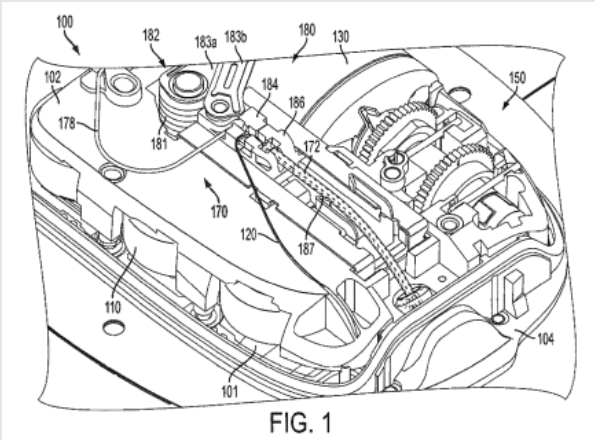


**UPC CFI, Milan Local Division, 4 September 2024,
Insulet v Menarini**

*fluid delivery device with transcutaneous access tool,
insertion mechanism and blood glucose monitoring for
use therewith*



PATENT AND PROCEDURAL LAW

Confidentiality club ([Article 58 UPCA, R. 262A RoP](#))

- **[Article 58 UPCA must be interpreted as meaning that it extends protection not only to trade secrets but also to confidential information;](#)**
- **[Club includes](#)** (a) authorised representatives and their assistants (b) any private expert upon request, and witnesses which require access to the Confidential Information for the purposes of these proceedings; (c) the following employees of the claimant [...]; **(d) Applicant's legal representatives in the parallel US proceedings** against EOFLOW before the United States District Court in the District of Massachusetts.

Source: [Unified Patent Court](#)

**UPC Court of First Instance,
Milan Local Division, 4 September 2024
(Zana)**

UPC CFI NO. 400/2024

Procedural Order

of the Court of First Instance of the Unified Patent Court
issued on 04/09/2024

Order no. ORD_45723/2024

APPLICANT

1) A. MENARINI DIAGNOSTICS S.R.L.

(Applicant) via dei Sette Santi 3 - 50131 - Florence -
Italy

Represented by Christopher Maierhöfer

RESPONDENT

1) INSULET CORPORATION

(Respondent) 100 Nagog Park - MA 01720 - Acton -
United States of America

Represented by Marc Grunwald

PATENT AT ISSUE

[EP4201327](#)

DECIDING JUDGE

Judge-rapporteur Alima Zana

COMPOSITION OF PANEL – FULL PANEL

Presiding judge Pierluigi Perrotti

Judge-rapporteur Alima Zana

Legally qualified judge Anna-Lena Klein

Technically qualified judge Uwe Schwengelbeck

LANGUAGE OF PROCEEDINGS: English

ORDER

**1. SUMMARY OF FACTS AND STATEMENT OF
FORMS OF ORDER SOUGHT BY THE PARTIES**

A. Menarini Diagnostics s.r.l. (defendant in the main proceeding) puts forward information in the Objection to Application for provisional measures dated 6 August 2024, allegedly being of confidential nature. The respective information is highlighted in grey. With regard to said information the defendant submitted an application for protection of confidential information under R. 262A RoP using the dedicated workflow in the CMS (App_45575/2024) and uploaded redacted versions of their written submissions.

The defendant requests the Court to order the following:
A. the portions of this Objection that are highlighted in gray to be “Confidential Information”, specifically:

1. the technical descriptions, including drawings, of the Attacked Embodiment of Defendant of para. 175 and paras. 177 through 183 of this Objection; and
2. Defendant’s business figures in respect of the Attacked Embodiment, such as sales numbers, market share, and number of patients as specified in paras. 195, 205, 213 and 308 of this Objection;

B. access to Confidential Information to be restricted to Defendant, one of Applicant’s employees to be named by Applicant, their UPC representatives, and witnesses and expert witnesses which require access to the Confidential Information for the purposes of these proceedings;

C. these persons not to disclose any Confidential Information outside of these court proceedings unless the receiving outside party has gained knowledge of the Confidential Information outside of the proceedings. This obligation shall continue to apply even after the conclusion of the court proceedings.

D. the public to be excluded from the oral hearing, insofar as any Confidential Information is to become the subject of the oral hearing;

E. if necessary, the public to be excluded from part of the announcement of the grounds for the judgment, insofar as any Confidential Information is concerned;

F. the public to be excluded from any access to any filing in the present court proceedings, insofar they include Confidential Information, or to access only redacted versions thereof;

G. prior to publication of the reasons for the decision or other announcements, any Confidential Information to be redacted therein.

The Presiding Judge (on behalf of judge-rapporteur) by way of a preliminary order dated 7 August 2024 granted access to the unredacted version of said documents exclusively to the claimant’s authorised representatives

pending a final decision upon the confidentiality request and invited the claimant to comment.

In response, the claimant submitted that the information allegedly is not secret. Accordingly, the claimant requests the Court to order the following:

I. Defendant's motion that certain portions of the Objection highlighted in gray contain confidential information, which in turn shall trigger certain access restrictions on the part of Applicant, is rejected.

Auxiliary:

II. The following persons on the part of Applicant shall be granted access to confidential information in the Objection to the application for provisional measures as well to all information classified as confidential (in submissions, exhibits etc.) in the future by the Court:

a) Applicant, Applicant's legal representatives including staff, witnesses, experts, further representatives of Applicant and all other persons involved in the present proceedings or who have access to documents of this proceedings, and

b) in particular the following reliable natural persons: [...] Senior Director, Intellectual Property Counsel at Applicant, Acton, Massachusetts, USA.

2. GROUNDS OF THE ORDER

1. General profiles

1.1. This ruling complies with:

- the principles of flexibility, proportionality and fairness set out in Preamble 2 of the P.o.R. and the need to protect confidential information;

-the [Rule n. 58 UPCA](#), the [Rule N. 262A RoP](#), the [Directive \(EU\) 2016/943](#) on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure;

- case law of the UPC on the protection of confidential information.

1.2. This order:

- takes into account that this is an application within an urgent procedure, which requires - on the one hand- respect for confidential information and -on the other hand- respect for the principle of a fair trial in view of the urgency of the case, without prejudice to the hearing already scheduled for 15 October 2024.

-concerns only points A and B of the application. Points C, D, E, F and G will be decided by the Court at a later date, at the latest at the hearing.

2. Nature of information

2.1. Confidential information declared by the applicant (defendant in the main proceeding) regards:

a. the technical descriptions, including drawings, of the **Attacked Embodiment** of Defendant (of para. 175 and paras. 177 through 183 of the Objection);

b. Defendant's business figures in respect of the **Attacked Embodiment**, such as sales numbers, market share, and number of patients (as specified in paras. 195, 205, 213 and 308 of the Objection).

2.2. In support of their argument, the applicant argues that this information:

- contains details about:
- defendant's financial situation and

- proprietary technology, which are considered to be trade secrets within the meaning of [Art. 2\(1\) of Directive \(EU\) 2016/943](#).

- has commercial value;

- is not generally known and is not available to third parties;

- is protected by appropriate confidentiality measures.

2.3. The respondent (applicant in the main proceeding) disputes the secret nature of this information, pointing out that:

- with regard to the information mentioned above under a):

all technical information relating to the infringing embodiment is publicly available. Defendant confirmed that several customers have already obtained the infringing embodiment and also the Applicant could obtain a sample as proven by the pictures in the Application for provisional measures in marg. no. 62 – 93;

- with regard to the information mentioned above under b)

- the number of patients using the infringing embodiment is not secret: in the US proceedings the defendant submitted patient data and figures partly in unredacted form;

- as regards the information contained in marg. no. 205, there is no benchmark whatsoever which would allow third parties to infer absolute figures;

- the R&D costs allegedly incurred by EOFLOW are not a secret, because EOFLOW is a listed company that is required to prepare a balance sheet, so that corresponding investments can be viewed by anyone via the balance sheet or the earnings call.

2.4. The Court observes that:

- according to a non strict construction in accordance with the purpose of the law, [Article 58 UPCA](#) must be interpreted as meaning that it extends protection not only to trade secrets but also to confidential information;

- although the Court has doubts as to whether the information referred to in point (a) is confidential, since it concerns technological choices that appear to be incorporated into the products offered to the public, at this urgent stage- when not all defences have been carried out- it seems prudent to grant the requested confidentiality, also in order to avoid a possible prolongation of the proceedings in the event of an appeal by the owner of the information.

- the information referred to point (b) appears to be confidential. Indeed:

a. it concerns commercial sales data (including the number of patients using the infringing embodiment) and is therefore relevant to Merarini's business;

b. it is not public. The filing of such information in another legal proceeding, even if not with the protection of confidentiality, is not likely to make it public;

c. the applicant has an interest in maintaining confidentiality, indicating the sales and market attractiveness of its products;

Its disclosure to a competitor - such as Insulet - could have a detrimental effect on the applicant that outweighs the risks of litigation and could unfairly distort competition.

3. Confidentiality club

3.1. Menarini's claim for confidentiality is modulated by a request for limited access to:

- one of Applicant's employees to be named by Applicant;
- their UPC representatives;
- witnesses and expert witnesses which require access to the Confidential Information for the purposes of these proceedings.

3.2. The claimant has observed that the confidentiality request is too narrow and disproportionate. According to [R. 262A RoP](#), the number of persons who have access to confidential information shall be no greater than necessary to ensure compliance with the right of the parties to the legal proceedings to an effective remedy and to a fair trial.

3.3. The Court recalls the case law of the UPC on this matter and in particular:

- *“When deciding the application of the defendants to grant protection for the allegedly confidential information, the court has to weigh the right of a party to have unlimited access to the documents contained in the file, which guarantees its fundamental right to be heard, against the interest of the opposing party to have its confidential information protected. Both fundamental principles have to be balanced against each other on the instant facts of the particular case”* ([Düsseldorf Local Division App 6761/2024 related to the main proceeding ACT 578607/20239](#))

- *“R. 262A.6 RoP establishes with all desirable clarity as a ground rule of paramount importance that at least one natural person from each party and the respective lawyers or other representatives are to be granted access in order to ensure a fair trial. The provision therefore reflects the spirit of the trade secret directive, which also demands for access of at least : -one natural person from each of the parties and -their respective representatives in order -to guarantee the fundamental right to a fair trial (see recital 25 and Art. 9 (2) of the trade secrets directive). This has been an express decision by the Member States of the European Union which is to be respected by the UPC (Art. 20, 24(1)(a) UPCA)”* ([Düsseldorf Local Division App 6761/2024 related to the main proceeding ACT 578607/20239](#));

- *“When deciding upon the level of restriction, again the circumstances of the case are to be taken into consideration (...) In a dispute revolving around technical aspects it is of fundamental importance that a party may have resort to technically qualified employees in order to exercise its right to be heard* ([Düsseldorf Local Division App 6761/2024 related to the main proceeding ACT 578607/20239](#));

- In case, parallel proceedings abroad are pending, also lawyers representing the party in parallel proceedings must be part of the confidentiality club in order to align the respective briefs and arguments as well as to co-

ordinate the strategy (cf. [LD Paris, order of 19.12.2023, UPC CFI 230/2023](#)).

3.4. In the light of all foregoing considerations, The Court, balancing opposing interests, considers to include the club:

- a. the claimant's authorised representatives and their assistants;
- b. any private expert upon request, and witnesses which require access to the Confidential Information for the purposes of these proceedings;
- c. the following employees of the claimant [...] Senior Director and Intellectual Property Counsel at Applicant and coordinates the overall litigation strategy. He is aware of his obligations under a confidentiality order and is a highly trustworthy person. His appointment is in line with Defendant's request to name one employee of Applicant according to item VIII. of Defendant's confidentiality request;
- d. [...] partner at the US law firm Goodwin Procter LLP.

He is Applicant's legal representatives in the parallel US proceedings against EOFLOW before the United States District Court in the District of Massachusetts.

As attorney-at-law, he is bound to strict ethical rules of professional conduct for lawyers in accordance with the Model Rules of Professional Conduct of the American Bar Association.

3.5. With regard to the persons mentioned above under a), b) and c):

There is a coincidence between Menarini's application and the applicant's application as regards the composition of the confidential club.

- Indeed, Their appointment is in line with Defendant's request. Therefore, there is no disagreement on the inclusion of these persons in the confidential list.

With regard to the person mentioned above under d):

- there is no coincidence between Menarini's and the applicant's claim Indeed does not fit into the categories of persons referred by Menarini.

However, in order to respect the adversarial principle and the right of the defence - including the right to adopt a common defence strategy in different jurisdictions - and in the light of the earlier decision of the Paris local division of the UPC (19 December 2023, concerning the defendants of the same party in parallel proceedings), the Court considers that this person should be included in the club.

This is also in view of the fact that the request for confidential information covers essential issues (non-infringement and balancing of interests) which, according to Merinarini, would justify the request to reject the measure. The right of defence must therefore be fully respected.

These considerations lead to the following assessments as regards the appealability and suspensive effect of this order.

4. Leave to appeal

Since the questions decided upon in the case at hand are far from being well settled in the newly established Unified Patent Court, leave to appeal is granted.

5. Suspensive effect

So as not to create a *fait accompli*, the Court decides not to grant access for the further person named by the claimant- which is in dispute, before the time period for bringing an appeal and an appropriate time period to bring an application for suspensive effect before the Court of Appeal before it has elapsed.

On the contrary it appears to be in the interest to further the proceeding to already grant the persons named by claimant (and included in the categories specified by the defendant) immediate access to the information concerned in order to them being enabled to assist claimant's representatives in preparing its defences (Düsseldorf Local Division UPC_CFI_355/2023)

Indeed, pursuant to Section 354 of the RoP, decisions and orders of the Court are directly enforceable from the date of their notification and an appeal, pursuant to Section 74 of the UPCA, has no suspensive effect unless the Court of Appeal decides otherwise. However, these provisions do not prevent the Court of First Instance from deciding that an action should be enforced at a future date.

If this Order were to take effect immediately, and [...] access was contemporaneous with the adoption of the Order, Menarini's possible appeal could not be effective. Therefore, the Court considers it appropriate to defer the enforceability of this order after the period of 15 days for bringing an appeal under R. 220.2 RoP and an additional week, after having brought the appeal, during which an application for suspensive effect may be lodged, has elapsed (Düsseldorf Local Division UPC_CFI_355/2023).

This gives Merarini sufficient time to appeal and request suspensive effect, pursuant to Article 223 of the RoP.

ORDER

I. access to the unredacted version of the Menarini's Objection to Application for provisional measures dated 6 August 2024, containing confidential information as highlighted in grey therein, which is hereby classified as confidential, shall be restricted from the Insulet Corporation side exclusively to the persons as follows:

- with immediate effect

- a. the claimant's authorised representatives and their assistants
- b. any private expert upon request, and witnesses which require access to the Confidential Information for the purposes of these proceedings;
- c. the following employees of the claimant

[...] Senior Director, Intellectual Property Counsel at Applicant, Acton, Massachusetts, USA,

- After the period of 15 days for bringing an appeal under R. 220.2 RoP and an additional week, after having brought the appeal, during which an application for suspensive effect may be lodged, has elapsed:

d. Partner [...] at Goodwin Procter LLP, Boston, Massachusetts, USA.

II. The information referred to in paragraph 1 shall be treated as confidential by the persons referred will be treated confidentially in that paragraph;

III. Such information shall not be used or disclosed outside of these court proceedings, except to the extent that it has come to the knowledge of the receiving party outside of these proceedings, provided that the receiving party has obtained it on a non-confidential basis from a source other than the defendant or its affiliates, provided that such source is not bound by a confidentiality agreement with or other obligation of secrecy with the defendant or its affiliates.

IV. The foregoing persons shall also be under an obligation to the claimant to maintain the confidentiality of the information contained in the unredacted versions of the foregoing documents. This obligation of confidentiality shall continue to apply after the termination of these proceeding;

V. in the event of a breach of this order the Court may impose a penalty pursuant to Rule No. 354(3) R.o.P.;

VI. leave to appeal is hereby granted; VII. the costs relating this proceeding will be settled together with the costs of the main proceedings.

Issued in Milan on 4 September 2024

NAMES AND SIGNATURES

Alima Zana

ORDER DETAILS

Order no. ORD_45723/2024 UPC number: UPC_CFI_400/2024 Related proceeding no. Application No.: 40442/2024 Application Type: Application for provisional measures (RoP206)
