# DYOUNG<sup>&</sup>CO PATENT NEWSLETTER<sup>no.107</sup>

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Also: UPC and biotech webinar invitations



# Editorial

As we mark the second anniversary of the Unified Patent Court and the unitary patent, both are now firmly embedded in the European patent landscape. In this special edition newsletter, we take a closer look at how the court has evolved over the past two years: exploring trends and statistics surrounding the UP and UPC, examining key issues such as inventive step and claim construction, and considering points of convergence and divergence between UPC and EPO case law. I'm also delighted to share that our firm has once again been recognised as a top-tier "Gold" firm by IAM Patent 1000. Thank you to all those who participated in the survey.

# Simon O'Brien, Editor

# Events

**Bio International Convention Boston, USA, 16-19 June 2025** Antony Latham, Jennifer O'Farrell and Tom Pagdin are attending BIO 2025.

Space & Communications Week 17-18 June 2025, London UK David Al-Khalili and Sean McCann are attending the International Satcomms, Quantum Engineering & Tech, and 6G Future Network Conferences.

## UPC Case Law, Observations & Analysis

D Young & Co webinar, 18 June 2025 Anthony Albutt, Rachel Bateman, Jonathan DeVile and Tom Pagdin present the latest in our ongoing UPC webinar series.

## **European Biotech Patent Case Law**

D Young & Co webinar, 08 July 2025 Catch up on new and important biotech case law with Matthew Caines and Nathaniel Wand.

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# Inventive step at the UPC Two years on

ssessment of inventive step at the Unified Patent Court (UPC) has included a mix of the problem-solution approach from the European Patent Office (EPO), the approach applied by the German Federal Court of Justice, and a smattering of national patent court assessments sprinkled in for good measure.

In this article, we discuss Edwards Lifesciences Corporation v Meril Life Sciences Pvt Ltd (UPC\_CFI\_501/2023) in which the Munich Local Division stated that the EPO's problem-solution approach should be primarily applied to the extent feasible and to align with the EPO for the assessment of inventive step throughout the UPC.

# A short history of inventive step at the UPC

Shortly after the launch of the UPC, we proposed that precisely how and under which criteria the UPC would assess inventive step during invalidity was unknown. At the time, we considered it was possible that the UPC might adopt the approach of the Boards of Appeal of the EPO; approaches of member states with broadly similar approaches to the EPO, such as France, Sweden, and Italy; or markedly different approaches such as those used in Germany.

Twelve months on, we investigated how the UPC Court of Appeal had evaluated inventive step in the long running Nanostring Technologies v 10x Genomics Inc dispute. In this decision the Court of Appeal appeared to follow a somewhat similar approach to the problem-solution approach at the EPO, without endorsing or criticising any particular approach, nor referring to any case law.

Two years after the launch of the UPC, the Munich Local Division (notably the most active of the local divisions, with over 120 cases lodged in 2024) appears in Edwards Lifesciences Corporation v Meril Life Sciences Pvt Ltd to suggest that the varying approaches to the assessment of inventive step by the UPC Courts of First Instance and Court of Appeal may need to align. In the decision, the Munich Local Division states that the UPC should align with the established jurisprudence of the EPO, namely by primarily following the EPO's problem-solution approach for the assessment of inventive step.

Key UPC inventive step decisions In an early decision, UPC\_CFI\_2/2023, issued on 19 September 2023, between NanoString Technologies and 10x Genomics Inc, the Munich Local Division stated, "An important criterion in choosing the most promising starting point is the similarity of the technical task". The court dismissed prior art references on the basis that "the court cannot see that this document suggests the invention according to the patent", appearing to follow a problem-solution approach for the selection of the closest prior art.

In UPC\_CoA\_335/2023, issued on 11 March 2024, also between NanoString Technologies and 10x Genomics Inc, the Court of Appeal found that the document dismissed by the Munich Local Division (Göransson – D6) "would have been of interest to a person skilled in the art".

In **UPC\_CFI\_1/2023**, issued on 16 July 2024, between Sanofi-Aventis and Amgen Inc, the Munich Central Division laid down some basic steps to follow for the assessment of inventive step. These were:

- determining a realistic starting point in the art, which has a similar underlying technical problem;
- 2. comparing the claimed subject matter, after interpretation, to this starting point; and
- establishing whether it would be obvious for the skilled person to, starting from the realistic starting point, in view of the underlying problem, arrive at the claimed solution.

Notably in UPC\_CFI\_1/2023, the Munich Central Division stated that for a piece of prior art to be realistic it merely needed to be "**of interest**" to the skilled person. Case details at a glance

Decision level: Munich Local Division Case: ORD\_598588/2023 Parties: Edwards Lifesciences Corporation v Meril GmbH, Meril Life Sciences Pvt Ltd and Meril Italy Srl Date: 04 April 2025 Decision: dycip.com/upc-ord-598588-2023

Additionally, the underlying technical problem was first to be established **from the background section of the patent**, and when that failed, **from the patent description as a whole**. This establishment of the underlying technical problem diverged from the EPO's problemsolution approach, where the technical problem is formulated objectively and based upon the closest prior art.

Accordingly, it appeared that the UPC was in the midst of developing its own approach to the assessment of inventive step. This approach possessed some similarities to the EPO's problem-solution approach, whilst simultaneously possessing marked differences, particularly in the selection of "any realistic starting point", and consideration of the "underlying" technical problem as opposed to an "objective" technical problem.

### The present case background

Edwards Lifesciences Corporation's patent (EP 3 669 828 B2) concerns a transcatheter prosthetic heart valve and was first opposed by Abbott Cardiovascular Systems in February 2022 at the EPO. Following opposition proceedings, the patent was maintained in an amended form. In particular, claim 9 as granted was deleted from the granted claims and claim 10 was maintained in an amended form. The remaining claims, including independent claim 1 remained as granted. No subsequent appeal was filed.

Subsequent to these opposition proceedings, Edwards bought an infringement action in the UPC Munich Local Division against several Meril entities. A counter-claim for revocation was filed. In the decision from the Munich Local Division, **UPC CFI 501/2023**, the patent was upheld in the form maintained by the EPO's Opposition Division. The Munich Local Division further handed down an injunction enforceable by Edwards, alongside damages, and other remedies. As part of the decision the Munich Local Division made what could be considered a "landmark ruling" on the assessment

# ➢ Related articles

Inventive step? How will the UPC decide?, 11 October 2023: dycip.com/upc-inventive-step-oct2023

Inventive step at the Unified Patent Court: 12-months in, what do we know so far?, 06 June 2024: dycip.com/upc-1year-inventive-step

UPC Annual Report 2024 (PDF): dycip.com/upc-annual-report-2024

UPC departs from EPO selection principle in novelty analysis: Dexcom v Abbott, 08 August 2024: dycip.com/dexcom-abbott-aug24

of inventive step at the UPC, although this decision and statement may still be challenged at the UPC Court of Appeal.

## The Munich Local Division's ruling

The second headnote of the decision states: "For assessing whether an invention shall be considered obvious having regard to the state of the art, **the problem-solution approach** developed by the European Patent Office **shall primarily be applied** as a tool to the extent feasible **to enhance legal certainty** and **further align the jurisprudence of the Unified Patent Court with the jurisprudence of the European Patent Office and the Boards of Appeal.**" In its assessment of inventive step, the Munich Local Division discussed the current legal standard of the assessment of inventive step at the UPC.

First, the Munich Local Division set out that both the UPC Courts of First Instance and the UPC Court of Appeal have assessed inventive step in a variety of ways, with some using the problem-solution approach of the EPO, and others using a test that is similar if not identical to the one applied by the German Federal Court of Justice. The Munich Local Division then opines that, if applied correctly, both tests should result in the same outcome in the majority of cases. This suggests an admittance that the use of different assessments of inventive step may not always result in the same outcome, which is an uncomfortable position for any UPC user to deal with. However, the Munich Local Division stated explicitly its intention to use the EPO's problem-solution approach, and further, that there is a "need for legal certainty for both the users of the system and various divisions of the Unified Patent Court".

Of interest to those involved in both UPC and EPO proceedings is that when discussing a document cited as closest prior art during the prior opposition proceedings, the Munich Local Division explicitly included the appropriate passage from the EPO's Opposition Division's decision in its decision. Further, the reasoning of the Munich Local Division is reminiscent of decisions from



Webinar invitation UPC case law, observations & analysis 1pm, 18 June 2025 dycip.com/webinar-upc-jun2025

the EPO; for each document taken as closest prior art, it considers the difference, the technical effect associated with this difference, and then proceeds to formulate an objective technical problem. The final step is a consideration of whether the skilled person "would" be motivated to arrive at the claimed solution from the prior art.

If this case is taken to the UPC Court of Appeal, the Munich Local Division appears to be inviting the UPC Court of Appeal to comment, and provide explicit legal certainty on this issue. Whether it will choose to do so is another matter entirely.

# Moving forward, does the UPC intend to align fully with the EPO?

Users of the UPC system and patent practitioners welcome clarity and legal certainty on any substantive issue the UPC Courts provide. As the system continues to develop, even small changes in assessment of issues such as inventive step could result in significant divergence between the case law at the EPO and UPC.

Whilst this particular case appeared to also follow the established EPO practice in its assessment of novelty, not all UPC Courts seem to agree, with the Paris Local Division notably departing from standard EPO practice by finding a single selection from a list novel. One would think that if the UPC takes the stance that it should follow EPO jurisprudence on one substantive issue (for example, inventive step) that it would also want to align on other issues, such as novelty.

We will be keeping a close eye on future decisions, to see if this adherence to established EPO jurisprudence becomes a mainstay of UPC practice.

If you are considering initiating a legal action within the UPC and want more information on how the assessment of inventive step at the UPC may affect such action, please contact your usual D Young & Co representative for further information.

Authors:

**Rachel Bateman & William Hutton** 

# **UPC / claim construction**

# **Claim interpretation** More clarity on claim construction at the UPC

ince the Court of Appeal's decisions on claim interpretation in March and May 2024, Unified Patent Court (UPC) judges at all levels have applied the those decisions to shape the way claim interpretation is applied at the UPC. This article highlights the approaches taken in two recent decisions.

## Background

The principles set out by the UPC Court of Appeal in NanoString Technologies Inc v 10x Genomics Inc (UPC\_CoA\_335/2023) is that the description and drawings must always be used as explanatory aids for interpretation, not just to resolve any ambiguities in the claim language, such that only after examination of the description and drawings does the scope of the claims become apparent. Subsequent decisions at Local and Central Divisions demonstrated that the content of the description is critical to understanding the scope of the claims at the UPC.

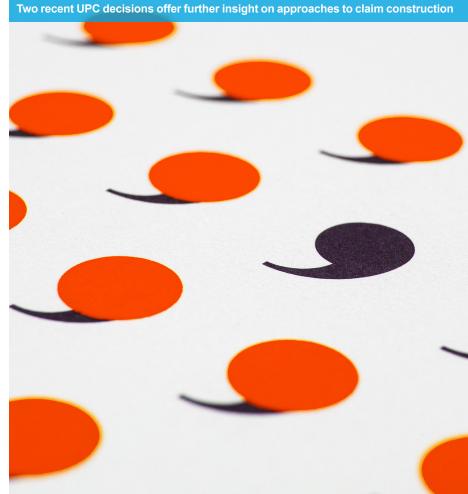
### Agfa NV v Kering

On 30 April 2025, the UPC Hamburg Local Division delivered its decision in the Agfa NV v Kering case in relation to infringement and validity of Agfa's patent related to a manufacturing method for decorating natural leather with a decorative image and a decorated natural leather having a decorative image. The defendants in this case were nine different European companies belonging to the French conglomerate Kering, which is the parent company of several luxury brands including Gucci, Saint Laurent and Balenciaga.

At the heart of the dispute was the feature "a base coat containing a pigment for providing an achromatic colour different from black", and in particular the definition of the term "achromatic".

Paragraph [0021] of the description of the patent provided the definition "[a] chromatic colour is any colour in which one particular wavelength or hue predominates. For example, blue and green the claims as a whole given that a later are chromatic colours, while white, grey, feature in the claim stated "the achromatic colour different from black of the base coat". and black are achromatic colours, as they have no dominant hue, meaning that all wavelengths are present in approximately Whilst acknowledging the established principle from NanoString Technologies Inc v 10x Genomics Inc (UPC\_CoA\_335/2023) The Hamburg Local Division first considered that a patent may be used as "own lexicon" whether the term "achromatic" refers to regarding the definition of claimed features, the pigment or the base coat as a whole. the court clarified that this is limited to the parts of the description that relate If only the pigment needs to be achromatic, to the feature in question. In particular, then the base coat can contain an achromatic the description of the patent in suit pigment different from black, whereas the discussed ∆E94 measurement, a metric latter interpretation requires the base coat as for understanding how the human eye a whole to have an achromatic colour different perceives colour. In the court's view, the from black. The court decided that the latter discussion of ΔE94 measurement related interpretation was correct when considering

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equal amounts within those colours."

# Related articles

UPC claim construction: recent approaches to claim interpretation, December 2024: dycip.com/upc-claim-construction

UPC v EPO: a comparison of claim construction approaches, June 2024: dycip.com/upc-epo-claim-construction

## Solution State State

Decision level: Hamburg Local Division Case: UPC\_CFI\_278/2023 Order/decision: ORD\_598576/2023 Parties: Agfa NV v Gucci Sweden AB, GG France Services SAS, Marbella Pellami SpA, Gucci France SAS, Guccio Gucci SpA, G Commerce Europe SpA, GG Luxury Goods GmbH, Gucci Belgium SA, Gucci Logistica SpA Date: 30 April 2025 Decision: dycip.com/agfa-kering

leather and was not part of the teaching in the patent regarding the definition of the term "achromatic", which was used in the claims of the patent in relation to a pigment in a base coat which is applied to crusted leather.

The claimant had asserted that ivory would be considered "an achromatic colour different from black" in accordance with claim 1, adding that leather was perceived as a luxury good, and that warmer shades of white, such as ivory, were more desired than a pure white.

The claimant considered that there are many shades of white, including ivory, and that "white colour" in the patent should be construed to include these shades. The court noted. however, that the claim refers to "achromatic" colour, and that whilst white is provided in the description as an example of an achromatic colour, not all shades of white will fall within the patent's definition of an achromatic colour.

The court therefore decided that the claimant's interpretation of this claim feature was overly broad and not supported by the patent.

In coming to this conclusion on the interpretation of the term "achromatic colour", the Hamburg Local Division decided that the patent was novel over each of the cited prior art documents, but also that the patent was not infringed.

## Insulet v EOflow

On 01 May 2025, the Court of Appeal handed down its decision concerning the appeal by Insulet Corporation regarding its patent directed to an infusion pump for delivering therapeutic liquids to a patient.

In the first instance decision, the Milan Central

Division held that the patent lacked novelty and therefore rejected the application for a provisional injunction against EOFlow.

EOFlow relied on the opinion of an expert for both interpretation of the patent and to understand one of the prior art documents, asserting that this opinion should be followed because Insulet did not provide an expert opinion of its own. The Court of Appeal did not agree, stating that the interpretation of a patent claim is a matter of law, and that this judicial task cannot be left to an expert; the court must construe the claims independently. Whilst the court acknowledged that the skilled person's understanding of the terms used in the patent claim is the basis for claim construction, this does not mean that the court must follow a party's expert opinion.

The court also emphasised the skilled person is a notional entity that cannot be equated with any real person, and that the individual knowledge of abilities of a person are not important, but rather the general specialist knowledge that is customary in the relevant field of technology and the average knowledge, experience, and abilities in this specialist field. The court did acknowledge, however, that expert opinions will be considered in circumstances concerning facts that can be proven, but only with respect to those facts.

The Court of Appeal disagreed with the Milan Central Division's observation that the patent does not appear to be limited to the assembled state of the fluid delivery device, stating that claim 1 is a product claim relating to a fluid delivery device designed to deliver liquids, and must therefore be in an assembled state.

The court also disagreed with EOFlow's assertion that the open term "comprising" allowed for a broader interpretation beyond the assembled state. The court considered that the claim being limited to the assembled state was consistent in the context of the claims as a whole when considering the description. In doing so, the court went on to find that the patent in suit was novel and more likely than not infringed.

Decision level: Court of Appeal, Luxembourg Case: UPC\_CFI\_768/2024 Order/decision: ORD\_ 69078/2024 Parties: Insulet Corporation v EOFlow Co Ltd Date: 01 May 2025 Decision: dycip.com/insulet-eoflow

Decision level: Court of Appeal, Luxembourg Case: UPC\_CoA\_335/2023 Order/decision: ORD\_595990/2023 (26 February 2024) & ORD\_12169/2024 Parties: Nanostring Technologies (Inc, Germany GmbH & Netherlands BV v President and Fellows of Harvard College, 10x Genomics Inc Date: 11 March 2024 Decision: dycip.com/nanostring-10x-coa

The first instance decision was therefore ordered to be set aside and a preliminary injunction was placed against EOFlow.

### Discussion

The idea that the skilled person is a notional entity that cannot be equated with any real person is in line with the established case law of the European Patent Office (EPO), for example, T 1462/14, and provides a welcome harmisation between the two systems. Equally, the Court of Appeal's decision in Insulet v EOFlow provides for a limited set of circumstances around the establishment of facts under which expert opinions will be considered, which is also generally in line with the established case law of the EPO (for example, T 543/95 and T 374/02).

It is clear that not only is claim interpretation an important first step when forming a decision, but that it is the job of the judges to decide on this, not any other party.

The content of the description is also critical to understanding the scope of the claims at the UPC. Earlier decisions (see UPC\_CFI\_373/2023 and UPC\_CFI\_252/2023) which applied the principles set out by the UCC Court of Appeal in NanoString Technologies Inc v 10x Genomics Inc (UPC CoA 335/2023) considered that the claims should be interpreted so as to include all the embodiments presented in the description as forming part of the claimed invention, provided they did not result in an irresolvable contradiction or were explicitly presented as not being in accordance with the invention. Both these decisions demonstrate, however, that this does not allow for an interpretation of claim breadth that goes beyond that which is supported by the description. A claim should therefore be interpreted so as to include all the embodiments presented in the description without extending broader to include embodiments not considered in the patent.

Author: Andrew Cockerell

# UPC / second medical use claims

# UPC infringement First decision for second medical use claims



recent first decision on infringement of a second medical use patent indicates how the Unified Patent Court (UPC) may treat this type of claim.

### Background

Article 54(5) EPC allows purpose-limited product claims (so called "second medical use claims") to protect a known product for a specific therapeutic application, provided that application is novel and inventive.

Second medical use claims can be very desirable, given their potential protection for the use of a drug in a new therapeutic method. However, the extent of third party activities prohibited by second medical use claims has historically been somewhat unclear, and has been the subject of several recent decisions across Europe. Consequently, a range of evolving standards has been applied to the question of infringement, varying by jurisdiction.

A common practice by generic pharmaceutical companies in an attempt to avoid infringing second medical use claims is "skinny labelling", where protected indications are "carved out" of a product's summary of product characteristics (SmPC) to avoid infringement related to those indications. Such practice was supported by the UK Supreme Court in Warner-Lambert v Actavis, as discussed in our article "Warner-Lambert Appeal: Swiss form claims & skinny labels". However, there are still unanswered questions in many jurisdictions as to how effective such a practice is to avoid infringement.

Complicating the issue is that many decisions in Europe are based on the previously used "Swiss-type" format of second medical use claim, which was replaced with the updated EPC 2000 revised second medical use claim. Interpretation of these claim variants also differs by jurisdiction.

The UPC has now issued its first decision on the matter, providing a key firstinstance insight into how this body will deal with the question of infringement of second medical use claims.

# The case at hand: Sanofi & Regeneron v Amgen (UPC\_CFI\_505/2024)

The Düsseldorf Local Division of the UPC very recently decided on the infringement of Regeneron's European Patent EP3536712B1, for which Sanofi is the exclusive licensee. Sanofi and Regeneron alleged infringement of the patent by the Amgen group. In response, Amgen filed a counterclaim for revocation on the basis that the patent was invalid on grounds of added matter, lack of novelty, lack of an inventive step and lack of sufficiency.

The independent second medical use claim at issue relates to an anti-PCSK9 antibody for use in reducing serum lipoprotein(a) (Lp(a)) levels in particular patients (notably, this claim is in the EPC 2000 purpose-limited product format, so avoids complications arising from the interpretation of Swiss-type claim format), making it a claim to a further specific treatment for a known use, and is provided in abbreviated form below:

"A pharmaceutical composition comprising a PCSK9 inhibitor for use in reducing lipoprotein(a) (Lp(a)) levels in a patient... wherein the PCSK9 inhibitor is an antibody or antigen-binding fragment thereof that specifically binds PCSK9, wherein the patient is not on a therapeutic statin regimen at the time of administration of the composition."

## Validity

When considering the validity of the patent, the court confirmed that the use in reducing Lp(a) levels was deemed a medical use, and was novel over the known prior art use in lowering LDL-C levels. On the novelty of second medical use claims more generally, and in accordance with Article 54(5) EPC, the court confirmed:

"A substance or composition X for any "specific use" in a method for treatment of the human body can be patentable, provided the specific use is novel."

Overall, the court found the counterclaim for revocation was unfounded on all

grounds, based on the facts of the case.

Second medical use claims therefore appear to be in good standing with the UPC, at least in respect of their validity.

### Infringement

Crucially, the court had to decide on the infringement of this second medical use claim.

The alleged infringement concerns Amgen's marketing of evolumab (Repatha®). Evolumab is an anti-PCSK9 antibody, and so clearly fell within the scope of the product element of the claim.

The court, in acknowledging the purposelimitation of the product claim, noted that "...to find infringement of a purpose-limited product claim, the claimants must therefore prove that the allegedly infringing product **fulfils the "use" feature(s) of the claim**." ([181] of the decision, emphasis added).

Considering the balance between granting a fair scope of protection for the patentee, and providing legal certainty for third parties, the court arrived at a framework to establish infringement. The court stated that protection being reserved for instances where the product was actually currently being used for the protected use would be too restrictive, and would not provide a fair scope of protection for the patentee.

"It is the opinion of the court that, for a finding of infringement of a second medical use claim, the alleged infringer must offer or place the medical product on the market in such way that it **leads or may lead** to the claimed therapeutic use of which the alleged infringer **knows or reasonably should have known that it does**. In other words, as **an objective element**, there must be either a prescription in order to lower Lp(a) levels, or there must be at least circumstances showing that such a use may be expected to occur. In addition, as **a subjective element** the infringer must know this or reasonably should have known." ([182] of the decision, emphasis added).

This approach appears to be in line with recent case law from Germany. Earlier

## Related articles

Warner-Lambert Appeal: Swiss form claims & skinny labels, 26 November 2018: dycip.com/warner-lambert-swiss-skinny

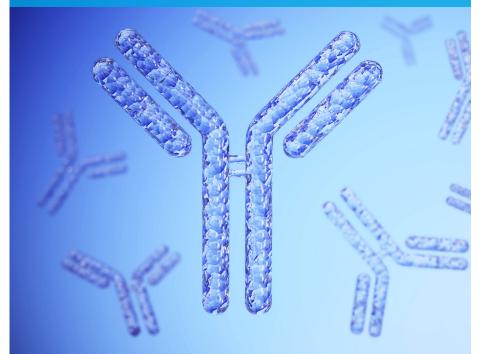
# Scase details at a glance

Decision level: Düsseldorf Local Division Case: UPC\_CFI\_505/2024 Parties: Sanofi Biotechnology SAS & Regeneron Pharmaceuticals Inc v Amgen Inc & Ors Date: 13 May 2025 Decision: dycip.com/ord-598583-2023

## OUP & UPC resources

As we mark the second anniversary of the launch of the unitary patent and Unified Patent Court, our regularly updated ibrary of UP & UPC commentary, guides and webinars can be accessed at www.dyoung.com/upandupc.

This decision concerns the UPC's approach to infringement of second medical use claims



German decisions only focused on an objective test as to whether the product was "manifestly arranged" for being used in an infringing manner (for example, Ribavarin, 2004, Düsseldorf District Court, [4a O 12/13]). Recent cases have expanded the scope of infringement to consider liability if patented use of a product occurred to a sufficient extent with the manufacturer's knowledge (or negligent ignorance) of such use (for example, Östrogenblocker, 2019, Düsseldorf Appeal Court [I-2 U 27/18]).

The court was careful to note that determining such infringement will require a full analysis of the relevant facts of an individual case. It exemplified the following considerations ([183] of the decision):

- The extent or significance of the allegedly infringing use,
- The relevant market including what is customary on that market,
- The market share of the claimed use compared to other uses,

 What actions the alleged infringer has taken to influence the respective market: either "positively", *de facto* encouraging the patented use; or "negatively" by taking measures to prevent the product from being used for patented use.

The court appeared to highlight, in particular, the practice of "skinny labelling", noting that the package insert and SmPC of a pharmaceutical product "can be important", but "are not always the only decisive factor".

In the case at hand, the court considered that Sanofi and Regeneron had not done enough to dispel doubts that Amgen's placing of Repatha® on the market necessarily leads to the claimed use. In particular, the following facts appeared to be key in this case:

1. the SmPC of Repatha® mentioned lowering Lp(a) levels in the "pharmacodynamic properties" section as opposed to the "therapeutic indications" section;

- 2. Sanofi and Regeneron had not provided evidence that prescriptions of Repatha® for the claimed use had been made or were likely to be made; and
- 3. expert evidence supported that physicians would not prescribe Repatha® specifically to lower Lp(a) levels.

Interestingly, the court noted that "In the context of infringement of a second medical use claim it is irrelevant that reducing LDL-C may have the windfall effect to reduce an elevated Lp(a) value." ([191] of the decision). The court was not convinced by the evidence as to the likelihood of physicians taking the lowering of Lp(a) into account when prescribing.

Ultimately, the court found no infringement by Amgen in this case, and dismissed the infringement action further to the dismissal of Amgen's counterclaim for revocation.

# Implications for bioscience patents and second medical use claims at the UPC

At this point, only a first instance decision has been taken on this case. However, it seems highly likely that this case will proceed to the UPC Court of Appeal, as both sides can challenge the court's decisions. Concurrent EPO opposition proceedings that upheld the validity of the same patent have also been appealed.

This precedent-setting decision is likely to garner a fair amount of attention now and in the future. Given the UPC's growing importance for the enforcement of patent rights in Europe, it is interesting to consider how this decision and subsequent cases may not only set out the UPC's initial approach to infringement of second medical use claims, but also how it may influence European national courts' approaches.

If you are seeking any advice with respect to infringement at the UPC, please contact your usual D Young & Co representative for further information.

Author: Chris Weekes

# UPC / effective service

# Good service at the UPC Service of claims

n order to initiate a legal action within the Unified Patent Court (UPC), a statement of claim must be served on the defendant. Effective service is extremely important for many reasons: various deadlines in the UPC are calculated from the date of service. For example, during an infringement action the defendant is entitled to lodge a statement of defence, the deadline being three months from service of the statement of claim.

We provide here a short guide to help you navigate through any potential pitfalls regarding service of claims. If you have any questions or are considering initiating a legal action within the UPC, please contact your usual D Young & Co representative for further information.

# **Overview of Requirements**

The requirements for service are detailed in Rules 270 to 279 of the Rules of Procedure of the Unified Patent Court (RoP).

The rules pertaining to service are written such that for (1) service in a contracting member state of the law of the European Union (EU) and, (2) service outside of the European Union, service should be attempted by specific modes in the first instance, with back-up modes of service available.

The rules of service form a hierarchical series of modes of service that, according to the majority of available case law, must be attempted in their given order. Where none of these modes of service are possible, the rules of service provide for further alternative modes of service as an ultimate back up.

Service in a contracting member state of the law of the EU Where the defendant is in a contracting member state, the means of service



should be attempted in the order below, in accordance with Rules 270-272:

- 1. Service by electronic means to the electronic address of the defendant or defendant's representative.
- 2. Where service by electronic means cannot be effected, any other method foreseen by the law of the EU [Regulation (EU) 2020/1784], such as by registered letter, may be used.
- Where service cannot be effected by a method foreseen by EU law, service may be effected by any method permitted by the law of the member state of the EU where service is to be effected or authorised.

For service to a company or legal person, service must be provided to its statutory seat, central administration or principal place of business within the contracting member states, or at any place within the contracting member states where the company or legal person has a permanent or temporary place of business. For service to an individual, service must be provided to the individual's usual or last known residence within the contracting member states.

Furthermore, written pleadings shall be served **by the Registry** on the other party by methods indicated in the rules. For service to be deemed effective, written pleadings must be served by the Registry, as was found in Alexion v Amgen (UPC\_CoA\_405/2024; ORD\_44709/2024). Here, it was held that prior communications between the parties themselves via another electronic system like the German special electronic lawyer's mailbox (besonderes elektronisches Anwaltspostfach, beA) cannot be considered as effective service under Rule 278.1 RoP.

# Service outside the

contracting member states Where the defendant is not in a contracting member state, the means of service should be attempted according to the below, in accordance with Rules 273-274:  Case details at a glance Decision level: Court of Appeal, Luxembourg Case: UPC\_CoA\_405/2024 (ORD\_44709/2024) Parties: Alexion v Amgen Date: 08 August 2024 Decision: dycip.com/upc-coa-405-2024

Decision level: Court of Appeal, Luxembourg Case: UPC\_CoA\_205/2024 (ORD\_34253/2024) Parties: Nera v Xiaomi Date: 06 August 2024 Decision: dycip.com/upc-coa-205-2024

- 1. Service in accordance with EU law [Regulation (EU) 2020/1784] where applicable, or service in accordance with the Hague Service Convention or any other applicable convention where it applies.
- 2. Where no such convention or agreement is in force, service through diplomatic or consular channels.
- 3. Lastly, service may be permitted via alternative means (see below).

It should be noted that where a statement of claim is to be served on multiple parties, extra care should be taken to serve via the appropriate route.

In Nera Innovations v Xiaomi (UPC\_CoA\_205/2024) it was confirmed that a defendant company in China cannot, as a starting point, be served a statement of claim via a related company within the same group located within a contracting member state. The Chinese Xiaomi companies had registered offices outside the territory of the contracting member states and did not have their statutory office, central administration or principal place of business or their own permanent or temporary establishment in a contracting member state.

Furthermore, care should be taken when serving in China or Hong Kong, as detailed in NEC v TCL (UPC\_CoA\_69/2024 & UPC\_CoA\_70/2024). Although the Hague Convention applies, China is opposed to the possibility of postal service, requires a translation in Chinese of all documents to be served, and only allows service by electronic means, such as via email, with the consent of the recipient. It was also held that service cannot be made by public service in the form of a written notice to be displayed in the publicly accessible premises of a UPC Local Division.

Therefore, attempts to serve in China should be by a method provided for in the Hague Service Convention and taking into account national requirements.

Service by an alternative method Where service in accordance with the above cannot be effected, a backup option is provided with Rule 275.1 RoP, which stipulates that where there is a good reason, the court may authorise service by a method or at a place not otherwise permitted.

It has been confirmed in the recent case law that said alternative means of service may only be permitted following an earlier attempt at service in accordance with Rules 270-274 RoP.

In NEC v TCL (UPC\_CoA\_69/2024 & UPC\_CoA\_70/2024) the Mannheim Local Division held that Rule 275.2 is an exceptional provision that can only be relied upon if service has first been attempted in accordance with Rules 270-274 RoP, following which alternative means of service are attempted in accordance with Rule 275.1 RoP.

Where alternative means fail under Rule 275.1 RoP, Rule 275.2 RoP may then be applied.

In some circumstances, as in air up group v Guangzhou Aiyun Yanwu Technology (UPC CFI 508/2023 & UPC CFI 509/2023), previous failed attempts at service may be deemed good service. In this case, service in accordance with the Hague Service Convention could not be effected. Service documents were posted to the competent authority in China, but after a number of attempts to chase the status of service, the Chinese authority provided no information. The court found that service under Rule 274 RoP must be regarded as impossible, and thus an alternative attempt of service under Rule 275.1 RoP must be made where factually and legally possible.

The applicant and court had unsuccessfully attempted alternative means of service through both formal and informal channels. There was no other known method or location of service.

Thus, it was held that, given the attempted service by the standard means of the Hague Service Convention **and** service by alternative means was not possible, Rule 275.2 RoP allows for the court to order that said steps taken to bring the statement of claim to the attention of the Decision level: Court of Appeal, Luxembourg Cases: UPC\_CoA\_69/2024 & UPC\_CoA\_70/2024 Parties: NEC v TCL Date: 29 July 2024 Decisions: dycip.com/upc-coa-69-2024 & dycip.com/upc-coa-70-2024

Decision level: Munich Local Division Cases: UPC\_CFI\_508/2023 (ORD\_68822/2024) & UPC\_CFI\_509/2023 (ORD\_68821/2024) Parties: air up group v Guangzhou Aiyun Yanwu Technology Date: 21 January 2025 Decisions: dycip.com/ord-68822-2024 & dycip.com/ord-68821-2024

defendant may be deemed good service.

# Why establishing effective service can be crucial

Air up group v Guangzhou Aiyun Yanwu Technology (UPC\_CFI\_508/2023, UPC\_CFI\_509/2023) demonstrates the importance in establishing effective service.

As discussed, because the correct channels had been followed (that is, attempted via the Hague Service Convention and subsequently attempted by alternative means), service was deemed effective.

Consequently, it was held that service of the decision by default should also be deemed effective. In particular, where it has not been possible to serve the application for a provisional measure in accordance with Rule 274 and there is no indication that the decision by default issued subsequently can also be served in accordance with Rule 274, it is not necessary to undergo a new service attempt under Rule 274 for serving the decision by default.

With no alternative means of service existing, the publication of the decision by default on the court's website also constituted good service pursuant to Rule 275.2 RoP.

Thus, despite a lack of reply from the defendant, service was deemed effective and a decision by default issued.

Evidently, despite the importance of establishing an effective date of service, service of a statement of claim can be a complex procedure.

Author: Ben Wood

# UPC / EPO

# Differing decisions from the UPC and EPO Sanofi v Amgen

ollowing the Munich Central Division's decision in the first-filed case of the Unified Patent Court (UPC) between Sanofi-Aventis v Amgen (UPC\_CFI\_1/2023), the Opposition Division has now issued its decision in the corresponding European Patent Office (EPO) opposition proceedings in which Sanofi is one of the opponents.

Interestingly, whilst the Munich Central Division revoked EP 3666797B across the UPC member states in which it was in force for lack of inventive step, the EPO Opposition Division rejected the opposition.

## Background and technology

Sanofi's patent EP 3666797B granted with claim 1 directed to a monoclonal antibody or an antigen-binding fragment thereof for use in:

- treating or preventing hypercholesterolemia or an atherosclerotic disease related to elevated serum cholesterol levels, or
- reducing the risk of a recurrent cardiovascular event related to elevated serum cholesterol levels.

The monoclonal antibody or antigenbinding fragment thereof was functionally defined as binding to the catalytic domain of a PCSK9 protein of the amino acid sequence of SEQ ID NO:1, and preventing or reducing the binding of PCSK9 to low density lipoprotein receptor (LDLR).

The patent explains that PCSK9 is involved in regulating the levels of the LDLR, which is in turn important in the removal of low density lipoprotein cholesterol from the bloodstream into liver cells. Thus, the claimed antibodies have a cholesterol-lowering effect.

### Inventive step assessment

The Central Division did not strictly follow the EPO's problem-solution approach in the assessment of inventive step and instead referred to the approach used in NanoString Technologies Inc v 10x Genomics Inc (UPC\_CoA\_335/2023). Although the approach applied by the Central Division possesses some similarities with the EPO's problem-solution approach applied by the Opposition Division, there are also some key differences, particularly in the selection of the "realistic starting point" as opposed to "closest prior art" and formulation of the "underlying" technical problem rather than the "objective" technical problem. We consider these differences in more detail in our article on inventive step at the UPC (Inventive Step at the UPC: Two years on, see page 02 of this newsletter).

Despite these differences, both divisions considered Lagace (cited as C3 in the UPC proceedings and D5 in the EPO proceedings) as the starting point for the assessment of inventive step. This research article described the role of secreted PCSK9 in regulating LDLR protein levels in heptaocytes.

In fact, the divisions focused upon the same paragraph of Lagace: "If PCSK9 functions as a secreted factor as suggested by the current data, then additional approaches to neutralize its activity, including the development of antibodies to block its interaction with the LDLR or inhibitors to block its action in plasma, can be explored for the treatment of hypercholesterolemia."

From this teaching it was held that the skilled person would have an **incentive** [Central Division] or **motivation** [Opposition Division] to pursue antibodies blocking the interaction, and **only routine experimentation** would be required to develop the antibodies. Therefore, both decisions were in line with established EPO jurisprudence on antibodies, where generating an antibody to a known target is considered routine work for the skilled person.

Similarly, both divisions considered that a difference with the claimed invention was that Lagace did not disclose any antibodies blocking the interaction between PCSK9 and LDLR for use in the treatment of hypercholesterolemia.

This brings us to the question of reasonable expectation of success.

# Diverging approaches to reasonable expectation of success

Amgen provided extensive arguments in both sets of proceedings as to why the skilled person would lack a reasonable expectation of success.

The Central Division opened its discussion of reasonable expectation of success with the following comment: "The Central Division can leave undecided the question of whether or not under the circumstances of the present case, where there is an incentive in the prior art towards the claimed subject matter and the next steps would not amount to more than routine experimentation for the skilled person, a reasonable expectation of success is required to come to the conclusion that the claimed subject matter lacks inventive step".

This comment could be considered surprising in the context of a second medical use claim, in which a claimed therapeutic effect is considered a functional technical feature of the claim under established EPO practice.

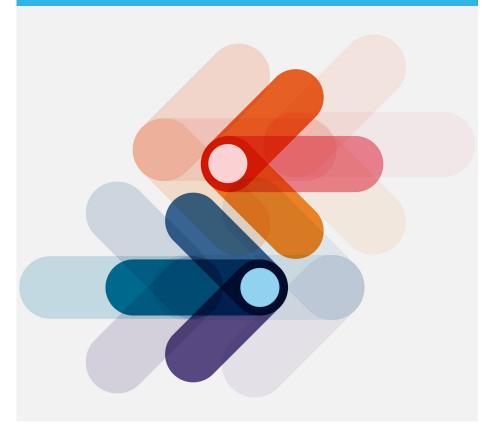
Indeed, the EPO's Opposition Division stated in its decision that it "**strongly disagrees**" with the UPC court on the point quoted above. The Opposition Division went on to comment that: "While the reasoning provided by the UPC Court might be applicable for a product claim, the **OD considers that in the case of a medical use claim, reasonable expectation of success plays a crucial role**."

Despite the initial comment provided by the Central Division that the requirement for a reasonable expectation of success could be left undecided, the Division goes on to provide its reasoning as to why the arguments presented by Amgen "must fail". In particular, the Central Division held that Amgen did not demonstrate that the skilled person would have had any "serious doubts" that a therapeutic antibody could be developed. Serious doubts were defined as: "doubts of such a nature that these would have dissuaded the skilled person from pursuing an antibody approach to block the Related articles Inventive Step at the UPC: Two years on, June 2025: page 02 of this newsletter

Lack of inventive step from a "realistic" starting point: Sanofi v Amgen, 05 August 2024: dycip.com/sanofi-amgen-aug24

Case details at a glance Decision level: Munich Central Division Case: UPC\_CFI\_1/2023 Parties: Sanofi-Aventis Deutschland GmbH et al v Amgen Inc Date: 16 July 2024 Decision: dycip.com/sanofi-amgen-jul24

Will the EPO Opposition Division be swayed by a parallel UPC Court of First Instance ruling?



interaction...as suggested by Lagace".

Accordingly, the Central Division considered that the skilled person would possess a reasonable expectation of success, such that the claimed subject matter lacked an inventive step.

By contrast, the Opposition Division held that: "While D5 [Lagace] provides a suggestion to use antibodies that block the interaction of PCSK9 to LDLR in the treatment of hypercholesterolemia, it does not provide the skilled person with a reasonable expectation of success that using said antibodies would be indeed therapeutically effective".

Furthermore, Amgen presented an additional argument for lack of reasonable expectation of success in the EPO proceedings, based upon figure 6d of the prior art document Qian (cited as D24 and in the UPC proceedings as C6). Amgen argued that this figure shows a trend that (at physiologically relevant levels, 500 ng/ml) PCSK9 does not have an effect on cell surface LDLR levels. Based upon this evidence, the Opposition Division held that the skilled person would not have reasonably expected that an anti-PCSK9 antibody that prevents or reduces the binding of PCSK9 to LDLR could have a therapeutic effect.

Accordingly, the Opposition Division considered that the skilled person would lack a reasonable expectation of success based upon Lagace alone or Lagace in combination with Qian, such that the claimed-subject matter possessed an inventive step.

## **Final comments**

These proceedings provide an indication that the EPO's Opposition Division will not necessarily be swayed by a parallel UPC ruling by a Court of First Instance, although it remains to be seen whether the Opposition Division would diverge, and so openly, from a UPC Court of Appeal decision.

In its approach to reasonable expectation of success, the Central Division appeared to diverge from the established EPO practice in the context of second medical use claims. In particular, the Central Division appeared to set a lower bar for reasonable expectation of success for second medical use claims and placed the onus on the patentee to prove that a skilled person would not have expected the suggested antibody approach to succeed. This might be contrasted with established EPO practice for second medical use claims, in which a reasonable expectation of success plays a crucial role and the patentee must show that it was not obvious to try the suggested approach with a reasonable expectation of success.

Thus, these proceedings evidence that even small changes in the assessment of issues such as inventive step could result in significant divergence between the case law at the EPO and UPC.

Both of these decisions have been appealed, with the UPC Court of Appeal ruling expected to issue first this summer and oral proceedings before the EPO Board of Appeal already scheduled for April 2026. It will be interesting to see whether, and how, the Court of Appeal and Boards of Appeal address the diverging approaches to reasonable expectation of success in the context of second medical use claims in their respective decisions.

Any clarity on the assessment of inventive step for second medical use claims provided by the UPC Court of Appeal would be welcomed by users of the UPC system. We will be keeping a close eye, in particular, on any indications from the UPC Court of Appeal that the standard for assessing reasonable expectation of success in the context of second medical use claims will be lower in the UPC courts than under established EPO practice.

Author: Rebecca Price

# **UP & UPC / statistics**

# UP & UPC statistics and trends A two-year check in

n the two years since the UPC opened, patentees have also been able to protect their inventions across Europe through obtaining unitary patents (UPs), which increased in territorial scope from 01 September 2024 when Romania became the 18th member state of the UPC. This article takes a look at how various trends are developing as we pass the two-year mark.

### **UPC Court of First Instance**

On 05 June 2025, the UPC published an update on the case load of the courts, covering 01 June 2023 to 31 May 2025. As of 31 May 2025, 883 cases have been filed before the Courts of First Instance. This includes 320 infringement actions and 369 revocation actions. Of these 883 cases, the breakdown across the First Instance Courts is as shown in figure 1 below.

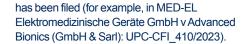
### Infringement

In respect of infringement actions, the German Local Divisions still lead the way, with 244 actions (over 75% of the total number) being filed across the Munich, Düsseldorf, Manheim and Hamburg Local Divisions; the four most popular first instance courts. The Paris, Hague, and Milan Local Divisions are also fairly frequently used for filing infringement actions, but the Nordic-Baltic regional division (which appeared popular during the initial months of the UPC) has only seen a single infringement action lodged during the past 12 months. Only three infringement actions have been initiated before a Central Division court (two in Paris and one in Milan), while the Munich Central Division and Ljubljana Local Division have yet to hear any infringement cases.

## Revocation

Over the past two years, 65 standalone revocation actions have now been filed, with the 47 lodged at the Paris Central Division representing the lion's share. This is dwarfed however by the 304 counterclaims for revocation which have been lodged by defendants across 174 infringement cases (many of which have multiple defendants bringing their own separate counterclaims).

The number of bifurcated proceedings at the UPC has been relatively low so far, with the UPC by default being a non-bifurcated system. Local and Regional Divisions have seemed more willing to bifurcate when a standalone revocation action is already pending before a Central Civision for the same patent in respect of which a revocation counterclaim



# **Other applications**

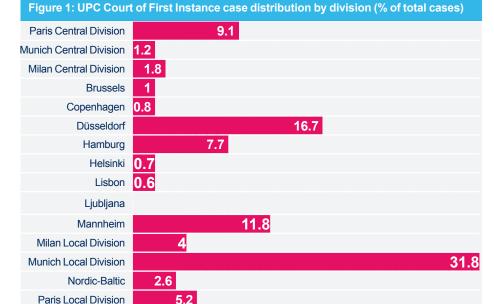
The UPC First Instance Courts have seen a number of other applications over their first 24 months; 66 for provisional measures, 18 for preserving evidence, three for orders for inspection and one each for an order to freeze assets and a request for damages. There have also been 4 applications filed for a declaration of non-infringement, and 97 applications for a decision on costs.

### **UPC Court of Appeal**

As we cross the threshold into the UPC's third year, enough time has passed for a number of early-filed cases to have been heard by the Court of Appeal in Luxembourg. In total, there have been 279 appeals, requests, and applications now filed at the Court of Appeal. This includes 70 appeals against decisions issued by the first instance courts, and 42 appeals against orders issued by those courts. There have also been 85 appeals filed in respect of preliminary orders, and 6 against issued cost decisions. In addition to this, there have been applications filed for suspensive effect and orders for expedition of appeal (27 each), 18 requests for discretionary review, and four applications for rehearing under RoP 245.

## UP requests and uptake rate

As of 02 June 2025, 57,500 UPs have been registered, with another 627 requests pending, 77 requests rejected, 53 requests withdrawn, and 326 registered UPs now lapsed. With the number being 28,326 on 01 June 2025, the number of UP requests filed in the second 12 months of the UP and UPC is almost exactly the same as the number filed in the first 12 months. In 2024, the uptake rate of UPs (the number of granted European patents for which unitary effect was requested) was 25.6%, a significant increase on 2023's 17.5%. During 2025 to date, the uptake rate is up to 27.7%, demonstrating that the popularity of the UP is still growing. This may be partly due to the increasing strength of the UP, with UPs having covered Romania since 01 September 2024. With the UPC and UP systems now having been in existence for just over two years,



The Hague

Vienna 0.5

4.5



Webinar invitation UPC case law, observations & analysis 1pm, 18 June 2025 dycip.com/webinar-upc-jun2025

Figure 2: procedural (left) and translation (right) language Italian 3.826 French English 14,566 2,955 Dutch English 1,315 42,974 German Spanish German 11,290 17,771 12,453

patent proprietors may also now have more familiarity and confidence in the system.

The global uptake rate is 22.5% as of 02 June 2025. However, for patent proprietors based in EPC states, this rises to 32.3%, and for those based only in EU states, up to 32.9%. While patentees from around the world are utilising the unitary patent system, it is still European patentees with the highest uptake rate.

The relative share of UPs obtained by technical field remains fairly well distributed, with no technology fields seeing their share fall or rise particularly sharply.

## Language choices

Upon filing a request for unitary effect to obtain a UP, a full translation of the patent specification in one of the languages of the European Union must be filed. A little over a quarter of these translated specifications (where the procedural language of the patent is French or German) must be English. However, for all patents where the procedural language of the patent is English, it is up to the applicant to choose the language of translation.

The most popular choice of translation language for UP requests remains Spanish. In fact, its popularity has increased from 40.7% of all UP requests for patents where the procedural language of the patent is English 12 months ago to 41.4% now. This therefore represents 30.9% of all requests for unitary effect being accompanied by a filing of a translation of the patent into Spanish. This demonstrates that Spanish is becoming established as the primary UP translation language of choice for UP holders. Since obtaining patent protection in Spain also requires a full translation of the specification into Spanish, patentees are therefore able to make use of this same translation to obtain a UP and a Spanish national patent.

At the UPC, English is still the predominant language at the Court of First Instance despite the fact that the German divisions are favoured by applicants. Indeed, the share of proceedings in which English is used as the language of proceedings has now increased to 55%, with German dropping

to 38%, French at 3%, Italian at roughly 2% and Danish and Dutch both at around 1%.

UP requests by country of applicant Figure 3 below shows the number of UP requests across patentees from nine different countries; three which are members of the UPC and EU (Germany, France, and the Netherlands), one of which is a contracting state only of the UPC (Switzerland), one of which is an EPC contracting state but not a UPC or EU member state (the UK), and four-non European countries; the USA, Japan, China, and South Korea. As can be seen, the European-based countries (and specifically those which are UPC contracting states) have a higher uptake than the non-European countries. However, interestingly, it appears that there has been some catching up over the past 12 months in terms of the outright numbers of UPs being requested by non-European based patentees particularly.

USA

China

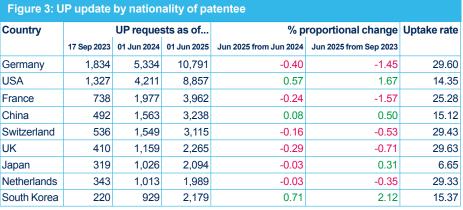
UK

Japan

The columns showing the proportional change with the numbers in red and green indicate the changes in the share of UPs requested among these nine countries. So, for example, while South Korean patent proprietors were responsible only for 3.54% of UPs obtained up to 17 September 2023 (220 of a total 6,219 among the nine countries listed), this grew to 4.95% by 01 June 2024, and further to 5.66% of all UPs across the nine listed countries by 01 June 2025.

This means that, though the uptake rate is still lower (particularly in Japan, which is becoming an outlier), non-European based patentees are beginning to grow their share of total UPs owned, demonstrating perhaps that knowledge of and confidence in the UP and UPC systems is now increasing around the world.

Author: **David Al-Khalili** 





# **UPC / document access**

# Accessing written pleadings and evidence at the UPC Rule 262.1(b) of the UPC Rules of Procedure

OUP & UPC resources

As we mark the second anniversary of the launch of the unitary patent and Unified Patent Court, our regularly updated library of UP & UPC commentary, guides and webinars can be accessed at www.dyoung.com/upandupc.

he Court of Appeal has provided useful clarity to guide prospective applicants under Rule 262.1(b) of the UPC Rules of Procedure (RoP), in respect of both the scope of documents which can legitimately be expected to be granted, and the likely conditions to be placed on use of any documents accessed.

In Ocado v Autostore (ORD 19369/2024), the Unified Patent Court (UPC) Court of Appeal established key factors in deciding requests for access to written pleadings and evidence pursuant to Rule 262.1(b) RoP. Significantly, where a "specific interest" in the subject matter of proceedings exists (such as where the requestor is a competitor or licensee concerned with the validity of the patent at issue) the Court of Appeal decided this typically outweighs a more general interest in protecting the integrity of proceedings. The court concluded that in such cases, the balance of interests should generally fall in favour of granting access to written pleadings and evidence prior to the relevant UPC proceedings being concluded.

D Young & Co has represented a client in lodging a series of requests under Rule 262.1(b) RoP in respect of UPC revocation actions (ACT\_571801/2023, ACT\_571761/2023, ACT\_571730/2023, and ACT 571795/2023) concerning European patents for which the client is a party to pending European Patent Office (EPO) opposition proceedings. The respective orders (ORD\_37687/2024, ORD\_38115/2024, ORD\_38946/2024, and ORD\_38127/2024), issued by the Paris Central Division of the UPC, each granted the applicant access. In doing so, it expressly followed the reasoning of Ocado v Autostore in acknowledging that the applicant's involvement in parallel proceedings before the EPO led to a "vested and immediate interest in accessing to pleadings and evidence lodged in the current proceedings". However, in the wake of Ocado v Autostore, some aspects of implementation of Rule 262.1(b) RoP remained ambiguous. For example, whilst a request must indicate the documents for which access is sought, it was not entirely clear the extent to which this indication might extend to documents not yet filed, but which

could be expected to be filed in the future. Notably, each of the orders (ORD\_37687/2024, ORD\_38115/2024, ORD\_38946/2024, and ORD\_38127/2024) granted access to written pleadings and evidence lodged after the date of the request, expressly including documents lodged up the date of the order itself.

Furthermore, while Ocado v Autostore allowed that UPC courts may "...impose certain conditions on granting access, such as the obligation for that member of the public to keep the written pleadings and evidence he [sic] was given access to confidential as long as the proceedings have not come to an end", the factors for deciding whether to apply such conditions were not further explained. Notably, the Paris Central Division placed no conditions on use of the accessed documents in any of its orders in the abovementioned applications under Rule 262.1(b) RoP.

A recent series of orders (ORD\_17094/2025, ORD\_20981/2025, ORD\_13786/2025, and ORD\_13796/2025) issued by the UPC Court of Appeal in Luxembourg has now brought further clarity to UPC practice surrounding access to documents requested under Rule 262.1(b) RoP.

We recently represented the same client in lodging a further series of requests under Rule 262.1(b) RoP, this time before the UPC Court of Appeal. The appeal proceedings relate to revocation proceedings (ACT 571801/2023, ACT\_571761/2023, ACT\_571730/2023, and ACT\_571795/2023) in which the earlier requests had been lodged at first instance. In each instance, the applicant is party to a parallel EPO opposition appeal, providing the necessary specific interest to support a request for immediate access to written pleadings at the UPC. The orders (ORD 17094/2025, ORD 20981/2025, ORD 13786/2025, and ORD 13796/2025 of the UPC Court of Appeal granted each request in part, and so clarified two significant aspects of UPC practice surrounding Rule 262.1(b) RoP (noting the reasoning is virtually identical across the orders).

First, the Court of Appeal clarified the scope of documents which can be successfully

requested. This includes written pleadings and evidence in the UPC case management system (CMS) at the time of lodging of a given request, and may extend to written pleadings or evidence that were "not yet in the casefile at the time when the request for access was made, but were added to the casefile before a party commented on the request". Of note is that access to such documents will only be granted if an express request to this effect is made. The reasoning expressly weighs a desire to avoid applicants having to make repeated requests for documents as proceedings progress, against the interest of parties in being able to comment specifically on any documents to which access might be granted. Thus, in practice, a new request under Rule 262.1(b) RoP will be required to obtain access to any written pleadings and evidence lodged after the date(s) on which parties file their comments on a preceding request.

Second, in each order, the Court of Appeal placed an express bar on verbatim refiling of accessed written pleadings or parts thereof with "other courts or judicial instances such as the EPO Boards of Appeal", or distribution of them elsewhere, until the conclusion of the relevant UPC proceedings. However, this bar does not exclude the applicant "informing itself of the arguments brought forward in the case before the Court of Appeal, including prior art, and if it chooses to, use the same arguments or prior art before the Boards of Appeal or elsewhere to support its own cases, or inform the Boards of Appeal that the arguments or prior art have been brought forward in the UPC proceedings".

We note when the first instance court granted access to documents it did not apply such a prohibition on refiling written pleadings in other forums. However, the bar is not particularly limiting in practice, given the possibility of reframing arguments from written pleadings before the UPC, if it is of interest to put these of file elsewhere (for example, before the EPO). Notably, the bar does not prohibit the filing elsewhere of any prior art documents accessed via a Rule 262.1(b) request.

## Author: Samuel Keyes

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# UPC Case Law, Observations & Analysis 1pm BST, Wednesday 18 June 2025

Our ongoing series of webinars, dedicated to analysing the Unified Patent Court's decisions, continues with expert speakers, UPC representatives Anthony Albutt, Rachel Bateman, Jonathan DeVile and Tom Pagdin, provide you with the most up to date UPC observations and analysis. Registration is now open: dycip.com/webinar-upc-jun2025 European Biotech Patent Case Law 9am, noon & 5pm BST, Tuesday 08 July 2025

Join European Patent Attorneys Matthew Caines and Nathaniel Wand to catch up with new and important EPO biotechnology-related patent case law. The webinar will run at 9am, 12pm and 5pm (UK time) on Tuesday 05 November 2024. Early booking is advised to secure your webinar seat: dycip.com/webinar-biotech-jul2025

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