-Defendant shall provide Counter-Claimant with adequate security of EUR 400,000 for costs within a reasonable time before the oral hearing.

INSULET requested that the amount in dispute for the counterclaim for infringement be set at EUR 2,500,000, and that the amount in dispute for the revocation action be raised to EUR 5,000,000.

On 10 February 2025, EOFLOW lodged a Reply to revocation and application for leave to amend the case, a 'defence to application to amend the patent' and a 'defence to counterclaim for infringement'.

EOFLOW submitted a new prior art document, namely US'159, a patent filed in April 2002 and issued in December 2003, which was not attached to the initial application, supporting the lodging with a request under Rule 263 RoP. The request to admit US'159 was rejected by this Court with order n.17190/2025 in ACT_56003/24 issued on 11 April 2025, due to the front-loaded nature of the UPC proceedings.

INSULET also applied to obtain security for the legal costs of the proceedings, stipulating that EOFLOW's financial position had deteriorated due to the outcome of a litigation involving the same patent before an US court, so that insolvency was likely to occur in the near future.

EOFLOW opposed INSULET's request for security, highlighting the successful outcome of the PI proceedings, and recalling that a preliminary assessment of the patent led to the conclusion that the patent at issue might not be novel.

EOFLOW further stipulated that security for costs on the defendant in an infringement action would contradict Art. 69 UPCA, as well as the practice of several European states, since "the UPCA does not provide for any means that a plaintiff in the proceedings could urge financial pressure on a defendant by way of a legal action which the plaintiff was completely free to start in the first place."

With order ORD_17190/2025 in ACT_56003/2024 UPC_CFI_597/2024 dated 11 April 2025, EOFLOW was ordered by the Court to pay a security deposit of €500,000 by 2 May 2025. The initial deadline was postponed to 13 May by Order ORD_21089/2025 on 5 May, following EOFLOW's application.

The Court observed that the financial and economic situation of the Korean company seemed to be quite severely compromised and that the wording of Rule 158 RoP does not preclude the possibility of providing security for the plaintiff, as in the present case, where the roles of plaintiff and defendant overlap in cross-actions for revocation and infringement. The Court stated that the security fosters the overall reliability of the procedure and the fairness of the proceedings, since no party acting in legitimate defense of its interests and in good faith may fear security that is automatically released when a decision in its favor is made.

At the interim conference on 13 May 2025, in the presence of the judge rapporteur, the TQJ Uwe Schwengelbeck, and the LQJ, Anna-Lena Klein, EOFLOW's lawyers declared that the security had not been paid and that the company was unwilling to proceed with any payment.

INSULET's lawyers insisted then on a decision by default as a consequence of the non-compliance with the Court's Order.

The Court then instructed the parties to indicate whether they still had an interest in the oral hearing (OH), at least for the counterclaim for infringement.

EOFLOW insisted on an oral hearing. INSULET requested a Decision by Default for both actions.

The decision of the Court on revocation is based on the following submissions and attached exhibits:

- a revocation application (EOFLOW 14/10/2024)
- a revocation defence (INSULET 10/12/2024)
- a reply to the revocation defence (EOFLOW 10/02/2025)
- a rejoinder to the revocation application (INSULET 06/03/2025).

As regards the counterclaim for infringement the decision is based on:

- a counterclaim for infringement (INSULET 10/12/2024)
- a defence to the counterclaim for infringement (EOFLOW 10/02/2025)
- a reply to the defence to the counterclaim for infringement (INSULET 06/03/25)
- a rejoinder to the reply to the defence to the counterclaim for infringement (EOFLOW 07/04/25).

POINTS AT ISSUE

- 1) PATENT VALIDITY AND (1a) PATENT AMENDMENTS
- 2) PATENT INFRINGEMENT AND CORRECTIVE MEASURES
- 3) COSTS OF PROCEEDINGS

1) PATENT VALIDITY - DECISION BY DEFAULT ON THE CLAIM FOR REVOCATION

The panel observes that the application for revocation filed by EOFLOW must be dismissed by default.

The decision by default expresses the principles of proportionality and speed set out in the preamble to the RoP.

The RoP provides for a decision by default in two cases:

- Violation of procedural rules (in which case, the decision is punitive and results in the plain dismissal of the case under letter a) of Rule 355.1);

- Absence of the defendant (or *in absentia*) where a party fails to appear at an oral hearing, or fails to submit all or part of its submissions. In this case, at the request of a party, the judge may issue a brief judgment substantially upholding the claim (see letter b) Rule 355.1).

In the first case, proceedings conclude with a summary statement only acknowledging the party's failure to comply with the required step, while emphasizing the need for proceedings to be conducted under the court's direction for the sake of efficiency and consistency, and in respect of the court's management powers (see Rule 331).

In the second case, the rules stipulate that a decision cannot be based solely on the defendant's failure to appear and provide for the regulation of proceedings in the absence of legal defence. Rule 355.2 provides for the decision by default to be accompanied by an assessment of the facts of the case and the conduct of the parties (if facts put forward by the claimant justify the remedy sought).

This Court notes that this provision applies only when the decision by default is given against the defendant (in a revocation claim or an infringement claim) and points out the difference between the term "party" referred to in Rule 355.1 and the terms "claimant" and "defendant" contained in Rule 355.2.

Rule 355.2 reflects, in fact, the UPC's commitment to delivering efficient, high-quality judgments, a principle that cannot be compromised for the sake of procedural speed or due to the absence of a defence.

Thus, an action for revocation or infringement cannot be upheld on the merits solely to punish the defendant for procedural conduct. The sanction referred to in Rule 355.2 is losing the case, certainly not losing the patent (in a revocation case) or being declared as an infringer (in an infringement case). A defendant not appearing in Court or overlooking an order of the Court is seen as an infringer only if the facts put forward by the claimant justify this assessment.

Therefore, if the claimant omits a step that the Court considers necessary to ensure the fairness of the proceedings and the proper balance of the parties' rights, the decision by default is based solely on non-compliance and results in dismissal of the case.

If, on the other hand, a decision by default is requested against the defendant, and the conditions for issuing such a decision are given, to prevent the claimant from gaining an unfair advantage through no-contest or lack of defence, and to avoid a decision being made based solely on one party's allegations, which would run contrary to the UPC's already mentioned commitment to judicial decisions of the highest quality, Rule 355.2 requires that this decision by default be supported by facts justifying the remedy.

The goal of expeditious proceedings must be balanced against the principles of proportionality and fairness. Whether the relief sought is a declaration of infringement or revocation of a patent, a decision cannot be issued 'by default' solely on the grounds of the defendant's failure to take a step.

Consequently, Rule 355.2 must be interpreted in light of the burden of proof principle set out in Rules 171.1 and 172.1, which reflects the front-loaded nature of UPC proceedings. This implies that the rules of procedure provide for acknowledgement of the claim, even in a decision by default, only if the facts behind the claim are sufficiently substantiated.

For this reason, the Court decides that it would be pointless to issue a decision by default on the counterclaim for infringement. In any event, although EOFLOW failed to fulfil its obligation to pay the security, the panel would still be required to assess, albeit summarily, the merits of the case.

The Court therefore concluded that holding an oral hearing would enable a more solid assessment of the evidence to be made, and thus allow a decision on the counterclaim for infringement to be reached with greater legal certainty for both parties.

As to revocation, the prerequisite for a decision by default outlined in Rule 355 appears to be

- non-compliance with a legally issued order and
- a request by a party (generally the counterparty).

In these proceedings, INSULET clearly expressed their preference for a decision by default (in both proceedings) during the interim conference. The decision by default for the revocation action is therefore admissible.

The request is also well-founded.

EOFLOW knowingly evaded an obligation imposed by the Court without even filing an appeal against the order for security under Rule 158.3 RoP. In doing so, EOFLOW impaired the trial, leaving INSULET with no other option but to continue legal proceedings in the revocation action without reasonable security for recovering the foreseeable legal costs.

The applicability of the decision by default due to non-compliance by the claimant is undisputed. This interpretation is also in line with the *ratio* behind Art. 69(4) UPCA to protect a defendant against an insolvent claimant, who initiates an action without having sufficient means to compensate the defendant for the legal costs incurred by the proceedings he was involved in at the initiative of the claimant (UPC_CoA_393/2025, order of 20 June 2025, para. 15).

Nor can it be claimed that EOFLOW acted to revoke the patent as a mere defence in response to INSULET's patent infringement claim, because EOFLOW had already objected to the validity of the patent during the provisional phase, when it submitted its legal defences.

Therefore, the decision to take independent action to invalidate the patent lay with EOFLOW, whose refusal to pay the security must result in the case being dismissed.

EOFLOW will bear the costs of the revocation action dismissed by default.

(1A) PATENT AMENDMENTS AND AUXILIARY REQUESTS

As the patent revocation claim has been dismissed, there is no need to adjudicate on the patent amendments proposed by INSULET.

2) DECISION ON THE (COUNTER)CLAIM FOR INFRINGEMENT

This court decides, as mentioned above, not to rule by default on the action for infringement.

The order issued on April 11, 2025, to provide INSULET with security has not been complied with by EOFLOW either.

The court acknowledges that the Court of Appeal addressed the disputed issue of whether security can be imposed on the plaintiff in its June 20, 2025, decision in UPC_CoA_393/2025 APL_20694/2025, where in point 21, the court stated that "the Enforcement Directive does not support a reading that would expand the UPCA's language in Art. 69(4) UPCA to also cover an order for security for costs at the request of the claimant."

This Court noted that the order to pay the security was not appealed by EOFLOW and seemed to be legally binding, even though there might be a limit on the defendant in its defenses, and asked both parties to file submissions on this issue with Order of 25 June 2025 ORD_30344/2025 in ACT_56003/2024.

The issue of deciding by default (since a security not compliant with Art. 69 UPCA was not appealed by Eoflow) or following an oral hearing appears to be of little significance *de facto*, since, as mentioned above, Rule 355.2 requires the Court in any case to take into account all the facts already in the case file.

For this reason, despite EOFLOW's failure to pay the security, on June 25, 2025, the court opted to discuss the case, specifying that the discussion should be preferably limited to the infringement action.

Given the above, the infringement action is well-founded.

The patent at issue relates to fluid delivery devices for delivering therapeutic liquids to a patient. According to the description, 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 patients. 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, paragraphs [0001]-[0002]). Although prior art pumps are effective and provide several advantages, the fluid driving mechanisms may also be improved to facilitate assembly and use of the pump (cf. patent at issue, paragraph [0004]).

The technical problem

The technical problem underlying EP'327 can be seen as that of reducing the size of the pump, improving user comfort and facilitating the compliance of the embodiment (paragraph [0004] 'to improve the comfort to the user, and/or to incorporate continuous glucose monitoring), providing a fluid delivery device where the filling of the fluid reservoir is simple, and changing the device into a state where delivering fluid to a patient is efficient and reliable (cf. also patent at issue, paragraph [0008] 'The insertion mechanism may also provide an increasing insertion force as the needle/trocar moves in the insertion direction').

Contrary to what EOFLOW said during the oral hearing, and specifically referring to paragraph [0008] the technical problem also concerns the ease of filling the reservoir and involves, therefore, the 'passing through' clutch mechanism.

The person skilled in the art

EOFLOW presents the person skilled in the art as 'a suitable person who has at least a bachelor's degree in mechanical engineering, or an equivalent degree, with several years of experience in medical device design and manufacturing, in particular in small mechanics. Based on this, the

person skilled in the art would have understood the basics of medical-device design and manufacturing, and the basic mechanical elements (e.g. gears, pistons) involved in drug-delivery devices.

INSULET does not provide its own specific definition of a person skilled in the art.

The Court identifies the person skilled in the art as a person who possesses at least a degree in mechanical engineering, or an equivalent degree, with several years of experience in the design and manufacture of medical devices, in particular in small mechanics.

On this basis, the person skilled in the art should have an understanding of the basics of medical device design and manufacturing and the basic mechanical elements (e.g., gears, plunger, clutches) involved in drug delivery devices.

Solution of the technical problem

According to claim 1, the problem underlying the patent is solved by the following product:

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 (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).

Features 1, 2, and 3 describe a mechanism for administering fluids (in this specific case, insulin) in which there is a reservoir (130) for storing the fluid, a transcutaneous injection mechanism (172), and a connection between the reservoir and the injection device.

The Court's interpretation is that the transcutaneous access tool allows fluid to be administered under the skin. The term 'transcutaneous' indicates that the device operates through the skin.

Furthermore, the tool (172) cannot be solely interpreted with exclusive reference to the (soft) cannula (176) but must also include, under a broad and functional interpretation of the mechanism, the instrument that allows the skin to be penetrated, consisting of a needle (or trocar). The cannula penetrates the skin only to the extent that the needle allows the dermis to be pierced and the cannula to be comfortably inserted subcutaneously.

This conclusion is reached by reading the description in paragraph [0013], stating that the instrument also consists of a needle (or trocar) that penetrates the skin and in light of paragraph

[0004] specifying the general features of all embodiments belonging to the same family: *‘These pumps also include fluid driving mechanisms for driving fluid from a reservoir through the transcutaneous access tool’.*

The interpretation of the claim construction in light of the view of the person skilled in the art requires that the approach to the product be carried out also – if not predominantly – from the perspective of one who is familiar with the general characteristics of equivalent products widely used in the field.

The concept of ‘fluid coupling’ must also be read with reference to description in paragraph [0013], where it is clarified that this is represented by a fluid ‘path’ that interconnects the reservoir (130) to the cannula (176) of the tool (172). It is therefore clear that the coupling refers not to the patient's body (as asserted by EOFLOW during the oral hearing) but to the reservoir. It is therefore irrelevant that the transcutaneous access device may not always be connected to the dermis of a patient.

Here, too, if the description refers to the “cannula 176 of the transcutaneous access tool 172”, the cannula (176) can only be a part of the tool (172) and is therefore not a synonym of the tool (172) itself, or interchangeable therewith.

The drive mechanism (150) – **feature 4** – serves to conduct the liquid from the reservoir (130).

The skilled person understands that if the tool (172) is the path by which the fluid is conducted from the reservoir (130) into and beneath the patient's skin, the drive mechanism is the element acting on the reservoir to push the liquid through the transcutaneous access tool (172) to the patient.

The claim feature 4 must be interpreted as meaning that the drive mechanism is composed of various distinct elements, including primarily a wheel (156) – **feature 4.1.**, a plunger (136) located inside the reservoir (130) **feature 4.2.**, and a leadscrew (152) extending from the plunger (136) – **feature 4.3.**

Responding to a specific observation filed by EOFLOW as to the filling method, the Court notes that it is true that paragraph [0021] provides that the reservoir may be refilled in alternative embodiments even when the plunger is retracted, but the skilled person would understand that this option is not achieved in the preferred embodiment and that the technical problem is solved here by loading the insulin mainly, if not exclusively, when the plunger is in the extended position.

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 before 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).

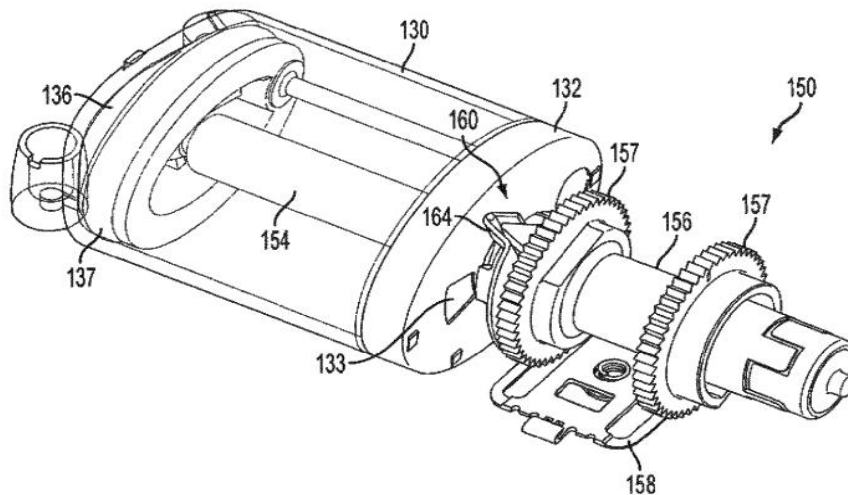


FIG. 11

The claim further defines other elements of which the drive mechanism (150) is comprised: a nut (154) threadably engaged with the screw (152) - **feature 4.4.**, and a clutch (160) coupled to the wheel (156).

Of relevance is the fact that the nut is described as ‘threadably’ engaged with the leadscrew (see paragraph [0020]: *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*).

This description suggests that in the claim construction the nut and screw are ‘already’ engaged, expressing thus a prior engagement which is instrumental to interpreting the whole patent claim construction and that suggests that the embodiment relates to a mechanism that is already assembled and ready for operation. See description in paragraph [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’*.

See i.e. Fig. 12, which is a cross-sectional view of the fluid driving mechanism, which shows an embodiment where the reservoir (130) is not filled with fluid.

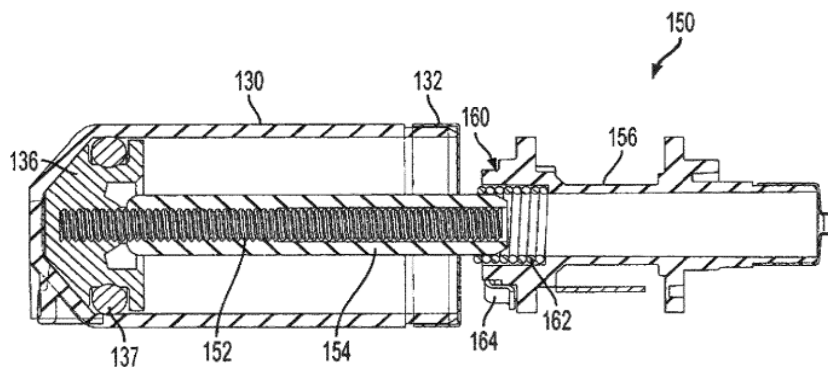


FIG. 12

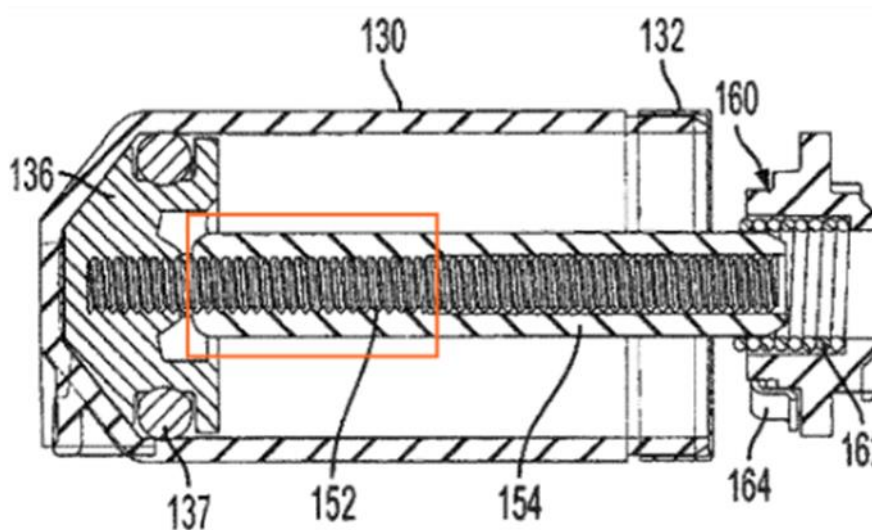
Administration of the fluid is therefore accomplished according to the description in paragraph [0021]: “rotation of the drive wheel (156) causes the clutch mechanism (160) to rotate the tube nut (154), which causes the leadscrew (152) to advance the plunger into the reservoir (130)” and thus by pressing the fluid from the reservoir through the tube (in)to the patient.

The close interconnection between the leadscrew (152) and the threaded nut (154) is therefore what allows the force to be transmitted to the plunger (136). This interconnection can only be brought about at the moment of assembly.

In Fig. 16 (see below) the device is shown with a plunger (136) in a position associated with a filled reservoir (130). Fig. 16 reveals the device with a removed drive wheel (156) and shows details of the clutch mechanism (160) (paragraph [0020]).

According to an embodiment/example shown in Figure 12, the nut (154) is therefore 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 another elongated part is only a tube or cylinder without any thread (right part of nut 154).

The Court holds that the nut (154) is to be understood by a person skilled in the art as a tube nut with internal threads, while the leadscrew is the second threaded element. The Court considers that, from the drawings, only part of the nut is threaded and engaged with the threaded part of the leadscrew.



EOFLOW raised several interpretive issues, proposing a different interpretation of the term "nut," limited to the threaded part of the leadscrew.

The patent claim is not only the starting point, but the decisive basis for determining the protective scope of a European patent under Art. 69 EPC in conjunction with the Protocol on the Interpretation of Art. 69 EPC. The interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used. Rather, the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim, and not only to resolve any ambiguities in the patent claim. However, this does not mean that the patent claim merely serves as a guideline and that its subject-matter also extends to what, after examination of the description and drawings, appears to be the subject-matter for which the patent proprietor seeks protection. The patent claim is to be interpreted from the point of view of a person skilled in the art. In applying these principles, the aim is to combine adequate protection for the patent proprietor with

sufficient legal certainty for third parties (UPC_CoA_335/2023 APL_576355/2023, order of 11 March 2024).

Claim features must always be interpreted in the light of the claim as a whole (UPC_CoA_1/2024, APL_8/2024 , decision of 13 May 2024, para. 29). Thus, as it will be elaborated below in further detail, a feature in a dependent claim cannot contradict the same feature in the main claim.

The description and the drawings may show that the patent specification defines terms independently and, in this respect, may represent a patent's own lexicon (CD Munich UPC_CFI_14/2023 decision of 16 July 2024). However, preferred embodiments highlighted in the description and drawings may generally not be understood as limiting or restricting the scope of the patent claims (LD Düsseldorf UPC_CFI_373/2023 decision of 31 October 2024). The primacy of the patent claims must be respected avoiding any literal interpretation which is artificially aimed (stretching their meaning or limiting it) at removing certain terms from the patent's scope. Finally, patent terms should be interpreted following a straightforward reading of the claims and drawings, without looking – result oriented – for a way out of a possible infringement.

Thus, the terms of the patent must be interpreted according to their principal functional meaning, bearing in mind the language used in the patent itself rather than solely for the purpose of avoiding patent infringement (*When interpreting a patent claim, the person skilled in the art does not apply a philological understanding, but determines the technical meaning of the terms used with the aid of the description and the drawings. From the function of the individual features in the context of the patent claim as a whole, it must be deduced which technical function these features have individually and as a whole. The patent description may represent a patent's own lexicon*, CD Munich UPC_CFI_14/2023 decision of 16 July 2024).

The nut shown in the pictures is clearly a tube nut and the threaded part is only a part of the nut.

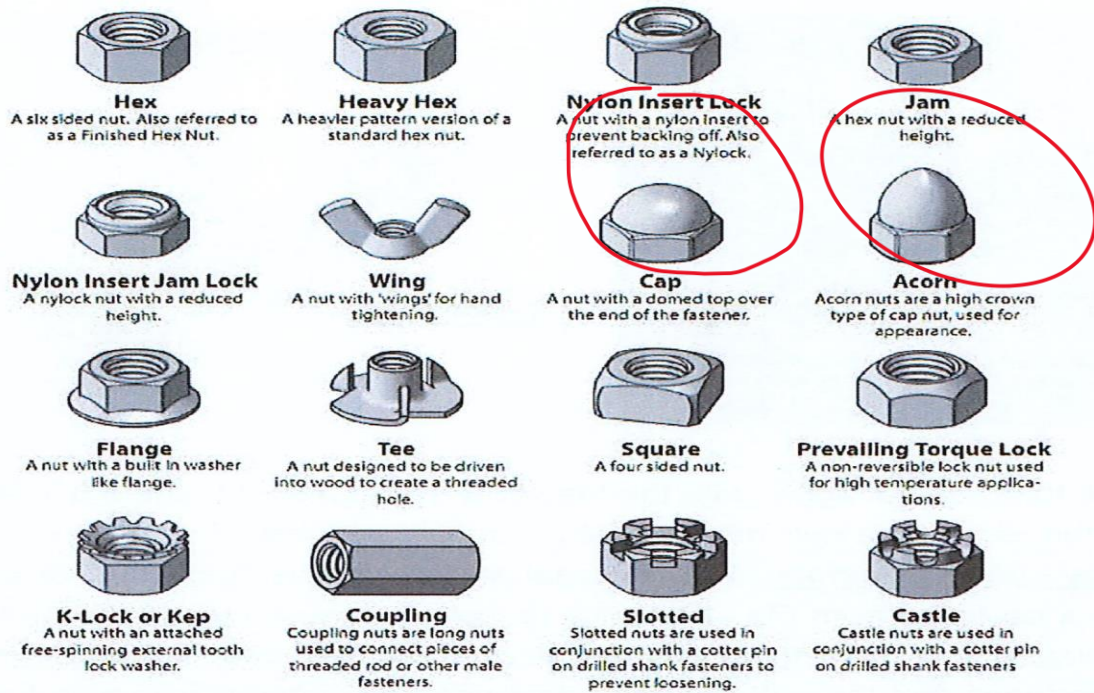
Claim 2 also clarifies, to avoid any misinterpretation, that “nut” should be understood as “tube nut”. Patent claims must be read as a whole to avoid any misinterpretation, as stated above, so that a feature in a dependent claim (in this case, in claim 2) cannot contradict the same feature in the main claim.

EOFLOW (page 151 of the defence to the counterclaim for infringement) maintains that the (tube)nut would be only the threaded part of the tube nut, so that, when assembled, the embodiment would not present a nut (or a threaded part) passing through the clutch, as highlighted by the cross-sectional technical drawings of EOFLOW's embodiment.

This issue must be dismissed based on correct claim interpretation.

Even Prof. Pott, EOFLOW's ‘proposed’ expert in the field, pointed out in his sworn statement (Exhibit. HRM 4 in the PI proceedings) that a thread is limited to its function and that, if the threaded part of a nut “[has] too many turns[,] this could result in unwanted friction between nut and screw/bolt”.

Claiming that only the threaded part defines the nut flatly contradicts EOFLOW's exhibit file (Pott's statement, point 18), which shows nuts of various shapes and types, some of which are partially threadless on the inside.



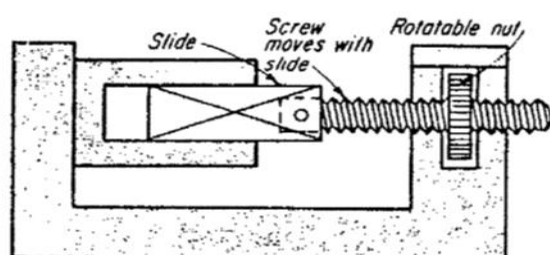
The decision to maintain the length of the threaded portion at eight turns corresponds to the expert's choice, aiming to maximize efficiency and economy (it should therefore be emphasized that both EOFLOW and INSULET's embodiments feature eight turns, so that EOFLOW also undisputedly uses in its pump a nut with partial thread in its embodiment similar to the one of the preferred embodiment).

The Court concludes that the nut of claim 1 must be interpreted as a tube nut partially threaded in its interior so that the operation of filling the reservoir causes the nut to pass through the clutch. Thus, the narrow interpretation of "nut" as referring solely to the threaded portion is not supported.

Feature 4.5: the Clutch

A screw mechanism converts rotational motion into translational motion, which is central to the operation of devices of this kind. Various alternatives exist, the differences between which will be well known to a skilled person in the field of mechanical engineering.

This picture of a basic screw mechanism is taken from Peter Pott's Opinion (Exhibit. HRM 4 in the PI proceedings), and features a "non-rotating screw" with a rotating nut:



The nut is free to rotate but is constrained in the longitudinal direction, and the slide is free to move longitudinally without rotating. The screw moves longitudinally, being prevented from rotating by the slide.

The Court understands that a screw mechanism refers to a system that converts rotational motion into translational motion. The Court further understands that in the preferred embodiment a rotary movement of the tube nut (154) is converted into a longitudinal movement of the leadscrew (152), which in turn pushes the plunger (136) that pumps the liquid into and through the access tool (172) (see fig. 12).

The clutch is coupled to the drive wheel (**feature 4.5**), meaning that the rotational motion is conveyed from the drive wheel to the clutch and on to the nut and leadscrew assembly, which converts the rotational motion into a translational motion of the plunger.

The Court notes that the clutch is not made up solely of the clutch spring (162) that grips the nut (154) and thus allows transmission of the rotary movement to cause the plunger (136) to extend. The clutch also comprises a latch (164) by means of which the clutch spring is held or released: when the latch falls into the window (133), the clutch spring is released and thus grips the tube nut (154).

This feature is made clear from description in paragraph [0023]: *“the spring latch 164 may be biased by the clutch spring 162 such that as the drive wheel 156 rotates the spring latch 164 moves rotationally against a surface of a reservoir cap 132 until clutch spring 162 deflects the spring latch 164 into a window 133 in the reservoir cap 132. When the spring latch 164 moves into the window 133, the end of the clutch spring 162 held by the spring latch 164 is released, thus engaging the clutch mechanism 160. 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.”* Thus, in the patent in suit EP’327 the clutch can have a disengaged state and an engaged state.

In the disengaged state, the helical spring is open and allows the tube nut to pass-through (See Fig. 16 below) which also is the technical problem addressed by the patent: to allow easy filling of the reservoir using a clutch which, when disengaged, allows the tube nut to pass through and without any rotation of the tube nut.

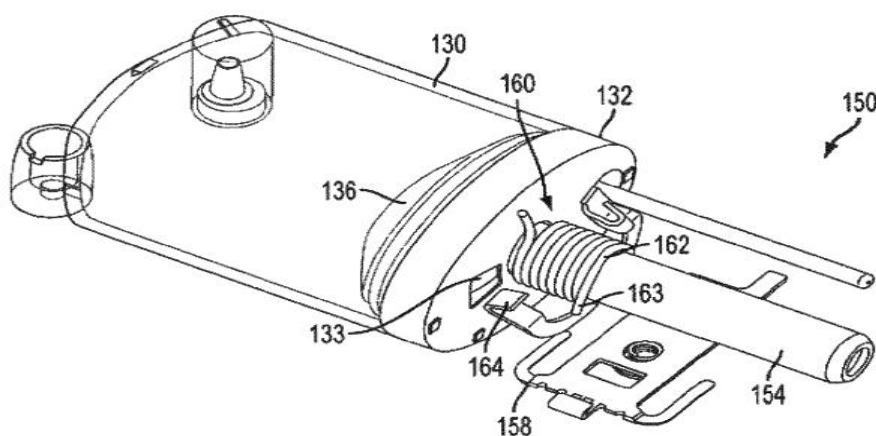


FIG. 16

According to description in paragraph [0020] *“the fluid drive mechanism 150 [...] 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 solution is provided by a clutch that opens and closes as needed, thus allowing an easy filling process, also minimizing the dimensions of the embodiment.

EOFLOW raised several interpretive issues, proposing a different interpretation for the “clutch” and its gripping force and for the “passing-through” expressed in **feature 4.5.1**.

The Court raised a general issue of correct interpretation of feature 4.5.1, as the “passing-through” could be interpreted as either passing through during the assembly phase or during operation of the embodiment.

The Court also questioned the parties as to whether the verb “pass through” should be interpreted statically as “to be placed through” during assembly, or dynamically as “being placed through during assembly and passing through during operation”. In the case of claim feature 4.5.1, both interpretations could be valid: the patent description uses that wording only in paragraphs [0022] and [0023], where the words “pass through” apply to the second threaded member (the tube nut), so that both interpretations were theoretically viable in the light of the description. Moreover, the German and French texts of the claim cannot shed more light on the issue (the German text shows the same ambiguity: ‘zu ermöglichen, dass sich die Mutter durch den Kupplungsmechanismus bewegt’, as does the French version: ‘pour permettre le passage de l'écrou à travers le mécanisme d'embrayage’).

As previously stated, the Court maintains that a person skilled in the art would interpret the embodiment as a fluid delivery device in an already assembled state, considering the functionality of the embodiment. The second interpretation is therefore to be preferred.

Only in its assembled state does the embodiment show its distinctive functionality. Claim feature 4.5.1 requires, in fact, special consideration in connection with the other claim and in particular with claim features 4, 4.1 to 4.5 and 4.5.2.

All these features relate specifically to the arrangement of components in an assembled state and specifically of the nut in dynamic relation to the clutch:

- Features 4, 4.1 and 4.2: a drive mechanism (150) for driving fluid from the reservoir (130) of the fluid delivery device comprises a drive wheel (156; 256) and a plunger (136) received in the reservoir (130).
- Features 4.3 and 4.4: a leadscrew (152) extending from the plunger (136); a nut (154) threadably engaged with the leadscrew (152).
- Features 4.5, 4.5.1 and 4.5.2: 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 grips 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).

If the tube nut can pass through the clutch mechanism during filling of the reservoir (see above and para. [0021]), it is because the nut is already in threaded engagement with the leadscrew (see

in particular the state prior to filling, shown in Fig. 12). The drive wheel (156) rotates the nut when the clutch mechanism engages the nut (cf. Fig. 12 and Fig. 16).

In the assembled state of the fluid delivery device, the container needs to be filled, meaning that the tube nut has to move through the clutch to increase the volume of the space where the liquid is to be stored.

In view of both the assembled state and feature 4.5.1 ("to pass through"), it is not sufficient for the nut to extend through the clutch mechanism statically. The nut must be allowed to slideably pass through the clutch in the assembled state of the fluid delivery device, thereby retracting the plunger and allowing the container to be filled. Therefore, in the assembled state of the fluid delivery device, the nut can move and thereby slideably pass through the clutch mechanism when the latter is disengaged, i.e. when the nut is decoupled from the clutch (feature 4.5.1).

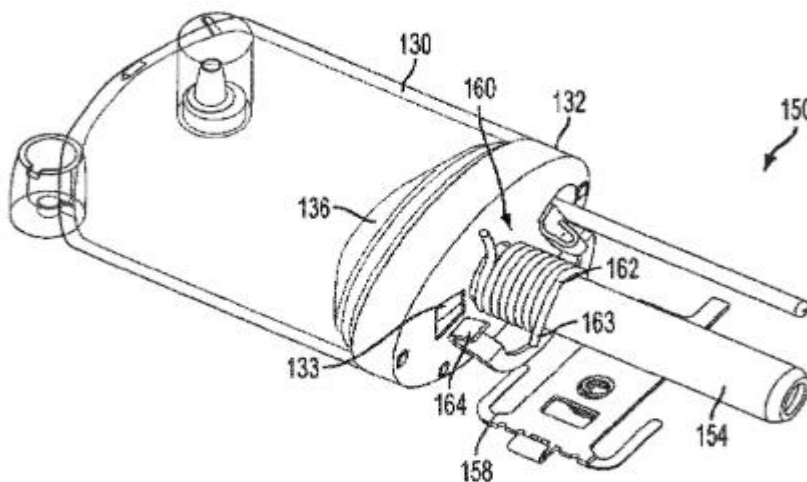


FIG. 16

The consideration of embodiment in the assembled state can also be inferred from the wording of other claim features:

- Feature 3: a transcutaneous access tool (172) fluidly coupled to the fluid reservoir (130);
- Feature 4.4: a nut (154) threadably engaged with the leadscrew (152); and
- Feature 4.5: a clutch mechanism (160) coupled to the drive wheel (156; 256).

All these features together suggest a dynamic and functional approach to the embodiment.

Furthermore, concerning claim 4.5.1 again, this Court finds that, from a functional interpretation of the claim, passing through is directly linked to the filling procedure. The preferred embodiment expresses two possibilities (see paragraph [0021]): the first relating to filling the reservoir when the plunger is in the retracted state, and the second when it is in the extended state. In both cases, filling the reservoir is functional for the subsequent administration of the liquid, because if the plunger is not retracted or is not suitable for retraction, the filling procedure cannot take place.

Besides, *'the interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used. Rather, the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim'* (ORD_595990/2023 in CoA_335/2023, 26 February 2024).

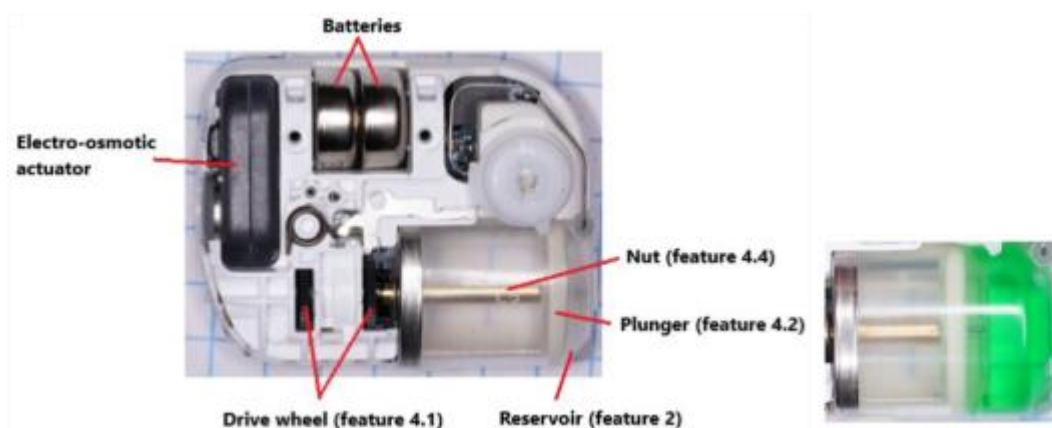
Therefore, when the spring is open (disengaged state), filling the reservoir causes the nut (154) to pass through the clutch (160), whereas when the spring is closed and grips the nut, the rotational motion of the drive wheel is transmitted to the nut and is thereby converted into a longitudinal motion of the plunger (136), allowing the administration of the fluid to the patient throughout the tool (172).

Feature 4.5.2 relates to the engaged state, where the clutch grips the nut (see figures 13 and 14). According to this feature, when the clutch is closed, i.e. does not allow the tube nut to pass through, the drive wheel, clutch and nut rotate together and in doing so, allow the fluid to be administered to the patient through the transcutaneous access tool (172).

In the opinion of the Court, the EOPatch pump, or ‘GlucoMen Day Pump’, infringes EP’327 in all features.

The embodiment is a fluid delivery device containing a fluid reservoir (cf. Exhibit PS 10 no. 4, showing an empty and a filled reservoir (green fluid) / features 1 and 2).

The pictures are taken from the affidavit of technical expert Ian McLaughlin (PS8).



The insulin pump “EOPatch” contains a transcutaneous access tool (a bent needle/cannula), which is fluidly coupled to the fluid reservoir (cf. Exhibit PS 10, no. 5, the needle is marked with a yellow circle/feature 3). The bent needle structure is, therefore, always in fluid connection with the reservoir as described in feature 3 of the preferred embodiment.



Connection of the needle structure to the reservoir



Bent structure of the needle

The insulin pump also has a drive mechanism for driving fluid from the reservoir (feature 4), including a drive wheel and a plunger (cf. Exhibit PS 10, no. 6 / features 4 and 4.1).



Drive wheel having two interconnected ratchet wheels

Notably, the drive wheel of the insulin pump “EOPatch” is identical to the drive wheel (156) of EP’327, which also has two interconnected ratchet wheels (157): see para. [0024] and Fig. 11 of the patent at issue:

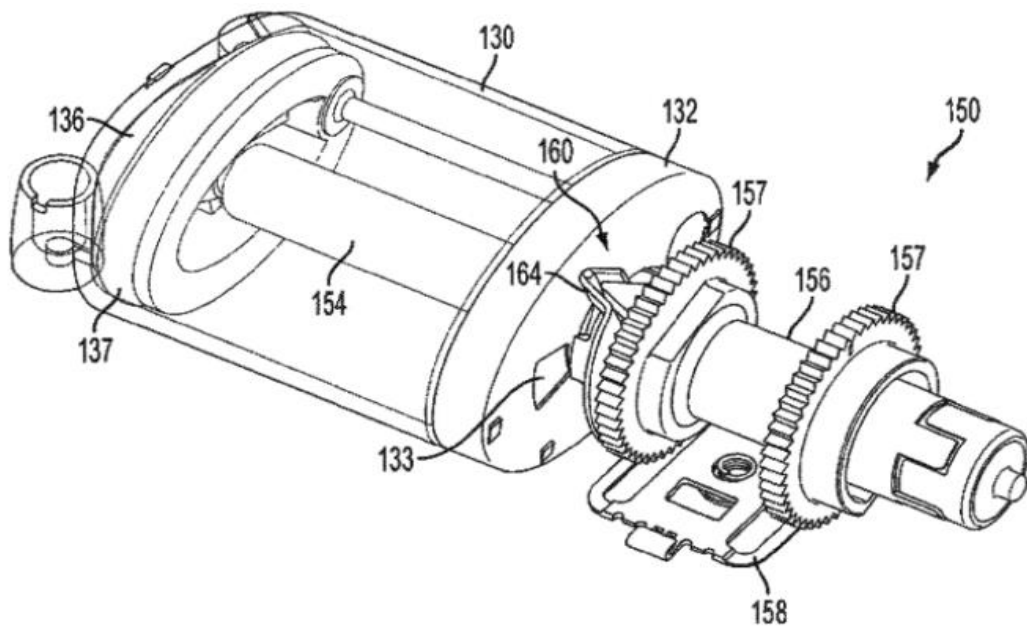
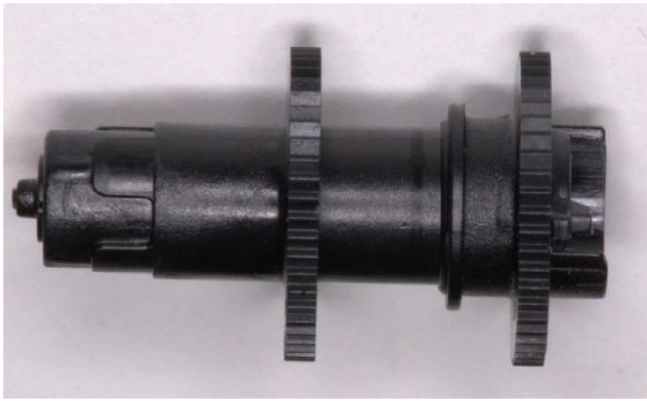
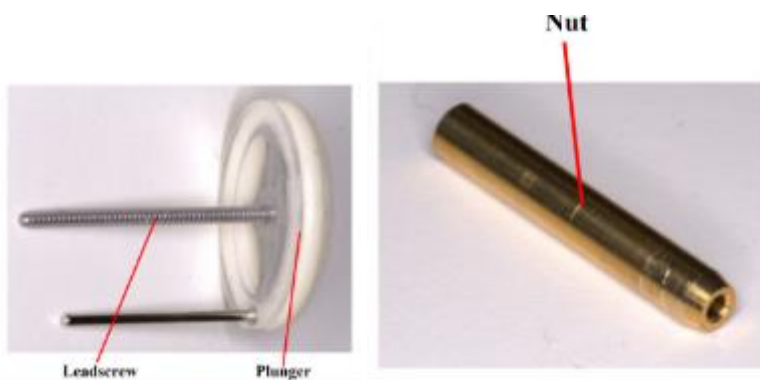


Fig. 11 of the patent in suit

The drive wheel of the EOPatch:



This insulin pump further comprises a plunger received in the reservoir (feature 4.2) and a leadscrew extending from the plunger (feature 4.3); cf. Exhibit PS 10, no. 7).



The drive mechanism of the insulin pump also comprises a tube nut with a thread on one side, wherein the nut is threadably engaged with the leadscrew (cf. Exhibit PS 10, nos. 8 and 9 / feature 4.4).



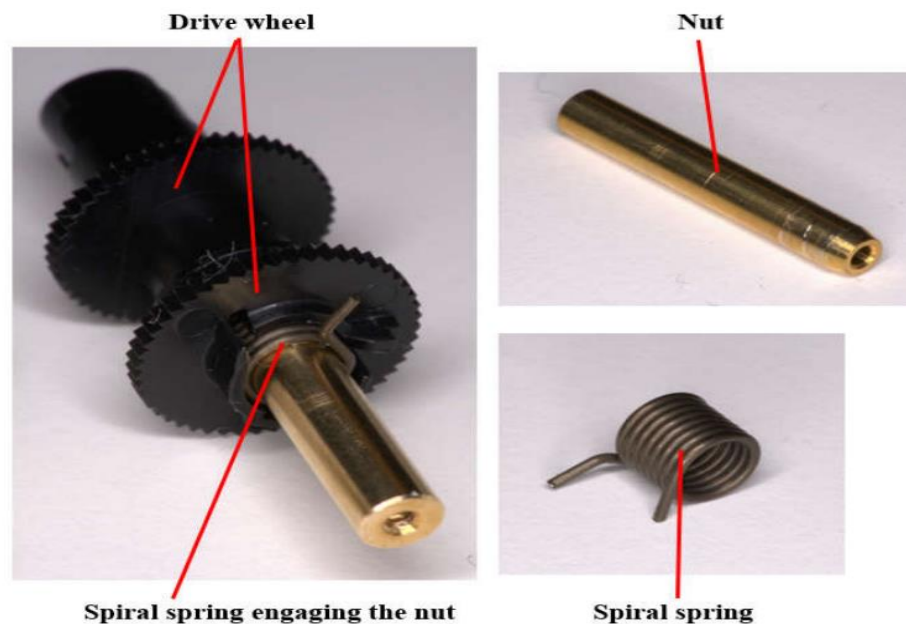
Finally, a clutch mechanism, with a spring and a protrusion connected to the drive wheel, appears to be coupled to the drive wheel, wherein the clutch mechanism is configured to allow the (elongated) nut to (dynamically) pass through the clutch mechanism when disengaged (cf. Exhibit PS 10, nos. 9 and 10 / feature 4.5.1).

The clutch mechanism of the insulin pump EOPatch is also configured to allow the nut to pass through the clutch mechanism when disengaged (feature 4.5.1) and to grip the nut when engaged, such that the drive wheel rotates the nut to advance the leadscrew and the plunger into the reservoir (feature 4.5.2).

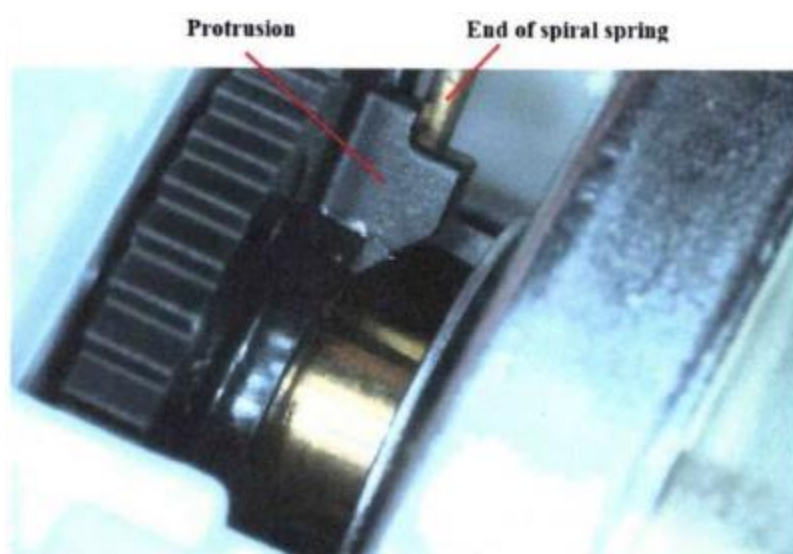
This has been tested and confirmed by the technical expert Mr. Ian McLaughlin (cf. Exhibit PS 8 and Exhibit PS 10, no. 10 / feature 4.5.2).

Recalling the interpretation of claim feature 4.5.1, it is not required that a nut (or an elongated nut) and its internal thread have to pass entirely through the clutch mechanism. Rather, the clutch mechanism does not need to grip the part of the elongated nut that contains a thread (cf. patent at issue, Figs. 12 and 16, see the length of the parts/components of the device).

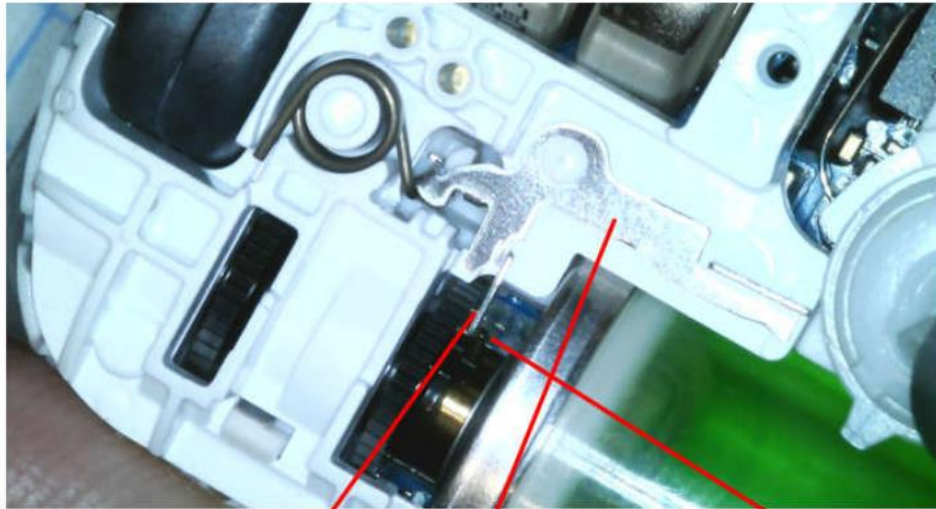
Moreover, the spiral spring used in EOPatch is identical to that of EP'327, as can be seen in the images below:



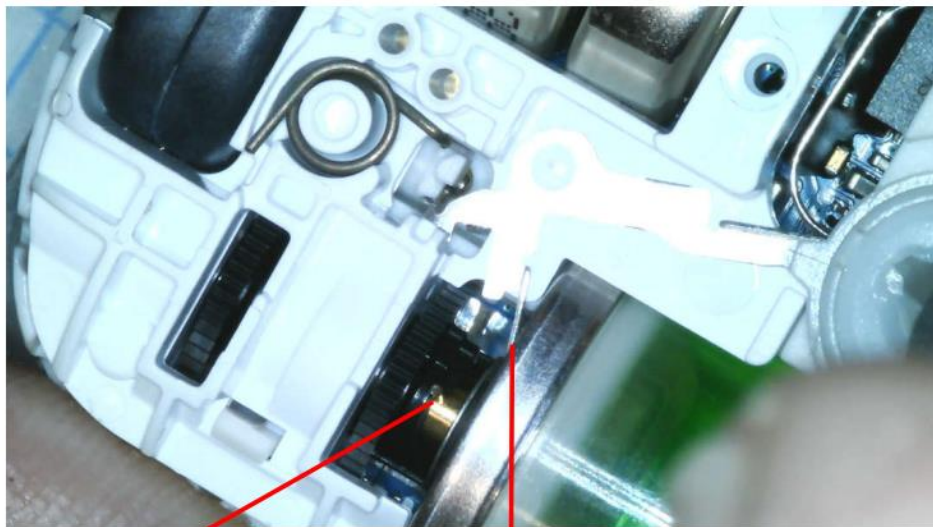
The technical expert Mr. Ian McLaughlin prepared a video showing how the nut passes through the clutch mechanism when filling the reservoir (see PS8 affidavit of Ian McLaughlin)



In the following images, it is evident that the spiral spring is first engaged and then released to reach the final position. In this regard, it should be reiterated that EOFLOW's defense that the two mechanisms are different because they have a different application of the spring latch is pointless, since the spring latch (as part of the clutch) is not contained in the claim and, therefore, infringement can also occur with two different modes of implementation of the spring latch.



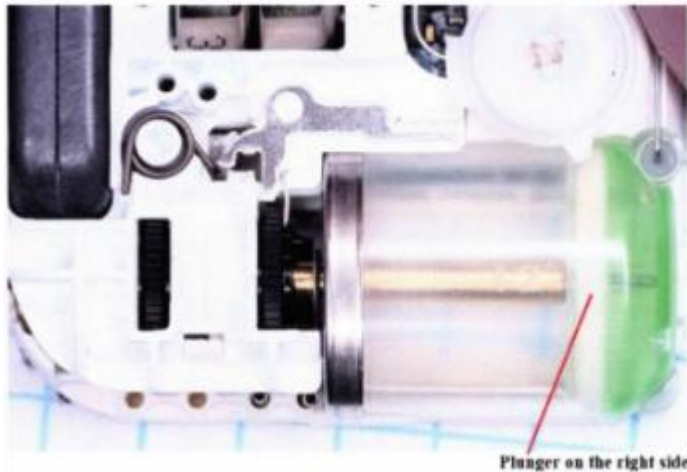
“Clutch disengaged” – An arm of the lever mechanism contacts the end of the spring



End of the spring

Arm of the lever mechanism

In the final position:



Given this, the contested device falls entirely within the scope of protection of claim 1: all features of claim 1 are infringed by 'GlucoMen Day Pump'.

INSULET requested the implementation of the following measures with respect to the infringer:

- (a) permanent injunction in accordance with Art. 63 UPCA;
- (b) compensation for damages pursuant to Art. 68 UPCA;
- (c) corrective measures under Art. 64 and 67 UPCA, including the recall of products from the channels of commerce, their definitive removal from the channels of commerce, and/or their destruction;
- (d) reimbursement of legal costs, including representation fees and expenses, under Art. 69 UPCA.

A) PERMANENT INJUNCTION

The EOPatch pump (also known as the 'GlucoMen Day Pump') falls entirely within the scope of claim 1 of EP'327 and therefore infringes it.

Under Art. 63 UPCA, an injunction can be issued whenever a decision is taken finding an infringement of a patent. The injunction is aimed at prohibiting the continuation of the infringement and may be accompanied, as requested by INSULET, by a periodic penalty payment under Rule 354.4 RoP.

Risk of repetition can be presumed if one case of infringement has been shown. Subsequently, it is not for the claimant in infringement to prove the risk of repetition, but for the defendant to eliminate this presumption (Milan LD, UPC_CFI_241/2023, decision of 4 November 2024, para 7.4).

Against this background, the Court finds for danger of repetition. Although a cease-and-desist agreement has been concluded with Menarini, which was the principal distributor of the embodiment on the European market, thereby preventing EOFLOW from further distributing EOPatch in Germany and France, this Court considers that there remains a risk of EOPatch being marketed within the UPC signatory states. The cease-and-desist order signed by the principal distributor does not preclude the manufacturer from distributing the product through another

distributor. The settlement with Menarini concerned only the downstream market of the insulin pump at hand, not preventing the distribution from occurring through other distribution channels. Additionally, the fact that the main distributor of the infringing goods has signed a cease-and-desist declaration makes it still possible for the manufacturer to carry out infringing activities through new and different and still unidentified intermediaries.

Furthermore, in the preliminary injunction proceedings, INSULET maintained that sales activities (including those conducted through Menarini) had taken place not only in Italy, but also in other European UPC jurisdictions such as Sweden, Belgium, Luxembourg and the Netherlands.

EOFLOW, as the manufacturer of the infringing embodiment, issued a press release on its website on 22 May 2024, announcing its intention to resume the marketing and sales of its insulin pumps to new users in the EU (see Exhibit PS 14), thereby demonstrating a clear intent to promote sales of the EOPatch pump at least within the above-mentioned UPC signatory states.

In the first defence to the counterclaim for infringement dated 10 February 2025, EOFLOW did not specifically contest these facts. On the contrary, EOFLOW took a specific position on the infringing nature of the EOPatch pump in relation to the Omnipod (pages 150-167), the request for security (pages 167-175), the claim amendment (pages 175-176) and the grace period (pages 176-186), articulating a complex and comprehensive defence on each of these issues.

EOFLOW did not take a specific position on the factual allegation that it was offering and distributing (or intending to offer and distribute) the infringing embodiment in the markets of the Contracting Member States, including, but not limited to, through Menarini as the main distributor. This omission (or lack of specific counterargument) occurred both in the preliminary injunction proceedings and on the merits.

EOFLOW developed a defence based on the assumption that it was merely a minor market player, claiming market shares that were not detrimental to INSULET's market strategies.

Under Rule 171.2 RoP a statement of fact that is not specifically contested by any party shall be held to be true as between the parties. Since the parties did not dispute the market penetration of the EOPatch Pump in either the Reply or the Rejoinder, the (attempted) distribution of the infringing embodiment within all UPC signatory states must be regarded as undisputed.

Consequently, INSULET's request for an injunction under Art. 63 UPCA is well-founded.

The parties further debated in court whether the rights arising from EP 327 had expired, given that INSULET had allegedly allowed Menarini, the main distributor of EoPatch, to distribute a limited number of products still in stock after coming to a settlement agreement.

The Court notes that the settlement agreement between Menarini and Insulet was referred to by the Court in the Order of July 2nd solely to understand the current distribution network for the product.

The filing of the settlement agreement with Menarini as a document by EOFLOW and INSULET (respectively HRM 32 as a draft and Exhibit PS 14a) is inadmissible. Lodging such a document is against the front-loaded nature of the UPC proceedings, since it took place after the written (and the Interim) proceedings had been closed, in proximity (only few days) before the oral hearing and,

above all, without any consent from the judge rapporteur, and for purposes not consistent with those mentioned by the Court in its order of July 2, 2025.

The document cannot be taken into consideration by the Court, even for the purposes of confidentiality requested by INSULET, as it was submitted in violation of the principle expressed in point 7 of the preamble, according to which documents must be lodged ‘as early as possible’, and with the consent of the Court, if lodging occurs after the written procedure is closed. Since the document has been voluntarily disclosed by INSULET without any Court’s permission and outside the framework of the Court’s case-management control, no issue of confidentiality can now be envisaged.

Furthermore, referring to the issue that was raised during the oral hearing, the issue of patent’s rights’ exhaustion governed by Article 29 UPCA and referred to in Article 6 of EU Regulation 1257/12 concerns only products that have been placed on the market in the Union after (explicit or implicit) consent of the patent proprietor. In the case at hand, the embodiments of EOFLOW were introduced into the European territory without the consent of the patent owner; proof is that INSULET filed a preliminary injunction with this court to prevent further distribution.

Moreover, a proprietor’s (retroactive) consent (or renunciation of their right to object) to the placing of the goods on the market within the EEA for distribution must be ‘unequivocally demonstrated’ in court (see the ECJ ruling in the joined cases C-414/99 and C-416/99, Zino Davidoff/Levi Strauss, point. 47; see also ECJ case C-367-21Hewlett Packard Development Company LP vs Senetic S.A). ‘Unequivocally’ means that the infringer must prove that the behavior of the IP right holder can only be explained as retroactive consent to the distribution of the products.

The exhaustion must be explained and proven in relation to specific, individualized embodiments. It depends on the circumstances of each specific case if, and to what extent, the objection of exhaustion is dealt with in the main proceedings or in eventual enforcement proceedings. Certain issues that are ready to be decided may be addressed already in the main proceedings (cf. LD Munich, UPC_CFI_9/2023, 18 December 2024). Individualization is only possible if the Court is given characteristics that the exhausted attacked embodiments can be qualified by.

In the present case, the exhaustion objection does not relate to all attacked embodiments. Counterclaimant has not explained which individualized attacked embodiments are governed by exhaustion. They have not qualified the relevant products by e.g. production dates or numbers or import dates. Thus, regardless of the fact explained above that the settlement agreement is disregarded by the Court, the Court can’t address the issue of exhaustion in the operative part of the decision.

Thus, under art. 63 UPCA EOFLOW must be ordered to cease making, offering, placing on the market, using or possessing, for the purposes mentioned, or importing or storing the “EOPatch” / “GlucoMen Day Pump”¹ within the territories of the Member States of the Unified Patent Court in which the Unified Patent Court Agreement was in force on 19 June 2024. The injunction must

¹ Or in general 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; wherein 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;

necessarily cover all possible infringements, even those for which there is no immediate evidence in the proceedings (in relation to EOFLOW's objection that there is no evidence of 'making' of the embodiment on the territory of the UPC states), since the acts undebatedly put into practice by EOFLOW presents a rebuttable presumption that the act of "making" is also put into practice by EOFLOW (see LD Düsseldorf, UPC_CFI_7/2023, 3 July 2024).

Pursuant to Art. 63.2 and Rule 354.3 RoP, the Court's decisions and orders may provide for periodic penalty payments payable to the Court if a party fails to comply with the terms of the order. The value of such payments shall be set by the Court having regard to the importance of the order and of the case.

In assessing the amount of the penalty to be imposed, the Court takes into account the extent of INSULET's dominance in the relevant market, given that it is one of the major players in the sector, as well as the necessity for this penalty to have a genuinely dissuasive effect. The amount of EUR 30,000 for each day or part thereof, counted as a full day, of non-compliance with this order appears reasonable and consistent for that purpose.

B) COMPENSATORY DAMAGES (requests III and IV)

Art. 68 UPCA provides for compensatory damages as a consequence of the infringement.

Directive no. 2004/48/EC of 29 April 2004 too, on the enforcement of intellectual property rights, devotes Article 13 to the subject of compensation for damages, which states that 'Member States shall ensure that, at the request of the injured party, the competent judicial authorities order the infringer who knowingly, or with reasonable grounds to know, engaged in an infringing activity, to pay the right holder damages appropriate to the actual prejudice suffered by the latter as a result of the infringement. When the judicial authority sets damages (a) shall take into account all relevant aspects, such as the negative economic consequences, including lost profits suffered by the injured party, the benefits illegally realized by the infringer, and, in appropriate cases, elements other than economic ones, such as the moral prejudice caused to the right holder by the infringement; (b) or, as an alternative to subparagraph (a), it may fix, in appropriate cases, a lump sum based on elements such as, at a minimum, the amount of royalties that would have been due if the infringer had requested authorization to use the intellectual property right in question'.

This Court does not doubt that this reference to judicial authorities can also apply to the UPC as a European court dealing with patent litigation.

EOFLOW is, therefore, liable to pay damages to INSULET (Art. 68 UPCA, R. 118.1 RoP), as it is a specialized company with substantial IP consciousness and could reasonably have been aware of the infringement had it exercised the level of diligence expected of market participants.

Here, too, any reference to the agreement reached between INSULET and MENARINI is void. This is also in consideration of the fact that, in the event of patent infringements, each link of the distribution chain is individually and separately liable for the damage caused to the patent holder, since every stage of infringement interferes with the IP rights of the patent owner INSULET is also entitled to a declaratory judgment regarding liability for damages.

The criteria for quantifying damages are based on the availability of data, of a qualitative and quantitative nature, correlated with the volumes and margins of the parties in question, the

volumes and margins of competitors, and other information that can be deduced from analyses of the reference market.

About the assessment of damages, the Court may also defer a more detailed assessment of damages to a later stage (UPC_CFI 239/2023 App_549536/2023 Decision 22.11. 2024 point 114: “Claimant is entitled to payment of preliminary damages following Art. 68 UPCA in combination with R. 119 RoP”).

In the present case, INSULET has provided the Court with little, if any, information on updated data regarding market shares, unit prices, profit margins, distribution networks, etc., all of which are essential for assessing compensatory damages.

INSULET reserved the calculation of compensatory damages for a later stage, pursuant to Rule 125. RoP, filing a request for preliminary award of damages. The Court acknowledges this choice.

This Court is now called upon to determine the amount of the interim award of damages under Rule 119 RoP, which provides: *‘The Court may order an interim award of damages to the successful party in the decision on the merits, subject to any conditions that the Court may order. Such award shall at least cover the expected costs of the procedure for the award of damages and compensation on the part of the successful party’*.

At the oral hearing, the parties agreed that 69,723- Eopatch units were sold between June 2024 and March 2025. According to the parties' statements at the hearing, each embodiment would provide EOFLOW with a profit of at least €3.

Therefore, exercising its equitable powers under Rule 119 RoP, the Court considers it reasonable to award damages pursuant to Art. 68 UPCA in the amount of EUR 230,000.

C) CORRECTIVE MEASURES I.E., THE RECALL AND REMOVAL OF EMBODIMENTS FROM THE MARKET AND THEIR DISTRUTION (REQUESTS I.12, I.13. I.14)

Under Article 64 UPCA, the Court may, at the request of the applicant, order appropriate corrective measures in relation to products found to infringe a patent.

The Court shall take into account the need for proportionality between the seriousness of the infringement and the remedies to be ordered, the infringer’s willingness to convert the materials into a non-infringing state, as well as the interests of third parties.

In this case, the Court takes into consideration several factors in determining the seriousness of the infringement: a large-scale infringement carried out by EOFLOW, which affects many contracting states to the UPCA, also through a major European company, Menarini, capable of carrying out widespread distribution in a short time, the proven economic difficulties faced by EOFLOW, which suggest a commercially reckless attitude on the part of the company, and the impact of the EOPatch on the insulin pump reference market, in which INSULET plays a pivotal role.

All these factors lead to the conclusion that the infringement must be considered serious under Art. 64(4) UPCA. For this reason, corrective measures may be imposed to the fullest extent, in line with INSULET's requests.

The Court shall order EOFLOW to recall from commercial customers and permanently remove, at its own expense, all infringing products currently on the market.

Given that the CoA issued the interim measures approximately three months ago, the request for a grace period no longer appears justified. EOFLOW should have had sufficient time to arrange for the withdrawal of the infringing products from the market.

This Court further observes that, while on page 90 of the counterclaim for infringement INSULET requested the appointment of a bailiff for the destruction of the infringing goods (point I.14), on page 120 (point 398) of the same written submission it also requested, together with the recall, the destruction of the infringing products still in the possession of EOFLOW at the expense of EOFLOW. At the oral hearing, elaborating on this discrepancy, INSULET opted for the appointment of a bailiff for the subsequent destruction of the assets under the bailiff's supervision.

The Court therefore orders EOFLOW to recall the products from commercial customers, to remove them and to provide them to a bailiff to be appointed by INSULET for the purpose of their further destruction. Attacked embodiments that are still in EOFLOWs direct or indirect possession or ownership must also be provided to a bailiff. Furthermore, the attacked embodiments must be definitively removed from the channels of commerce, Art. 64 (2)(d).

Under Art. 67 UPCA, INSULET also requested that the Court order EOFLOW to inform the applicant of:

- (a) the origin and distribution channels of the infringing products or processes,
- (b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products; and
- (c) the identity of any third person involved in the production or distribution of the infringing products or in the use of the infringing process.

This request is well-founded, as this measure ensures the effectiveness of the compensation provided for in Article 68.2 UPCA.

Indeed, only by obtaining all the information relating to the infringement can the injured party file a complete, plausible, and substantiated compensation claim. Furthermore, the identity of third parties involved in the distribution of the infringing embodiment is relevant for INSULET's ability to effectively enforce its rights.

In light of INSULET's request to enforce the orders of the Court issued under Arts. 64, and 67 UPCA by means of periodic penalty payments, the panel gives particular consideration to Rule 354.3 RoP.

The Court's decisions and orders may also be enforced through penalty payments. This refers clearly to Art. 82(4) UPCA, which states that *"if a party does not comply with the terms of an order of the Court, that party may be sanctioned with a recurring penalty payment payable to the Court"*.

The court sets the amount of the penalty with reference to the value of the claim and in a manner that it is effectively dissuasive but not unduly punitive. An amount of EUR 15,000 per day appears appropriate for this purpose.

D) DECISION ON COSTS

This decision is also intended to adjudicate on the costs of these proceedings (revocation and infringement) as well as those arising from the preliminary injunction (ACT_25378/2025), as concluded by the CoA on 30 April 2025. INSULET submitted an application for costs (App. 25378/2025) on 28 May 2025, seeking compensation for legal costs against EOFLOW, following the outcome of the PI proceedings before both the Milan CD and the CoA.

On 25 June 2025, EOFLOW responded that the application should be dismissed for lack of legal basis, arguing that cost compensation may only be awarded following a decision on the merits (Rule 150.1 RoP). However, as the present phase concerns the merits, this objection is no longer applicable.

In the alternative, EOFLOW argued that the claimed costs were excessive and should be reduced to a reasonable and proportionate amount (RoP 152.1). EOFLOW contended that INSULET had effectively doubled the litigation costs by filing two separate, yet nearly identical preliminary actions before two divisions (the first one before the Milan CD against EOFLOW and the other one before the Milan LD against Menarini s.p.a., the main distributor of the EOPatch pump in Europe).

As mentioned above, INSULET entered into a settlement agreement with Menarini s.p.a., while the proceedings were still pending before the CoA.

As part of the settlement, Menarini agreed to reimburse INSULET for the legal costs in the parallel case for EUR 600,000. This payment was accepted as undisputed by the parties in the cost decision proceedings under Rule 171.2. According to EOFLOW, this amount already covers a substantial portion of the total legal costs incurred by INSULET in the overall preliminary injunction proceedings.

Finally, EOFLOW requests to be allowed to pay in four equal instalments, with each instalment payable at the start of each quarter, starting in Q3 2025.

The Central Division of Milan has jurisdiction to adjudicate on the costs of the preliminary injunction.

The CoA has clarified that an application for a cost decision under R. 151 et seq. RoP as to the costs of the first and second instance PI proceedings must be directed to the Court of First Instance. This applies irrespective of whether the application is filed after a decision of the CoA and relates, in whole or in part, to the costs of the appeal proceedings. The reason is that the Rules of Procedure do not provide for a distinct procedure for the assessment of costs following an order issued by the CoA (Court of Appeal, Order dated July 29, 2024, UPC_CoA_1/2024, App_36394/2024, para. 9 et seq. – Hanshow v. VusionGroup).

Furthermore, since the decision on costs is subject to appeal under Rule 157 RoP, filing the application directly with the CoA would preclude the right to appeal on that decision.

This decision is also aimed at covering (provisionally under Rule 150.2 RoP) the costs of the first-instance phase on the merits, as requested by INSULET in relation to both the revocation and infringement proceedings (point V, page 91 of the counterclaim for infringement).

The Court acknowledges that INSULET did not file an estimate of the costs incurred during the proceedings on the merits under Rule 118.5 (despite the Court inviting INSULET to do so).

However, the Court is in a position to carry out a brief yet thorough assessment of the first-instance costs, as most of the defences and objections raised during the PI proceedings (whose costs are well documented) were also raised and reiterated during the proceedings on the merits.

Nevertheless, the Court deems it prudent to adjudicate costs under Rule 150.2 RoP, i.e. as a purely preliminary award. The Court considers that additional costs may exist which can be more thoroughly assessed at a later stage.

The Court also considers that Rule 150.2 RoP serves a clear function of procedural simplification and is intended to provide advance compensation to the wronged party for costs that might otherwise arise from pursuing an action for costs (see UPC_CoA_30/2024 APL_4000/2024 16.01.2025 regarding the parallel application for damages: *'The proceedings pursuant to R.125 et seq. RoP are merely a separate procedural stage of a normal action for patent infringement, which the RoP has "outsourced" procedurally for reasons of procedural economy'*). Accordingly, where the *interim* assessment of costs under Rule 150.2 RoP is sufficiently accurate, parties may also choose to refrain from filing a further application for costs.

EOFLOW has set the value of the revocation at EUR 2,500,000.00, while INSULET, in its defence to revocation, set the same value under Rule 152.3 RoP at EUR 5,000,000.00.

Both parties agree on a value in dispute of EUR 2,500,000.00 for the counterclaim for infringement.

The Court considers that, if the value of the infringement is estimated at EUR 2.5 million, a valuation of EUR 5 million for the revocation of the patent appears reasonable. It is reasonable to assume that if a patent infringement has an impact on a company's profits, the revocation of the same patent cannot have the same impact, and therefore, the starting point should be a value that is at least 50% higher than the value of the infringement. Under Rule 152.2 RoP, the ceiling for recoverable costs must be set at euro 7,5.

The combined value of infringement and revocation actions amounts to EUR 7.5 million, which results in a ceiling for recoverable costs of EUR 600,000.

Art. 1.3 of the Decision on scale of ceilings (Scale of ceiling for recoverable costs of the Administrative Committee of 24/04/2023 in AC/10/24042023) provides that 'the ceiling shall be applied to each instance of the Court proceedings regardless of the number of parties, claims or patents concerned'.

The ceiling, therefore, applies to all proceedings conducted within the same instance of jurisdiction, including the PI proceedings.

For the appeal proceedings (second instance), the amount in dispute was set by the CoA at EUR 2.500,000, which results in an additional ceiling (only for the appeal) of EUR 400.000.00.

This Court acknowledges that the LD Düsseldorf, in its decision *Ortovox v. Mammüt* of 22 April 2025 (ACT_7605/2025 and ACT_7736/2025), expressed the opinion that representation costs incurred in summary proceedings are separately reimbursable.

However, in its order of 15 February 2025 (UPC_CFI380/24 App. 39640/24) the CD Milan maintained that *'where a PI is followed, irrespective of its outcome, by an action on the merits, any decision on the costs must be considered at the end of the proceedings on the merits. Preliminary*

injunction proceedings only involve a summary assessment of the patent at issue Injunctions, as the Court of Appeal pointed out, are almost always followed by a trial on the merits in which all the evidence already submitted to the Court (and even possibly more) is explored and considered in greater detail and depth. However, splitting the costs of a single patent litigation and awarding costs compensation only for the PI proceedings while the merits case is already pending does not seem to be in line with the principles of proportionality and flexibility dictated by the preamble to the RoP. It does not seem 'proportionate' to leave room for a double assessment of costs, firstly [...] at the preliminary injunction stage and secondly on the merits, since the assessment on the PI cannot be separated from the overall outcome of the proceedings. [...] [I]t does not seem to meet the principle of flexibility set out in preamble for the Court to be involved twice in the assessment of the same legal costs. Flexibility, according to the preamble, is strictly related to efficiency and cost effectiveness. If the Court is called upon to decide on the same legal situation twice, first on a preliminary assessment, and later in a more in-depth evaluation, valuable time is taken away from the examination of the other [...] cases'.

This Court will carry out an overall assessment of the cost of first and second instance, bearing in mind a cap of EUR 600,000 for the first instance and EUR 400,000 for the appeal.

INSULET's request for reimbursement of the costs incurred in the PI proceedings is partially well-founded.

INSULET has requested reimbursement of the following legal costs (limited to the PI proceedings):

Costs for legal representation (1st and 2nd instance)	EUR 672,482.50
Travel Expenses	EUR 11,329.51
Translation Costs	EUR 4,034.00
Courier Costs	EUR 386.00
<u>Court Fees</u>	<u>EUR 22,000.00</u>
Total Costs	EUR 710,232.01

Under Rule 156.1 RoP, the judge-rapporteur may request written evidence of any claimed costs, however, such a request is discretionary. In principle, the cost decision can be rendered without written substantiation, provided that the documents submitted demonstrate that the costs are reasonable and proportionate.

INSULET submitted detailed statements in addition to its written submissions, indicating the number of hours each attorney-at-law and the patent attorney handling the case devoted to specific tasks, as well as their respective hourly rates. The submitted overviews enable both the Court and the defendants to understand the corresponding activities to the necessary extent and to assess, on that basis, the necessity and reasonableness of the representation costs.

'Reasonableness of costs' refers in fact to the necessity of incurring a given expense, whereas 'proportionality of costs' refers to the appropriateness of the amount paid for a given service.

The costs requested for legal representation, translation and courier services, as filed by INSULET, appear to be reasonable and proportionate, following Art. 69 UPCA and R. 152.1 RoP, and do not need further examination. The defendants have not raised any objections concerning translation and courier costs; accordingly, no further justification is required in respect of these items.

Regarding the legal costs (see Exhibit 2), all invoices and payment receipts (see Exhibit 3) appear to correspond to the legal costs claimed. These costs do not exceed the maximum reimbursable costs established under the administrative exclusion pursuant to R. 152 para. 2 RoP and are therefore presumed to be reasonable.

The services provided by the law firm Peterreins-Schley also appear to be proportionate to the difficulty of the case, given its high degree of complexity and the pivotal role played by the legal team in resolving it. Furthermore, EOFLOW submitted patent documents to the Court that challenged the patent's validity, which certainly required additional investigative and research efforts on the part of the applicant.

The number of lawyers involved in handling the case does not appear disproportionate to its difficulty. A team of five legal professionals, including legal counsel and patent attorneys, appears adequate given the complexity of the case and the volume of documentation contained in the case file (see LD Düsseldorf Ortovox/Mammut 22.04.2025 in ACT_7605/2025 and ACT_7736/2025: *'The fact that several lawyers from the same law firm worked on the plaintiff's side does not preclude the reasonableness and appropriateness of the costs incurred as a result. As the plaintiff has comprehensibly explained, this was not only due to the scope and complexity of the proceedings and the time pressure prevailing in summary proceedings, but also served to save costs. Such a division of tasks among several lawyers and patent attorneys is harmless as long as - as in this case - no additional costs are generated, but only the tasks to be performed and thus the costs incurred are divided between different lawyers and patent attorneys'*).

However, the travel costs incurred by Mr. Anderson, CEO of INSULET, are not consistent.

The attached documents show that Mr. Anderson, to attend the OH in Milan on 13.10.24, flew from the United States to Munich, where he stayed at the Sofitel hotel from 12 to 14 October. He then travelled to Milan, where he stayed for an additional two nights (14–16 October), before returning to the United States a few days later (25 October).

While the intention to attend the hearing and consult with legal counsel in Munich regarding the case is understandable, this travel arrangement appears unreasonable and disproportionate in light of the aforementioned principles. Accordingly, the court considers that the sum of EUR 2,000 for Mr. Anderson's travel to Milan from the United States and his accommodation in Milan is proportionate.

Similarly, when the case was heard by the CoA in Luxembourg, Mr. Anderson stayed at the Hotel Melia for six nights, a duration which also appears disproportionate. The Court deems it reasonable to award, in respect of Mr. Anderson's stay in Luxembourg, a total of EUR 500 for hotel expenses, corresponding to approximately two nights' accommodation, and EUR 889.50 for the flight (see invoice).

Court fees paid by the applicant in the amount of EUR 22,000.00 (see Exhibit PS 4/4a) are also to be considered and reimbursed by the Defendant. Court fees are also included in cost proceedings and court fees disbursed by a party are deemed reasonable if levied in accordance with Art. 70 UPCA and the Rules of Procedure.

INSULET's total eligible costs amount to EUR 702,292.

EOFLOW's objection to the legal costs did not focus on the fact that they were excessive, unjustified, or disproportionate, but rather on the fact that they had already been (in part) paid by Menarini.

As stated in the above-mentioned order of the Central Division of Milan on 15 February 2025, an overall assessment of the case costs must be carried out. The documents on record demonstrate that the same strategies were put forward first during the preliminary proceedings, then in the appeal of the preliminary proceedings, and also to some extent in the proceedings on the merits.

An overall examination of proportionality and reasonableness of legal costs requires the Court to consider not only the preliminary and merits phases together, but also the fairness of the total litigation, taking into account parallel proceedings and defence duplication.

It does not appear reasonable that the claimant should be paid double costs for the same case. Art. 69 UPCA, by requiring legal costs to be proportionate and reasonable, establishes a general principle that enables the Court to assess the entirety of the defence strategy of the party in question. The upper limit on reimbursable representation costs, as defined in the scheme of recoverable costs, is a safeguard against excessive reimbursement of costs and cannot be circumvented through duplicative litigation.

Pursuant to Article 1(3) of the above-mentioned decision of the Administrative Committee of 24 March 2023, the cap applies in each instance of the court proceedings, regardless of the number of parties or patents involved. Consequently, when considering patent infringement, where both an infringing manufacturer and an infringing distributor are involved in two separate but parallel proceedings concerning the same patent and the same act of infringement, a unitary approach is warranted. The cap established in Article 1(3) would be otherwise violated.

Accordingly, the costs already paid to INSULET by Menarini following the settlement must be considered part of the overall cost assessment, as they relate to the same litigation, i.e. the same parties, patent and alleged infringement.

INSULET chose to bring the same action before two different divisions with two different legal teams (Bird&Bird and Peterreins Schley), thereby doubling the defendant's legal costs. Therefore, INSULET cannot gain an undue advantage from a lawful but disproportionate procedural choice, given that cost compensation occurs within the framework of proportionality set out in Art. 69 UPCA, and INSULET could have sought the same injunction before the same division with greater procedural efficiency.

Finally, while the employment of five lawyers by INSULET in one of these proceedings appears proportionate, the use of two parallel legal teams does not.

Menarini compensated INSULET for the preliminary and appeal proceedings (at least in part), paying a total of EUR 600,000. The court considers that one-third of this amount relates to the appeal stage, and two-thirds to the merits in the PI first instance.

As the two actions overlap significantly (the applications for provisional measures against EOFLOW dated 3 July 2024 and Menarini dated 8 July 2025 are almost identical, differing by only 5%), and given that the settlement with Menarini occurred during the oral hearing immediately before the CoA rendered its decision (see point 14 of the CoA order UPC_CoA_768/2024), this Court considers

that 90% of the appeal costs and the costs of the PI phase have already been compensated by the unsuccessful party.

The remaining 10% corresponds to the partial discrepancies between the two proceedings, as well as to the brief stage before the CoA during which Menarini had already settled the case.

Therefore, INSULET is entitled to recover costs for PI litigation in the amount of EUR 702,292.00 – EUR 600,000.00 + EUR 60,000.00 = EUR 162,292.00.

The request to pay the amount(s) in instalments is rejected due to a lack of legal basis for this application.

EOFLOW further stipulates that pre-litigation costs are not eligible for compensation.

The Court considers that pre-litigation costs, i.e. costs incurred immediately before the judicial phase, such as lawyers' letters, are also eligible for legal compensation, as they facilitate out-of-court dispute resolution.

Furthermore, Article 69 UPCA, as well as Rules 150 and 152 RoP, when referring to legal costs or 'costs of representation', do not imply a limitation to court costs alone. These provisions can be interpreted broadly as covering all litigation-related costs. In any case, such pre-litigation costs may also be considered as 'other expenses' under Art. 69 UPCA and therefore eligible for compensation for damages.

Interest payments are not to be granted, since interest compensation forms part of the overall assessment of the procedure for compensation for damages under Rules 126 and 131 and 68 UPCA (see LD Munich of 10 January 2025 UPC_CFI_249/2023, Meril vs. Edwards in which this topic was discussed: *'With regard to the interest on the costs incurred requested by Edwards, reimbursement is not possible in the costs assessment proceedings. There is no legal basis for this. Neither the Agreement on a Unified Patent Court nor the Rules of Procedure provide for interest on costs assessed in costs assessment proceedings. A corresponding application of Rules 125 and 131 of the Rules of Procedure, which govern the procedure for determining damages and compensation and expressly provide for interest, is ruled out. There is no unintended regulatory gap. Rather, the two provisions cited show that the legislature was aware of the problems of delay and inflation. Nevertheless, the legislature did not provide for interest on the reimbursement of costs. Accordingly, Rule 131.2.a RoP provides for the indication of interest in the context of an application for the assessment of damages, while the corresponding Rule 151 RoP concerning an application for the assessment of costs does not contain a corresponding provision'*).

This cost decision concludes APP ACT_25378/2025.

Finally, the Court addresses the issue of the interim award of costs for the merits phase in accordance with Rule 150.2 (RoP).

As previously stated, the value of the case is EUR 7.5 million, which entails a cap of recoverable costs of EUR 600,000.

When assessing the costs incurred at first instance, the Court will take into account the documentation relating to the costs of the interim proceedings filed in the case file. The total costs incurred during the interim phase amount to over EUR 600,000.

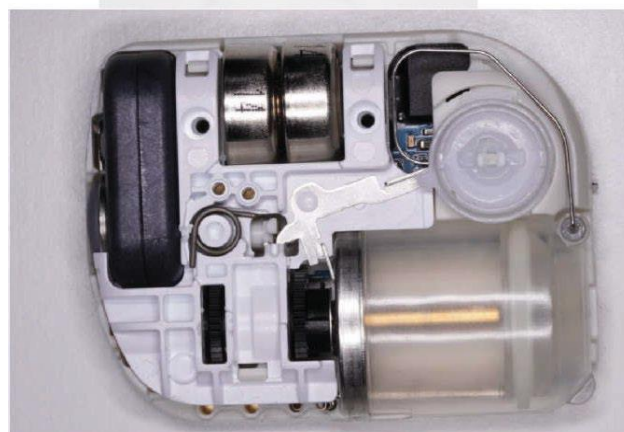
Considering that the defence during the merits phase reiterated many of the arguments previously presented in the preliminary phase, the Court nevertheless finds that the merits phase incurred expenses amounting to at least one-third of those of the preliminary phase. Accordingly, it is reasonable to award INSULET a provisional payment of EUR 200,000 from EOFLOW for the first-instance costs, pursuant to Rule 150.2 RoP.

FOR THESE REASONS

- The application for revocation of EP4201327 filed by EOFLOW is dismissed by default.
- An interim award of damages in favour of INSULET has been set at EUR 230,000.00 under Rule 119 RoP.
- EOFLOW shall bear the costs of these proceedings. The ceiling is set at EUR 600,000.00. The amount in dispute is set at euro 2,5mln for the infringement and at euro 5mln for the revocation.
- An interim award of legal costs for INSULET Co. has been set at EUR 200,000.00 under Rule 150.2 RoP.
- EOFLOW shall pay the cost of the PI litigation, totalling EUR 162,292.00

Furthermore,

a) The Court orders EOFLOW to refrain from making, offering, placing on the market, using or possessing, for the purposes mentioned, as well as from importing or storing 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; wherein 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 pump “EOPatch”/ “GlucoMen Day Pump” shown in the following:



a.

in the territories of the Contracting Member States of the Unified Patent Court in which the Agreement on a Unified Patent Court was in force on 19 June 2024 (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 Kingdom of the Netherlands, the Portuguese Republic, the Republic of Slovenia and/or the Kingdom of Sweden).

b) The Court orders EOFLOW to recall the products referred to in lit. a) above, which have been put on the market, from commercial customers, with reference to the infringing condition of the products determined by the Court and with the binding undertaking to refund any fees and to bear any necessary packaging and transport costs as well as customs and storage costs associated with the return and to take back the products;

c) The Court orders EOFLOW to definitively remove the products referred to in lit a) above, from the channels of commerce, with reference to the infringing condition of the products determined by the Court and with the binding promise to refund any fees and to bear necessary packaging and transport costs as well as customs and storage costs associated with the removal and to take back the products;

d) The Court orders EOFLOW to provide the products referred to in lit a) above, that are in their direct or indirect possession or ownership to a bailiff to be appointed by the Claimant for the purpose of destruction and to bear the costs associated with the destruction.

e) The Court orders EOFLOW to provide INSULET, within 30 days from the service of the decision, with complete information on the extent to which EOFLOW has committed acts of infringement referred to above since 19 June 2024, structured by each month of the calendar year, namely:

1. the origin and distribution channels of the infringing products;
2. the quantities produced, manufactured, delivered, received or ordered as well as the prices obtained for the infringing products;
3. the identity of any third person involved in the production or distribution of the infringing products;
4. the number and dates of the products offered;
5. the advertising carried out, broken down by advertising medium, manner of distribution, distribution period and distribution area, including evidence of these advertising activities;
6. the prime costs, broken down by the individual cost factors and the profit generated, whereby the data of the accounting information is to be transmitted additionally in a format that can be evaluated by means of electronic data processing and copies of the relevant purchase and/or order documents (namely invoices, or alternatively delivery notes) must be submitted as proof of the information, whereby details requiring secrecy outside the required information may be redacted.

f) INSULET is obliged to compensate INSULET for all damages which it has suffered since June 19, 2024 and will suffer as a result of the acts referred to in lit. a) above.

If EOFLOW fails to comply with the orders set out in lit. a) above, a penalty of EUR 30,000 per day will be imposed. Such a penalty must be paid to the Court.

If EOFLOW fails to comply with the orders set out in lit. b), c), d) and e) above, a penalty of EUR 15,000 per day will be imposed. Such a penalty must be paid to the Court.

These decisions are enforceable under Rules 350.2, 118.8, 354.1 RoP.

Milan 22.07.2025

Judge-rapporteur

Andrea Postiglione

Legally qualified judge

Anna-Lena Klein

Technically qualified judge

Uwe Schwengelbeck

For the registry

Gianluca Bartolotta

INFORMATION ABOUT APPEAL

The decision concerning the infringement claim is final and can be appealed under Rule 220 RoP.

Orders referred to in Article 67 of the Agreement can also be appealed under Rule 220 RoP.

Leave to appeal is granted in respect of orders issued under Arts. 63 and 64 UPCA.

A decision by default can be set aside under Rule 356 RoP within one month of service of the decision. The application to set aside a decision by default shall contain the party's explanation for the default. It shall mention the date and number of the decision by default.

INFORMATION ABOUT COSTS AND DAMAGES

Under Rule 157, a decision as to costs only may be appealed to the Court of Appeal in accordance with Rule 221. Leave to appeal is granted.

INFORMATION ABOUT PERIODIC PENALTY PAYMENTS

EOFLOW shall bear the cost of this decision. The amount in dispute for the counterclaim for infringement is set at EUR 2,500,000, the amount in dispute for the revocation is set at

EUR 5,000,000. Total amount in dispute is set at 7,5 mln. The ceiling of recoverable costs is set at EUR 600,000.

Under Rule 354.4 RoP, if it is alleged that a party has failed to comply with the terms of the order of the Court, the first-instance panel of the division in question may decide on penalty payments provided for in the order upon the request of the other party or of its own motion. The procedure foreseen in Rule 264 RoP shall apply. After having heard both parties, the Court may make an appropriate order which may be subject to an appeal pursuant to Rule 220.2 RoP.

ORDER DETAILS

Order no. ORD_22491/2025 in ACTION NUMBER: ACT_56003/2024

UPC number: UPC_CFI_597/2024

Action type: Revocation Action – Infringement action – cost decision.