New Court, new approaches: How the UPC is reshaping pharmaceutical patent litigation

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Introduction

Since its launch in June 2023, the Unified Patent Court (UPC) has developed a growing body of case law.

Initially cautious, pharmaceutical companies are now becoming more involved with the UPC. To date, the Court has issued over 50 rulings in pharmaceutical cases, including several highly relevant Court of Appeal decisions for originators, generics and biosimilar manufacturers.

These rulings have played a pivotal role in establishing procedural standards relating to preliminary injunctions, evidence preservation and the scope of injunctions. They have also addressed substantive issues such as inventive step analysis in a pharmaceutical context and the infringement and the enforcement second medical use claims.

The UPC's case law is now setting the framework for future pharmaceutical litigation in Europe.

Preliminary injunctions: Urgency and imminent infringement

Preliminary injunctions (PIs) are crucial in the pharmaceutical sector, particularly for originators seeking to prevent revenue loss from generic market entry. The UPC has developed case law on PIs, focusing on standards for granting measures, timeliness and market conditions.

Thresholds for granting preliminary measures

Article 62 (1) of the Agreement on a Unified Patent Court (UPCA) allows the Court to grant injunctions to prevent imminent infringement. The Court determines which acts in drug commercialisation constitute infringement and when such infringement is imminent.

Marketing a medicinal product in EU member states, Iceland, Norway and Liechtenstein requires a marketing authorisation (MA) from the European Medicines Agency. Under the Bolar exemption, activities related to the obtaining of an MA prior to patent expiry are non-infringing. This was confirmed in *Boehringer v Zentiva* (CoA_520/2025, CoA_446/2025, 13 August 2025). CE marks, a prerequisite for marketing, are also non-infringing *Aesculap v Shanghai International Holding* (UPC_CFI_213/2025 10 July 2025), which is consistent with national court precedent.

Regarding the question of when a generic manufacturer's conduct constitutes "imminent" infringement, the Court of Appeal (CoA) in *Boehringer v Zentiva* established this three-part standard:

- certain circumstances that suggest (…) that the potential infringer has already set the stage for the infringement to occur;
- the infringement is only a matter of starting the action; and
- the preparations for it have been fully completed.

The CoA held that the completion of health technology assessment, pricing and reimbursement procedures for a generic product may constitute imminent infringement, with the assessment depending on national regulatory context and case specifics. In *Boehringer v Zentiva*, imminence was found when the pricing and reimbursement completion was published. This timing varies across member states.

In Germany, for example, no further pricing process is required after the MA is granted for a generic product, meaning that any post-MA commercialisation act can create a risk of imminent infringement. The timing can be unclear for hospital or clinical drugs, as their availability may not be reflected in the Lauer-Taxe listing.

Relevance of delay and market circumstances

PI requests must be well reasoned, demonstrating both applicant's timeliness and the necessity of a PI, especially when considering market circumstances.

Timeliness

If the applicant does not act in a timely manner, the PI request may be denied for lack of necessity or urgency, as the rules discourage unreasonable delay.

The assessment of temporal urgency involves three elements: when the applicant should have initiated preparations for the preliminary injunction; the time taken to file the application; and whether urgency, once lost, can be restored.

- The "clock starts ticking" when the applicant, after due diligence, has the necessary facts and evidence (*Mammut v Ortovox,* UPC_CoA_182/2024, 25 September 2024; *Boehringer v Zentiva*). For products requiring examination, evidence is considered available once a sample has been examined. The CoA has accepted that such an

examination by an external expert could take up to three months from the receipt of the sample (*Abbott v Sibio,* CoA_382/2024, 14 February 2025).
As generic medicines have identical active ingredients and are bioequivalent, infringement allegations can be substantiated more quickly, so the Court is less generous with delays. The Court has deemed public notification of the completion of (national) pricing and reimbursement proceedings for a generic product a trigger point (*Boehringer v Zentiva*), creating a duty to monitor the market so as not to miss when sufficient information is available for filing a PI request. In *Merz v Viatris* (UPC_CFI_697/2025, 21 November 2025), the Court focused on the date on which the originator and patent holder was informed by the French authorities during the national pricing and reimbursement proceedings pursuant to the French LEEM CEPS agreement, that a generic manufacturer intended to market a corresponding product.

- Once urgency is triggered, applicants should act promptly; filing within one month (-*Mammut v Ortovox*) or two months (*Sumi Agro v Syngenta*, CFI_201/2024 27, August 2024) has been accepted.
- The possibility of "resetting the clock" has been discussed (*Merz v Viatris; Cilag v Rivolution,* UPC_CFI_374/2024, 29 August 2025) but not accepted. Moving from imminent to actual infringement or subsequent market effects does not revive urgency. The Court has not yet addressed whether urgency could be revived when unrelated infringing acts occur in different markets. For example, initial entry into a smaller market could be followed by entry into a larger market, such as Germany via the Lauer-Taxe, where the impact would increase due to the larger market size.

Market circumstances

The Court recognises that market circumstances such as the deprivation of patent-related market opportunities, the seasonality of the product, price erosion and negative price spirals can necessitate a PI (*Mammut v Ortovox, Sumi Agro v Syngenta, Boehringer v Zentiva, Abbott v Sibio*). Sufficient evidence of the claimed market circumstances must be provided *(Cilag v Rivolution)*.

Pretrial discovery before the UPC

Applications to preserve evidence and for inspection are essential for preparing a UPC main action. This summary highlights key case law for the pharmaceutical sector, focusing on the likelihood of infringement and ex parte orders.

Likelihood of infringement

Applicants must provide any reasonably available evidence that the patent is or may be infringed; the threshold is low.

In the pharmaceutical context, Local Division (LD) Brussels found that the mere submission of a marketing authorisation (MA) application can suffice to plausibly show imminent infringement; nonetheless, additional evidence, such as public statements and nullity

actions by the defendant, supported the likelihood of infringement *(Genentech/Roche v Organon,* UPC_CFI_407/2025, 12 November 2025).

Applicants sometimes submit expert reports and/or claim charts. Expert reports must be carefully prepared; simply alleging that the patented solution has been implemented is not enough. For instance, the LD Mannheim ruled that, when a technical result can be achieved in several ways, the applicant must demonstrate that the patented solution is in use and not an alternative solution. In that case, the expert report was deemed inadequate *(Centripetal v Palo Alto Networks*, UPC_CFI_142/2025, 3 March 2025).

Ex parte orders

The Court must decide whether to hear the defendant before granting an order. It considers factors such as urgency, the risk of irreparable harm to the applicant and the likelihood that evidence may be destroyed or become unavailable.

Is urgency required?

The CoA held that urgency is not required for the application itself but is relevant to whether to proceed ex parte.

In the pharmaceutical case before the LD Brussels, urgency was established as it was plausible that the MA would be granted within a year. Approval of the biosimilar was, therefore, expected by early 2026. Further actions by the defendant, such as public statements and nullity proceedings, indicated that the launch would take place in early 2026. Therefore, the application to preserve evidence and conduct an inspection in November 2025 was urgent (*Genentech/Roche v Organon*). Urgency was also found where trade fairs or conferences were involved due to the imminent or short-lived nature of these events.

Risk of evidence disappearing

It is not necessary to prove with certainty that evidence will be lost; a likelihood or demonstrable risk suffices. In many cases, the ease with which digital evidence can be deleted, changed or transferred justifies urgent action. Pharmaceutical regulations requiring documentation do not remove this risk, as documents may still be moved (*Genentech/Roche v Organon*).

Preparing the application

Orders for preserving evidence and for inspection without hearing the defendant constitute serious interference with the defendant's rights. The CoA has made clear that applicants must disclose all material facts within their knowledge that could affect the decision to grant the order ex parte. Omissions or distortions of critical facts cannot be remedied by later submissions (*Ecovacs v Roborock,* UPC_CoA_3/2026, 16 March 2026).

Other considerations

Under German law, the defendant has two hours to contact lawyers before an order to preserve evidence and conduct an inspection is enforced. However, the LD Brussels held that, although legal representatives may be present during enforcement, this cannot delay it. Therefore, enforcement may occur before lawyers arrive, so it is vital that employees are trained for such scenarios.

The extent to which the defendant must assist with inspections is still unclear. LD Mannheim deemed it "highly questionable" to compel a defendant to set up a test environment on their premises, as requested by the applicant. Generally, obligations are limited to providing access, operating machinery, supplying consumables or passwords, and disclosing requested information (*Centripetal v Palo Alto Networks*, UPC_CFI_142/2025, 3 March 2025).

The CoA confirmed that preservation or inspection orders are not granted if evidence can be obtained by other means and "fishing expeditions" are not permitted(*Ecovacs v Roborock*).

Conclusion

Recent case law suggests that the Court takes a practical, applicant-friendly approach to orders to preserve evidence and for inspection, balancing the interests of the parties involved. As a result, applications may increase. To protect against such orders, it may be advisable in some cases to file a protective letter against orders for the preservation of evidence and inspection.

The scope of injunctions

Both the plaintiffs and the Court may limit the scope of injunctions in the UPC through carve-outs, considering potential or actual objections from the defendants.

Territorial carve-outs

In the light of the *lis pendens* objections based on parallel actions before the UPC and national courts legal debate has focused on whether a European patent may be litigated before the UPC, if national parts are already subject to national proceedings.

As the UPCA permits a forum choice for European patents not opted out during the transitional period, parallel proceedings before the UPC and national courts may occur.

According to article 71c UPCA, *lis pendens* objections before the UPC are governed by article 29–32 of the Brussels Regulation (EU) 1215/2012, which regulate stays of proceedings. Pursuant to article 34 UPCA, UPC decisions on European patents apply across all contracting member states:

> Decisions of the Court shall cover, in the case of a European patent, the territory of those Contracting Member States for which the European patent has effect.

This prompts the question of whether UPC jurisdiction can be restricted by carving out a jurisdiction to avoid *lis pendens* objections.

In *Belkin v Koninklijke Philips* and *Sumi v Syngenta*, the CoA confirmed that a claimant may restrict infringement actions to certain contracting member states (UPC_CoA_534/2024, 3 October 2025; UPC_CoA_523/2025, 3 March 2025).

The principle of the parties defining the subject matter also applies to revocation actions. In *Aylo v DISH* (UPC_CFI_198/2024, 28 May 2025), the Court clarified that revocation of a European (bundle) patent may be limited to certain national parts, when requested by the claimant, since article 76(1) UPCA directs the Court not to exceed claimant's request.

In *Abbott v Dexcom* (UPC_CFI_230/2023, 4 July 2024), the UPC considered the impact of a jurisdictional carve-out in an infringement action on a revocation counterclaim. Earlier, infringement and nullity proceedings relating to the German part of the patent in question had begun in Germany. Dexcom sought to carve out Germany; Abbott counterclaimed for revocation of the entire patent in suit. Dexcom argued that the UPC lacked jurisdiction to rule on revocation regarding the German part, on the basis that its scope must mirror the infringement claim. The Court accepted Dexcom's carve-out but also held that revoking the patent in suit would have an *erga omnes* effect, as no Rule of Procedure restricts a revocation counterclaim to the parts of the patent that have been infringed.

Consequently, claimants in infringement actions may exclude national parts of a European patent to prevent a stay of proceedings when there are parallel proceedings pending before national courts. Although the scope of a counterclaim for revocation is not automatically restricted to the scope of the infringement action, claimants for revocation may limit revocation actions to specific contracting member states.

Carve-outs based on proportionality

Apart from territorial carve-outs, product-specific carve-outs are discussed in light of proportionality defences.

Article 63(1) UPCA states that the Court "may" grant an injunction, as does article 62(1) UPCA for preliminary measures. In addition, article 64(1) UPCA states that the Court "may"-order appropriate measures. Article 64(4) UPCA requires the Court to consider the:

> need for proportionality between the seriousness of the infringement and the remedies to be ordered, the willingness of the infringer to convert the materials into a non-infringing state, as well as the interests of third parties.

This raises the question of whether it is in the Court's discretion to grant injunctions and/or determine their scope.

In *Edwards v Meril* (UPC_CoA_464/2025, 25 November 2025), the CoA clarified that the granting of injunctions and corrective measures is not discretionary, and that patent proprietors are entitled to such relief under articles 63 and 64 UPCA, which implement articles 10 and 11 of the Enforcement Directive. Courts must grant injunctions unless special reasons, such as proportionality, justify an exception. Proportionality is derived from article 3 of the Enforcement Directive and EU law principles.

In *Valeo v Magna* (UPC_CFI_368/2024, 31 October 2024), the Court excluded certain products from the preliminary injunction due to disproportionate harm to the defendant.

In *Edwards v Meril* the CoA confirmed that Meril's XL valve prostheses could be excluded from the injunction, given the lack of alternatives that established patients' legitimate interests. When conducting proportionality assessments, the Court may consider the interests of not only the parties involved, but also those of third parties, such as patients. If an embodiment constitutes the "sole available treatment method" or an "improvement upon available treatment methods, resulting in a notable enhancement of patient care", the interests of patients may justify the restriction of the scope of an injunction.

Conclusion

The Court must generally grant injunctions, departing only for proportionality reasons. The proportionality test considers the interests of both parties and third parties, including patients. Exemptions are justified for medical or pharmaceutical products lacking alternatives or offering significant treatment benefits. In preliminary injunctions, products may be excluded to avoid disproportionate harm.

Inventive step analysis in the UPC

The assessment of inventive step in European patent law has long been contentious. The European Patent Office (EPO) uses a structured problem-solution approach, whereas national courts differ in their approach. Some favour a holistic method that considers multiple prior art documents. The UPC's approach remained unclear until the CoA clarified it in two decisions in November 2025: *Amgen v Sanofi* (UPC_CoA_528/2024, 25 November 2025) and *Edwards v Meril*.

Traditionally, the EPO assesses inventive step using the "problem-solution approach", involving three steps: (1) identifying the closest prior art; (2) defining the objective technical problem; and (3) considering whether the claimed invention would have been obvious to the skilled person.

Several member states' national courts have generally followed this approach, but others, such as Germany and England and Wales, have preferred a broader, more holistic assessment that considers several prior art documents.

It was uncertain which method the UPC would adopt. The CoA's November 2025 decisions established a new methodology based on three steps:

- establish the object of the invention from the perspective of the skilled person;
- identify realistic starting points in the prior art and in the relevant field of technology; and
- assess whether the skilled person would have arrived at the claimed solution from those starting points.

We will discuss each step in some more detail below.

The object of the invention from the perspective of the skilled person

First, the object of the invention (ie, the objective problem) must be established from the perspective of the skilled person with general knowledge at the priority date. The inventive

concept underlying the invention should be identified. In other words, it must be determined what the invention adds to the state of the art by examining the claims as a whole in the context of the description and drawings, rather than looking at the individual features of the claim.

The CoA stresses that, to avoid any hindsight, the problem should not contain pointers to the invention.

Realistic starting points in the prior art and in the relevant field of technology

Second, one or more realistic starting points in the prior art must be identified.

A starting point is realistic if the technical teaching identified in the first step would have been of interest to a skilled person trying to solve the objective problem; for example, if a prior art document discloses similar features or addresses a similar problem.

The relevant field of technology can extend to any area in which the same or a similar problem arises, of which the skilled person could reasonably be aware.

Multiple realistic starting points may exist, and the invention must be assessed for inventiveness starting from each of them.

Whether the skilled person would have arrived at the claimed invention

Finally, it must be assessed whether, at the relevant date, the skilled person, starting from a realistic prior art point and wishing to solve the objective problem, would (not merely could) have arrived at the claimed solution.

The skilled person lacks inventive skills and imagination; this person needs a pointer or motivation from a realistic starting point that directs it to implement a next step in the direction of the claimed solution. A solution is not considered inventive if, prompted by a pointer or acting as a matter of routine, the skilled person would have taken the next step in expectation of finding a solution to the technical problem.

This applies when the results of the next step are clearly predictable or subject to a reasonable expectation of success based on a scientific assessment of the known facts before research into the claimed invention began. Whether such an expectation exists depends on the circumstances of the case, such as the technical field (the less explored it is, the harder predictions are and the lower the expectation of success) and practical and technical difficulties (including costs) in testing the desired result. The stronger the pointer to the claimed solution, the lower the threshold for a reasonable expectation of success. The fact that others were working on the same project at the same time does not necessarily imply a reasonable expectation of success.

Notably, an inventive step can also be found in non-obvious alternatives to solutions known in the prior art, regardless of improvement.

The new UPC's approach to inventive step

The CoA has established its own approach to inventive steps, which is binding on all first-instance UPC divisions.

This differs from the EPO's problem-solution approach in that it assesses the invention as a whole and considers multiple realistic starting points, not just the closest prior art.

Despite these differences, the two approaches are similar enough that they should generally reach the same conclusion in practice.

Second medical use claims: Enforcement issues under the UPC framework

Second medical use claims allow protection of a known substance or composition to be protected for a novel and inventive second (or further) therapeutic application.

Since the entry into force of the EPC 2000, protection of medical uses has been permitted under article 54(4) and (5) in the form "Substance X for use in treating disease Y".

The scope of protection for second medical use claims, and the circumstances in which competitors (notably generics and biosimilars) may infringe such claims, especially in 'skinny label' cases where patented indications are excluded from the SmPC, has been widely debated. National courts across Europe have adopted divergent approaches and there is no harmonised test, which creates uncertainty for patentees and competitors alike. Infringement analysis may also depend on national prescription, substitution and procurement rules and practices.

In *Sanofi & Regeneron v Amgen* (UPC_CFI_505/2024, 13 May 2025), the Court provided guidance on claim construction and proposed an infringement test for the UPC. In *Sanofi v Stada, Dr. Reddy's & Zentiva* (UPC_CFI_146-148/2024, 12 December 2025), the LD Munich provided further clarification on claim interpretation (but revoked the patent and therefore did not rule on infringement).

Claim interpretation: Purpose-limited product claims

Both decisions address to varying degrees, the interpretation of second medical use claims and concur that they must be construed as purpose-limited product claims.

In *Sanofi & Regeneron v Amgen*, the LD Düsseldorf provided a detailed claim construction of the patent-in-suit, which claimed a PCSK9 inhibitor "for use in reducing lipoprotein(a) (Lp(a)) levels" in a specific patient group.

Lp(a) and LDL-C are lipoproteins associated with cardiovascular disease. Lowering LDL-C with PCSK9 inhibitors was known, but the patent claimed lowering Lp(a) as an inventive therapeutic application. Evolocumab (Repatha), marketed by Amgen, is approved for cardiovascular risk reduction linked to LDL-C, not Lp(a). Sanofi and Regeneron argued that safety data for Lp(a) in section 5.1 of Repatha's SmPC (not in the indications listed in section 4.1) would induce doctors to prescribe it for Lp(a) reduction, thus infringing the patent.

The LD confirmed that claim construction for both validity and infringement must follow article 69 EPC as in *NanoString v 10x Genomics*.The claim excludes use solely for LDL-C reduction; thus prescribing for LDL-C does not exclude infringement if Lp(a) reduction is also achieved.

In *Sanofi v Stada, Dr. Reddy's & Zentiva*, the patent covered cabazitaxel for patients with metastatic castration-resistant prostate cancer (mCRPC) who had previously been treated with docetaxel. LD Munich took a similar approach to claim construction, confirming that achieving the claimed therapeutic effect is a functional feature of the claim.

The infringement test for second medical use claims

The *Sanofi & Regeneron v Amgen* decision was the first (and, to date, only) opportunity for the UPC to provide guidance on the infringement test for second medical use claims, particularly in cases where the allegedly infringing product is suitable for, but not indicated for, the patented use.

The Court acknowledged that neither the UPCA nor the EPC specifically address the infringement of purpose-limited product claims, and that no harmonised approach exists. While the Court found that absolute product protection is unavailable for second medical use claims, it considered that restricting protection to cases where there is evidence of the product being used for the claimed purpose would "unduly limit" the protection. Instead, infringement of second medical use claims requires a two-limb test: (1) objectively, evidence of actual or expected prescriptions for the patented use; and (2) subjectively, that the defendant knew or ought to have known its marketing would lead to that use. Both limbs are fact-specific and, while SmPC content is relevant, it is not decisive; a carve-out is neither always required nor always sufficient.

Applying these principles to the case in question, the Court ruled against the claimants Sanofi and Regeneron on both limbs.

On the objective limb, the reference to Lp(a) reduction in section 5.1 of Repatha's SmPC was deemed insufficient, since section 5.1 provides safety information, whereas prescriptions are based on the indications in section 4.1 (no PCSK9 inhibitor has been approved for Lp(a) reduction).

On the subjective limb (obiter, as the first limb failed), the claimants' evidence was deemed insufficient to demonstrate a likelihood of off-label prescribing for Lp(a) reduction. Expert evidence indicated that elevated Lp(a) did not influence prescribing decisions, and that practical and financial disincentives (such as lack of reimbursement) weighed against this conclusion further.

In conclusion, the decision provides helpful guidance for stakeholders and proposes a clear, balanced infringement test. An appeal is pending, with a hearing expected in 2026. If the patent survives parallel EPO opposition, the CoA will have the opportunity to confirm or modify the test.

If the test is confirmed, further cases will be required to clarify its application in different scenarios. There are still many questions regarding generics and biosimilars with skinny labels, such as what steps the UPC will require from manufacturers (eg, communications to healthcare professionals), and how to proceed when the patented use cannot be excluded from the indication (eg, when adding text to the SmPC would be required, which regulators often do not accept).

In summary

UPC case law has now established the first key guidelines for the examination of pharmaceutical cases. It is to be expected that, on this basis, pharmaceutical litigation in Europe will increasingly be heard in this Court.

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