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UNIFIED PATENT COURT COURT OF FIRST INSTANCE MILAN LOCAL DIVISION

UPC CFI No. 3399/2026
ORDER FOR THE PRESERVATION OF EVIDENCE

issued on 30 September 2026

APPLICANT
YPSOMED AG
Brunnmattstrasse 6, 3401 Burgdorf, Switzerland
represented and defended by
Vittorio Cerulli Irelli, Luca Pellicciari and Lorenzo Battarino, of *Trevisan & Cuonzo*, Via Brera No. 6, 20121 – Milan, Italy
Luca Frasson and Lorenzo Lualdi, of *TBCM*, Via Plinio 63, 20129 – Milan, Italy

DEFENDANT
SHIJIAZHUANG XINFUDA MEDICAL PACKAGING CO., LTD.
Haixing Road, Zhao Xian County Industrial Zone, Shijiazhuang, Hebei Province, 051530 China

PATENT AT ISSUE
EP 3 795 194 B1, entitled *'Injection device for administering or transporting fluid product'* (hereinafter 'EP'194')

DIVISION
Milan Local Division

DECIDING BODY
This order is made by the Court sitting in the following composition:

- Pierluigi PERROTTI — presiding judge and judge-rapporteur
- Samuel GRANATA — judge qualified in legal matters
- Alima ZANA — judge qualified in legal matters

LANGUAGE OF THE PROCEEDINGS
Italian

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SUMMARY OF THE FACTS OF THE CASE

On 23 September 2026, Ypsomed AG lodged an application pursuant to Article 60(5) of the UPCA and Rule 192 et seq. of the Rules of Procedure (RoP) for the issuance of an *ex parte* order for the preservation of evidence against Shijiazhuang Xinfuda Medical Packaging Co., Ltd. (hereinafter 'XinFuDa'), prior to the commencement of the proceedings on the merits.

Ypsomed is the proprietor of patent EP'194. The applicant states that XinFuDa – a Chinese company and its direct competitor in the medical devices sector – intends to offer for sale on the European market, and in particular within the territory of the member states of the Unified Patent Court system, a non-refillable multi-dose injection pen, bearing the trade name *'Disposable Injection Pen',* which is likely to reproduce all the features of claims 1 and 14 of EP'194.

According to Ypsomed, sales and promotional activities are already underway, as can be seen from the advertisement for the aforementioned product on the website xinfuda-group.com, which is attributable to the defendant. XinFuDa presented this same product at two trade fairs held in China in June 2026 and announced its participation in the CPHI – Convention on Pharmaceutical Ingredients, one of the world's most important trade fairs in the pharmaceutical industry, which will take place in Milan from 6 to 8 October 2026. In the context of the same promotional communications relating to participation in the CPHI trade fair, the defendant also included specific references to *the Disposable Injection Pen*, making it entirely logical and highly probable that this product would be presented at the trade fair.

In August 2026, with the assistance of a professional intermediary, the claimant purchased twelve sample units of the product and had them analysed by its own technicians, obtaining confirmation that the teachings contained in claim 1 of EP'194 had been reproduced.

Ypsomed concluded by requesting the issuance of an order for the preservation of evidence, justified by the need to (i) prevent any possible challenge regarding the actual origin of the examined product sample from the defendant and to (ii) obtain all technical documentation relating to the *Disposable Injection Pen* product. Definitive confirmation of the suspected infringement of the patent it holds and the identification of all parties involved in the distribution chain would therefore have enabled it to initiate subsequent proceedings on the merits to establish the patent infringement.

ORDER SOUGHT BY YPSOMED

The claimant has requested that the Unified Patent Court – Court of First Instance – Milan Local Division issue, *ex parte,* an order for the preservation of evidence against the defendant XinFuDa, directing:

1. the description and collection of samples of the non-refillable multi-dose injection pens promoted and marketed by the defendant as *'Disposable Injection Pen'*;
2. the description and taking of copies of all technical documentation that may be available (including, without limitation: technical data sheets, user manuals, product specifications, leaflets, etc.) relating to the product referred to in the statement of claim, where

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such documentation enables the identification of the structural and functional characteristics relevant for the purposes of assessing whether the product infringes EP'194;

The requested measure for the preservation of evidence must be carried out:

a) at the stand (no. 11C113) of the defendant XinFuDa at the CPHI trade fair scheduled for 6 to 8 October 2026 in Milan (provided that the procedure commences, where possible, on the first day of the fair, so as to be able to deal with any unforeseen circumstances), as well as at any premises there intended for the storage of the defendant's products, including those belonging to third parties, which are at the defendant's disposal and/or are in any way used by the defendant for the storage and warehousing of the products and technical/promotional materials referred to in the statement of claim;

b) appointing, pursuant to Rule 196(4) of the Rules of Procedure, a technical expert selected from among patent consultants, with expertise in medical devices,

c) ordering the aforementioned appointed expert to collect five samples of the defendant's *Disposable Injection Pens* in order to ensure that multiple subsequent analyses may also be carried out on them, and furthermore

d) directing the aforementioned appointed expert to examine and describe in detail, in the report which he is required to file with the Court pursuant to Rule 196.4 of the Rules of Procedure, together with the samples and any documentation collected, XinFuDa's non-refillable multi-dose injection pen, known as *the 'Disposable Injection Pen'*, in all its structural and functional characteristics, accompanied by photographs of the relevant components, in order to enable subsequent verification of whether it infringes EP'194;

e) authorising the same to carry out any activity necessary to fulfil the purpose of the order and to have access to XinFuDa's exhibition stand, as well as to any premises, warehouse, office or other relevant site at the CPHI trade fair in Milan used by the defendant for the storage of its products and technical documentation, and authorising the same to make copies of the relevant documentation in the manner deemed most appropriate;

f) authorising, pursuant to Rule 196.3 of the Rules of Procedure (RoP), the presence of the claimant's representatives during the enforcement of the order, namely the claimant's undersigned legal representatives Vittorio Cerulli Irelli, Luca Pellicciari and/or Lorenzo Battarino, as well as the patent consultants Eng. Lorenzo Lualdi and/or Eng. Luca Frasson, in accordance with Rule 196.3 of the Rules of Procedure;

g) ordering that service of the application, together with the order to be issued, be effected by alternative means, in accordance with the combined provisions of Rules 275.1 and 276.1 of the Rules of Procedure (RoP), by the competent bailiff at the defendant XinFuDa's stand at the CPHI trade fair scheduled to take place from 6 to 8 October 2026 in Milan.

The applicant, Ypsomed, hereby requests authorisation to access the report of the technical expert to be appointed, as well as the material gathered during the evidence preservation proceedings, immediately upon their filing, in order to exercise its right of defence in view of the commencement of the proceedings on the merits within the time limits set out in the forthcoming order and running from the date of access to the aforementioned report and information.

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GROUNDS FOR THE ORDER

1. Jurisdiction and competence

The Unified Patent Court has jurisdiction over the application filed by Ypsomed, in accordance with the provisions of Articles 32(1)(c) and 60(1) of the UPCA, given that:

a) the right asserted by the claimant is a European patent granted on 1 November 2023, with unitary effect registered on 12 December 2023 (see documents TC16 and TC17), and therefore the patent is currently valid and in force in all member states of the Unified Patent Court;

b) the application brought here falls within the scope of the disputes referred to in Article 32(1)(c) of the UPCA (actions for provisional and protective measures and injunctions);

c) the application is brought *'before the court of the place where the harmful event occurred or may* occur' in accordance with the provisions of Articles 7 and 71b of EU Regulation No. 1215/2012.

The Milan Local Division has jurisdiction pursuant to Articles 32(1)(c) and 33(1)(a) of the UPCA, as the patent-infringing conduct attributed to XinFuDa may actually take place in Italy during the CPHI trade fair scheduled for 6 to 8 October 2026 in Milan.

Finally, the application has been lodged with the Milan Local Division, where the applicant intends to commence the subsequent proceedings on the merits pursuant to Articles 32(1)(a) and 33(1)(a) of the UPCA, in accordance with the provisions of Rule 192.1 of the RoP.

2. Fulfilment of the requirements set out in Rule 192.2 of the Rules of Procedure

2.1. Content of the application

The application for an order for the preservation of evidence contains:

(a) all the details required by Rule 13.1, sub-paragraphs (a) to (i), of the Rules of Procedure;

(b) a clear indication of the measures sought, including the exact location – as known or reasonably suspected – of the evidence to be preserved (namely the exhibition stand allocated to the defendant during the CPHI trade fair scheduled to take place from 6 to 8 October 2026 in Milan);

(c) the reasons why the proposed measures are necessary to preserve the relevant evidence;

(d) the facts and evidence adduced in support of the application.

2.2. Brief description of the forthcoming proceedings on the merits

On the basis of the evidence obtained following these proceedings, Ypsomed has made it clear that it intends to bring subsequent proceedings on the merits before the Milan Local Division against the defendant and any other party found to be involved in the production and distribution chain of the *Disposable Injection Pen* product, with a view to (i) establishing infringement of patent EP'194, (ii) obtain a permanent injunction pursuant to Article 63 of the UPCA, (iii) obtain any other appropriate ancillary or corrective measures pursuant to Article 64 of the UPCA, and (iv) obtain compensation for damages pursuant to Article 68 of the UPCA.

Consequently, the conditions set out in Rule 192.2 of the Rules of Procedure (RoP) are fully satisfied.

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3. Burden of proof on the applicant pursuant to Article 60 of the UPCA – reasonably available evidence provided by the applicant

3.1. Ownership of a valid patent

Ypsomed has demonstrated that it is the current proprietor of patent EP'194 (see doc. TC16), granted on 1 November 2023 and, as such, enjoying a presumption of validity (see Court of Justice C-44/21, 28 April 2022, para. 41).

The claimant has stated that no opposition was filed with the European Patent Office and has not reported the existence of any revocation or invalidity proceedings, as required by Rules 13.1(h) and 192.2(a) of the Rules of Procedure (RoP), nor did it disclose any other circumstances relating to the validity of the patent at issue that might influence the Court's decision on whether or not to issue an order *inaudita altera parte* (see Rule 192.3 of the RoP, second sentence).

As the case currently stands, the Court has no grounds to doubt the validity of the patent at issue, nor are there any grounds to doubt that the claimant has withheld relevant information.

The verification carried out by the clerks of the Sub-Registry at the Milan Local Division has also confirmed that no protective letters have been filed by the defendant.

3.2. The claimant's allegations regarding patent infringement

Patent EP'194 is entitled *'Injection device for administering or transporting fluid product'* and protects a pen-shaped medical injection device for the administration of a medicinal product, equipped with a dosing mechanism and a delivery mechanism characterised by a simpler construction than that of the prior art and, at the same time, capable of improving the patient's user experience, among other things, thanks to improved tactile feedback both when setting the dose and when correcting a dose set too high.

The patent builds on previous known dosing devices, which had various drawbacks: complex friction mechanisms, dose correction systems separate from the dose selection mechanism, or the absence of clearly perceptible feedback during dose setting and correction. The aim of the invention is therefore to provide a simpler and more intuitive device, capable of offering acoustic and tactile feedback that can be immediately associated with the selected or corrected dose.

The injection pen comprises: (i) a housing; (ii) a cartridge containing the medicinal product; (iii) a dispensing mechanism, comprising a piston rod and an actuating element that converts rotational movement into piston advancement; (iv) a dosing mechanism, comprising a dosing sleeve and a rotary knob; (v) a dispensing button arranged coaxially with the dosing sleeve.

During use, the patient selects the dose by turning the knob; subsequently, by pressing the button, the set dose is dispensed via the forward movement of the piston rod, which pushes the medication towards the injection needle.

The central feature of the invention is the coupling mechanism between the dosing device and the dispensing device. This mechanism comprises at least two toothed surfaces held in engagement by a spring. One of the surfaces is associated with the

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, whilst the other is associated with a specific coupling member mounted on the actuator.
In a particularly significant embodiment, a ‘click disc’ or ‘click ring’, featuring two sets of complementary teeth, is interposed between these two surfaces. This component provides an indirect coupling between the surfaces and produces a more perceptible tactile and acoustic feedback. In fact, every change in dose generates a ‘click’ directly at the point where the dosing mechanism interacts with the dispensing system, enabling the patient to precisely associate the perceived signal with the actual change in dose.
The coupling element is mounted on the actuating element in such a way that it cannot rotate relative to it but can move axially.
This is achieved by means of a system of cams and longitudinal grooves which prevents relative rotational movement but allows sliding along the axis of the device. When the patient presses the dispensing button, the toothed surfaces are clamped together and the entire system rotates as a single unit, converting the rotational motion into piston travel.
A further distinctive feature is the presence of a back-drive safety mechanism situated between the housing and the actuator. This system, which can be implemented using flexible arms fitted with detents, allows the actuator to rotate only in the dispensing direction and prevents any rotation in the opposite direction. This ensures dosing accuracy and prevents unwanted reverse movement of the mechanism. Furthermore, dependent claim 14 protects the specific design featuring a click disc positioned between the dosing sleeve and the coupling element, whilst other claims relate to the threaded configuration of the actuator, the flexible anti-reverse arms and the threaded connection to the piston rod.

XinFuDa promotes the *‘Disposable Injection Pen*’ product on its website (see docs. TC2, TC6, TC14) and has publicised its participation in the CPHI trade fair, scheduled for 6–8 October 2026 in Milan, with general references to the ‘Injection Pen’ category (see doc. TC7) and with more specific – and entirely unambiguous – references also to *the ‘Disposable Injection Pen’ product*, which is expressly depicted in promotional photographs accompanying the announcement of its forthcoming participation in the trade fair (see doc. TC15).
Ypsomed engaged a specialist intermediary to purchase a number of samples of *the Disposable Injection Pen*. The purchase was made on 8 August 2026 and comprised twelve injection pens (see doc. TC20).
The samples were then handed over to the claimant’s technical staff for a detailed examination of the devices, in order to verify whether the features set out in claim 1 of EP’194 were actually reproduced. The analysis report was issued on 7 September 2026 and concluded as follows (see doc. TC21, p. 7): *“The XinFuDa pen uses the same dosing and dose correction clicker with a click ring featuring sawtooth serrations on both sides as in the UnoPen. Furthermore, the XinFuDa dose and dispensing mechanism has a sliding, non-rotating piston rod, as in the UnoPen. Lastly, the XinFuDa pen has a reverse lock mechanism, as in the UnoPen. These features of the UnoPen are disclosed in and claimed by EP 3 795 194 (“EP’194”).*
According to the following analysis, the XinFuDa pen utilises all features A to R of claim 1 of EP’194”.

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As the case currently stands, the Court observes that the claimant has provided reasonable evidence in support of a well-founded suspicion that the defendant has infringed the patent held by the claimant. The burden of proof resting on the claimant must, however, be adjusted in accordance with the content of the application, which, in the present case, concerns a procedural right (to adduce evidence) and not a substantive right (as in the case of an injunction and/or compensation for damages).

The claimant has a well-founded fear that XinFuDa may dispute the identity of features between the product sample submitted for examination and the pens marketed by that company. It has also made it clear that it is unable to purchase the product from the defendant company due to the direct competitive relationship with the other party, which precludes the possibility of establishing a business-to-business sales channel.

The Court therefore considers that the acquisition of product samples and technical documentation is essential in order to obtain definitive confirmation of the suspected patent infringement.

4. Requirements set out in Rules 194.2 and 197 of the Rules of Procedure

Pursuant to Rules 194.2 and 197 of the Rules of Procedure (RoP), the Court, in exercising its discretionary power to rule on the application without hearing the defendant – as provided for in Rule 194.1(d) of the RoP – must take into account the urgency of the application and the grounds for granting an order *without the defendant being heard*.

In accordance with Rule 197 of the Rules of Procedure, the Court may order measures to preserve evidence *'without the defendant having been* heard', in particular *'where there is a demonstrable risk of evidence being destroyed or otherwise ceasing to be available*'.

In the present case, the existence of such a risk has been established.

4.1. Urgency

The results of the laboratory tests and the assessment by the party-appointed expert became available on 7 September 2026, a few days before the application was lodged.

As already explained, Ypsomed is not in a position to make a direct purchase of further product samples from XinFuDa, given the direct competitive relationship between the parties to the proceedings.

It is also clear that the claimant has no possibility of obtaining further technical documentation relating to the *Disposable Injection Pen* devices.

The defendant has publicly announced its imminent participation in the CPHI trade fair, scheduled to take place in Milan from 6 to 8 October 2026. Participation in the fair is, by its very nature, intended for promotional and marketing activities, in all likelihood including products known as *'Disposable Injection Pens*'.

The claimant therefore needs to obtain confirmation, within a reasonably short timeframe, of the suspected infringement of EP'194, so as to be able to initiate any subsequent proceedings on the merits.

4.2. Reasons for granting an order without hearing the defendant – risk of evidence being concealed

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Pen-shaped injection devices are compact and easily movable. Consequently, there is a real risk that samples of such products intended for display at the trade fair could be easily removed or concealed should the respondent be summoned to a hearing or otherwise informed of the existence of these proceedings prior to the order being enforced.

Consequently, taking into account all potentially relevant factors, this order must be granted *without a hearing*, as there is a demonstrable risk that the evidence may cease to be effectively available (Article 60(5) UPCA).

5. Payment of court fees

The court fees have been duly paid (see doc. TC22). The conditions set out in Rule 192.5 of the Rules of Procedure (RoP) are therefore satisfied.

6. Balancing of conflicting interests and methods of enforcement

6.1. Balancing of conflicting interests

The weighing up of conflicting interests leads the Tribunal to grant the measure, having regard to the potential risk of harm to each of the parties, should the measure be granted – in the case of the defendant – or refused – in the case of the claimant.

Taking into account the principle of proportionality, the threat to which Ypsomed is exposed of the evidence becoming permanently unavailable must be regarded as outweighing the risks arising from the enforcement of the measures against XinFuDa. These measures are strictly procedural in nature, being limited to enabling the gathering of evidence, and do not directly affect the defendant's legal position or its commercial activities

In this case, the Court considers that the application for an *ex parte* order for the preservation of evidence is adequately justified and must therefore be granted.

6.2. Methods of enforcement

Pursuant to Rule 196.4 of the Rules of Procedure (RoP), the authorised measures must be carried out by an expert appointed by the Court – specifically named in the operative part – in accordance with the national law of the place where the measures are carried out, namely Italian law.

The appointed expert is included in the list of patent experts who regularly collaborate with national courts, so that the choice ensures competence, independence and impartiality, as required by Rule 196.5 of the Rules of Procedure. The expert is subject to professional confidentiality obligations in relation to all information to which they have access in the performance of their duties.

The task entrusted to the expert is to safeguard the evidence. This order is made *without a hearing*, and the expert appointed by the Court is only in a position to act on the basis of the information provided by the applicant. The duty to act independently and impartially fundamentally precludes the provision of any advisory support to the applicant, as the expert must adhere solely to the instructions issued by the Court for the implementation of this order.

The appointed expert shall proceed with the assistance of the competent bailiff.

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Representatives of the applicant, whose names are set out in the operative part of this order, may be present during the execution of the authorised measure. No other representative, employee or associate of the applicant is therefore authorised to be present during the execution of the measures.

The respondent against whom the requested measure is authorised is entitled to contact their lawyers and technical advisers so that they may take part in the execution of the order for the preservation of evidence, with the express warning that – in any event – the actual execution of the order may not be delayed in any way.

The expert appointed by the Court must submit a written report, together with a complete copy of all documents obtained as a result of the implementation of the measures, immediately and no later than three days after the completion of the implementation of the measures.

For the sake of clarity, it is hereby specified that the expert appointed by the Court pursuant to Rule 196.4 of the Rules of Procedure (RoP) cannot be equated with the role of the Court Expert provided for in Article 57 of the UPCA and Rules 185 et seq. of the RoP; consequently – in particular – the costs of his professional services are to be advanced by the applicant, subject to a subsequent final settlement of the costs of the proceedings following the judgment on the merits.

Given the need to preserve the integrity of the samples for any subsequent proceedings on the merits, their safekeeping must be entrusted to a custodian appointed in accordance with Italian national law, which is the law of the place where the measure is to be enforced.

6.3. Protection of confidential information

As this Court has repeatedly stated (see, most recently, UPC CFI No. 342/2025, LD Milan, order of 19 May 2025), the principles of law established by the Court of Appeal of the Unified Patent Court in its decision of 23 July 2024 (see UPC CoA No. 177/2024), which provided a systematic interpretation of the subject of orders for the preservation of evidence. The most relevant passages from the grounds are reproduced in full in the original English text.

An application for the preservation of evidence or inspection of premises within the meaning of Article 60 of the UPCA and Rules 192 et seq. of the Rules of Procedure (RoP) implies a request to disclose to the applicant the outcome of the measures, including the report drawn up by the person who carried out the measures. This follows from the fact that the legitimate purpose of the measures is the use of the evidence in proceedings on the merits of the case (Rules 196.2 and 199.2 of the Rules of Procedure), which includes the use of the evidence to decide whether to initiate proceedings on the merits and to determine whether and to what extent the evidence will be submitted in those proceedings.

Disclosure of the evidence to the applicant or to certain persons acting on the applicant's behalf is essential for that purpose. Furthermore, Rules 196.1 and 199.1 of the Rules of Procedure provide that the Court may order that the evidence be disclosed to certain named persons and be subject to appropriate confidentiality conditions. This confirms that the procedure initiated by an application under Article 60 of the UPCA is aimed not merely at the preservation of evidence and the inspection of premises as such, but also at the disclosure of the evidence to the applicant.

However, the granting of an application for the preservation of evidence or the inspection of premises does not imply an unconditional order to disclose the evidence to the applicant. Pursuant to

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Article 60(1) of the UPCA, the order must be subject to the protection of confidential information (see also Article 7(1) of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights). Where the evidence may contain confidential information, this means that the Court must hear the other party before deciding whether and to what extent to disclose the evidence to the applicant. In this context, the Court must grant the other party access to the evidence and must provide that party with the opportunity to request the Court to keep certain information confidential and to give reasons for such confidentiality. If the other party makes such a confidentiality request, the Court must provide the applicant with the opportunity to respond in a manner that respects the other party's potential confidentiality interests. The Court may do this, for example, by granting access only to those representatives of the applicant whom the Court, pursuant to Rule 196.3(a) of the Rules of Procedure, has authorised to be present during the execution of the measures and subject to appropriate non-disclosure terms.

The opportunity for the other party to make a confidentiality request must be distinguished from the remedies available against the order for the preservation of evidence or the inspection of premises, such as the review of an order for the preservation of evidence without hearing the defendant pursuant to Rule 197.3 of the Rules of Procedure. Therefore, the Court must hear the other party on the request for disclosure even if that party has decided not to lodge a remedy against the order to preserve evidence or inspect premises. For the same reasons, a failure to apply for a review of an order for the preservation of evidence or for the inspection of premises cannot be regarded as tacit approval of the disclosure of evidence. 4. Pursuant to Article 60(8) of the UPCA, the Court shall ensure that measures to preserve evidence or to inspect premises are revoked or otherwise cease to have effect, at the defendant's request, if the applicant does not, within a period not exceeding 31 calendar days or 20 working days, whichever is longer, proceedings leading to a decision on the merits of the case before the Court (see also Article 7(3) of Directive 2004/48/EC and Article 50(6) of the Agreement on Trade-Related Aspects of Intellectual Property Rights). Rules 198.1 and 199.2 of the Rules of Procedure (RoP) specify that the time limit runs from the date specified in the Court's order, taking into account the date on which the report referred to in Rule

196.4 of the Rules of Procedure is to be submitted. These rules must be interpreted in the light of the purpose of the measures for the preservation of evidence or the inspection of premises, which is to use the outcome of these measures in the proceedings on the merits of the case (Rules 196.2 and 199.2 of the Rules of Procedure). In view of this, the Court must, as a general principle, specify in its order a time period that begins to run from the date on which the evidence is disclosed to the applicant or from the date on which the Court has made a final decision not to grant the applicant access to the evidence.

It is clear that the authorised seizure of technical documentation relating to the products alleged to infringe the patent entails a real risk of confidential information being obtained.

For this reason, the Court considers that a high standard of caution must be applied, temporarily preventing access to the contents of the expert's report and its annexes, even by the claimant's representatives, and making such access conditional upon the actual verification of the existence of confidential information worthy of protection.

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As clarified by the Court of Appeal, the application pursuant to Article 60 of the UPCA and Rule 192 of the Rules of Procedure (RoP) constitutes a request by the claimant for access to the contents of the documents obtained following the implementation of the measures. The claimant is not required to submit any further request for access after the measure has been implemented. The expert's report and its annexes will be filed with the Sub-Registry of the Milan Local Division, and the applicant will have full access to them from 22 October 2026, unless the respondent avails itself of the option to request protection of confidential information, irrespective of whether other remedies – such as a review or an appeal – are actually lodged.

The claimant's access shall take place by collecting a copy (previously made available by the expert, as already provided for in this order) at the Sub-Registry's offices, under the supervision of the judge-rapporteur and with the assistance of a clerk. The proceedings shall be recorded in a specific report, which shall then be uploaded to the CMS.

If, by 21 October 2026, the respondent has in fact submitted a request for the protection of confidential information, the Court will determine, by means of a specific order and after consulting the parties, whether access will be granted, to whom, and to what information.

Applications for review and appeal may be lodged separately (see paragraphs 6.7 and 6.8 below) and the outcome of any such remedies must, of course, be complied with.

Pursuant to Article 60(8) of the UPCA and Rule 198 of the Rules of Procedure (RoP), the order for the protection of evidence shall be revoked or shall otherwise cease to have effect, upon application by the defendant, if the claimant does not commence proceedings on the merits before the Court within a period not exceeding 31 calendar days or 20 working days, whichever is the longer, commencing from the date on which the claimant actually gains access to the content of the evidence or from the date on which the Court makes a final decision not to grant the claimant access to the evidence.

6.4. Restrictions on the use of the report by the Court-appointed expert

The expert's written report and any other document obtained following the execution of the order for the preservation of evidence may only be used in the subsequent proceedings on the merits, in accordance with the provisions of Rule 196.2 of the Rules of Procedure.

6.5. Service

Having regard to the need to ensure the element of surprise, service of the application – together with this order – shall be effected by the applicant in accordance with Italian national law at the stand occupied by XinFuDa at the *CPHI – Convention on Pharmaceutical Ingredients*, to be held in Milan from 6 to 8 October 2026 – immediately upon the execution of this order, in accordance with Rule 197.2 of the Rules of Procedure.

6.6. Security

Pursuant to Rule 196.6 of the Rules of Procedure (RoP), the Court considers that there are 'special circumstances' justifying that the enforceability of this order should not be made conditional upon the payment of security by the applicant.

The CPHI trade fair will take place from 6 to 8 October 2024, with extremely tight deadlines for the implementation of this measure. Imposing a security requirement would therefore entail

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the risk of an objective and irreparable impairment of the possibility of effectively implementing this order.

The collection of product samples is not, in itself, likely to cause potential economic damage to the defendant, arising from their temporary unavailability for the duration of any subsequent proceedings on the merits. The commercial value is, in fact, just under 1 euro per unit (see doc. TC20).

The claimant is, in any case, known to be one of the world's leading companies in the manufacture and sale of medical devices. Ypsomed should therefore be in a position to compensate the defendant for any damage caused by the enforcement of the measure.

The order is therefore immediately enforceable.

6.7. Review

The respondent may apply for a review of this order, as provided for in Article 60(6) of the UPCA and Rule 197.3 of the RoP.

6.8. Appeal

The parties may lodge an appeal within fifteen days of service of this order in accordance with Article 73(2)(a) of the UPCA and Rule 220.1 of the RoP.

ORDER

The Unified Patent Court – Court of First Instance – Milan Local Division

1. orders that the claimant be permitted, in relation to Shijiazhuang Xinfuda Medical Packaging Co., Ltd. at the *CPHI – Convention on Pharmaceutical Ingredients* trade fair to be held in Milan from 6 to 8 October 2026:
   a) to obtain, collect and retain, at the exhibition stand operated by Shijiazhuang Xinfuda Medical Packaging Co., Ltd., or at any other premises at the CPHI trade fair in Milan used by the defendant, all technical documentation relating to the product known as *the 'Disposable Injection Pen*';
   b) to provide a detailed description of the products identified by the trade name *'Disposable Injection Pen'* as they are present at the exhibition stand operated by Shijiazhuang Xinfuda Medical Packaging Co., Ltd., or at any other venue at the CPHI exhibition in Milan used by the defendant, including the taking of photographs and with express authorisation to collect five samples of *the 'Disposable Injection Pen'* product; the product samples thus obtained must be stored in accordance with the procedures indicated by the expert appointed by the Court and, in any event, in such a way as to ensure their integrity for the entire foreseeable duration of the subsequent proceedings on the merits, under the care of a custodian who must be appointed in accordance with the provisions of Italian law on the enforcement of judicial orders (and, in particular, pursuant to Articles 65 and 520 et seq. of the Italian Code of Civil Procedure, the custodian being a person designated by the bailiff at the time of enforcement of the order, whose name and title must be included in the report);

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2. orders Shijiazhuang Xinfuda Medical Packaging Co., Ltd. to allow the persons charged with enforcing this order (i) to enter the exhibition stand premises under its control and to carry out the necessary activities to preserve the evidence; (ii) to take photographs for documentary purposes, where deemed relevant to the preservation of evidence as ordered; (iii) to grant full and complete access to all technical documents, in any format, in its possession and under its control relating solely to *Disposable Injection Pen* products;
3. orders that, should the defendant fail to comply voluntarily with these instructions, the persons appointed to enforce this order are authorised – in accordance with the provisions of Italian law governing the enforcement of court orders – to request the assistance of the police where deemed necessary;
4. orders that this order be enforced by the bailiff with territorial jurisdiction, Mr Paolo Santonicola, whose practice is situated at [redacted], appointed as an Expert of the Court;
5. orders that, on behalf of the applicant, only the lawyers Vittorio Cerulli Irelli, Luca Pellicciari and Lorenzo Battarino and the patent attorneys Eng. Lorenzo Lualdi and Eng. Luca Frasson are authorised to be present during the enforcement of this order, with the strict exclusion of any other representative, employee or associate of the applicant; the authorised persons are required to keep confidential all information of which they become aware in the course of the execution of this order;
6. orders the Expert appointed by the Court to submit to the Sub-Registry of the Milan Local Division of the Unified Patent Court a written report on the results of the execution of the order for the preservation of evidence, attaching all the documents collected, immediately upon completion of the requested activities and, in any event, no later than three days after the conclusion of all operations; three copies of the aforementioned report and the documents must be made available: one for the Court and one for each of the parties;
7. orders that the written report and any other results arising from the execution of the order for the preservation of evidence may be used only in the subsequent proceedings on the merits;
8. notes that this order is immediately enforceable;
9. notes that the order for the preservation of evidence shall be revoked or otherwise cease to have effect, at the defendant's request, if the claimant does not bring the proceedings on the merits before the Court within a period not exceeding 31 calendar days or 20 working days, whichever is the longer, commencing from the date on which the claimant actually gains access to the content of the evidence gathered or from the date on which the Court has adopted the final decision not to grant the claimant access to the evidence;
10. orders that the claimant be granted access to the Expert's written report and its annexes from 22 October 2026, at the Sub-Registry of the Milan Local Division, under the supervision of the judge-rapporteur, with the assistance of a clerk, unless the respondent exercises the right to file an application for the protection of confidential information by 21 October 2026; should such an application for confidentiality be

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in fact submitted, the Court will decide whether and which persons shall have access to what information;

11. orders that this order, together with a copy of the application and its annexes, as well as the letter of service and the instructions for accessing the proceedings via the CMS, be served by the claimant at the exhibition stand allocated to the defendant at the *CPHI – Convention on Pharmaceutical Ingredients* trade fair to be held in Milan – Italy from 6 to 8 October 2026, immediately upon the execution of this order, in accordance with Italian law governing the service of judicial documents;
12. orders that the service and enforcement of this order take place, where possible, at a time other than when the venue is open to the public, or – where this is not possible – at a time when the expected number of visitors is at its lowest;
13. defer any decision on costs to the subsequent proceedings on the merits;
14. acknowledges that the respondent may request a review of this order within thirty days of the measures being carried out, in accordance with Article 60(6) of the UPCA and Rule 197.3 of the RoP;
15. acknowledges that the parties may lodge an appeal within fifteen days of service of this order, in accordance with Article 73(2)(a) of the UPCA and Rules 220.1(c) and 224.2(b) of the RoP.

Milan, 30 September 2026.

Pierluigi Perrotti Presiding Judge and Judge-Rapporteur	Digitally signed Perrotti Pierluigi 30 September 2026 10:05:43 +0200 Unified Patent Court Einheitliches Patentgericht Juridiction unifiée du brevet
Samuel Granata judge qualified in legal matters	Samuel Rocco M Granata Digitally signed by Samuel Rocco M Granata Date: 30 September 2026 07:40:11 +02'00'
Alima Zana legally qualified judge	ALIMA ZANA MINISTRY OF JUSTICE 30 September 2026 05:08:55 GMT+00:00
on behalf of the Deputy Registrar	Digitally signed Manuela Ferrari 30 September 2026 09:59:27 +0200 Unified Patent Court Einheitliches Patentgericht Juridiction unifiée du brevet