# D YOUNG & CO PATENT NEWSLETTER no.104

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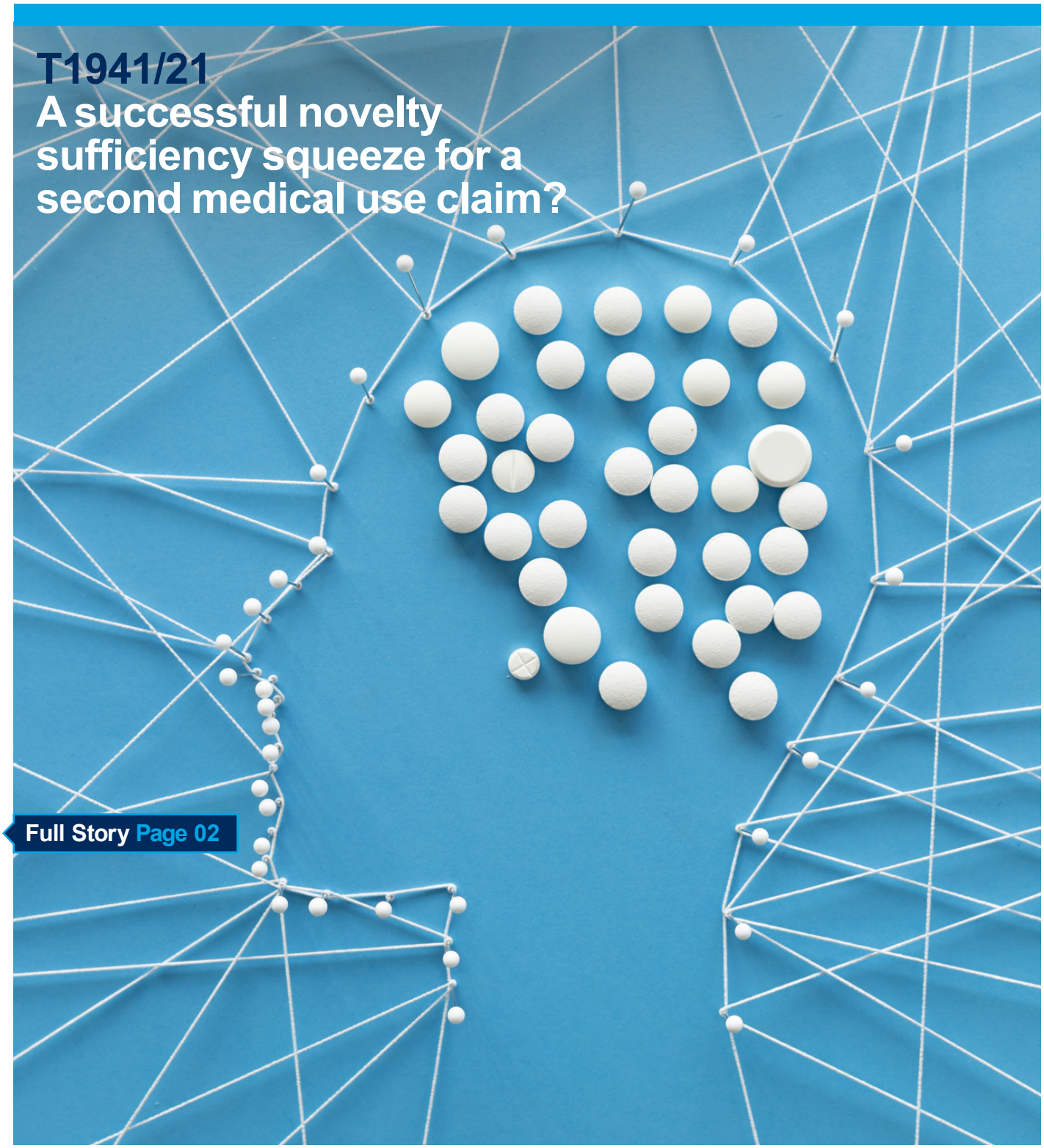
In this issue:





## T1941/21
## A successful novelty sufficiency squeeze for a second medical use claim?

Full Story Page 02

## Editorial

Welcome to the last newsletter of 2024. It has been an incredibly busy year for our clients and our patent teams. This year we are once again delighted to have been ranked as a top tier firm by Chambers & Partners UK for both patents and trade marks. This marks the 14th consecutive year of being ranked at this level. The UPC continues to develop and you will see number of updates on cases in this newsletter. Injunctions are proving to be of particular interest (see page 10). Finally, on behalf of everyone at D Young & Co, we wish all of our clients and overseas associates a warm and festive holiday season. See you in 2025.

**Anthony Albutt, Editor**

## Events & webinars

**European biotech patent case law**
**On demand webinar**
Simon O'Brien and Nathaniel Wand present our latest webinar update of new and important EPO biotechnology patent case law.

**Unified Patent Court case law, observations & analysis**
**On demand webinar**
Rachel Bateman, Samuel Keyes and Lawrence King present our latest UPC case law webinar.

**Patent Easter internship (electronics, engineering, physics, computer science)**
**Southampton, UK, 14 April 2025,**
Applications for our patent Easter internship are now open to physics, electronics, engineering and computer science undergraduate and postgraduate students.

**www.dyoung.com/events**

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*Second medical use claims*

# T1941/21
# A successful novelty sufficiency squeeze for a second medical use claim?

In recent decision T1941/21, the European Patent Office (EPO) Board of Appeal decided that a claim directed towards "substance A" for use in treating a disorder to lack novelty over a disclosure relating to "substance B + substance A" for use in treating the same disorder.

The prior art disclosure only provided data for the use of substance B alone, and the combination with substance A was an arbitrary selection from a list of around forty alternatives. The Board of Appeal nonetheless found the claim at issue to lack novelty, and may have been influenced by the accompanying data in the patent, which only showed the utility of substance A in a combination therapy. In view of this, it appears that the Board of Appeal applied a lenient standard for enablement when assessing the prior art.

> We discussed decision T1941/21 in our November 2024 European biotech patent case law webinar, which is now available on demand: dycip.com/biotech-patent-nov2024

### The patent at issue: sufficiency

Claim 1 of the main request was in the form of a second medical use claim directed to tauroursodeoxycholic acid (TUDCA) for use in the treatment of amyotrophic lateral sclerosis (ALS): "1. **Tauroursodeoxycholic acid** (TUDCA) or a pharmaceutically acceptable salt thereof for use **in the treatment of a neurodegenerative disorder** in a mammal, characterized in that said neurodegenerative disorder is **amyotrophic lateral sclerosis**."

Notably, the claim encompassed the use of TUDCA as a **monotherapy** to treat ALS. However, the data in the patent only showed efficacy in ALS patients for the **combination therapy** of TUDCA + riluzole + vitamin E.

At first instance, despite the absence of any data regarding the monotherapy, the Opposition Division decided that claim 1 was sufficiently disclosed, because the opponent had not provided any verifiable evidence that TUDCA would not have "at least to some extent" a therapeutic activity in the treatment of ALS.

On appeal, sufficiency of disclosure was not considered further by the Board of Appeal. It appears that this was due to the opponent's failure to maintain this ground in its reply to the appeal. However, although not explicitly mentioned, the Board of Appeal may nonetheless have considered it necessary to apply the same sufficiency standard to the prior art patent application, which was an important factor regarding novelty.

### The prior art patent application: novelty

A novelty objection was raised over D8, which was a patent application relating to compositions comprising low doses of diazoxide for use in the treatment of a mammal afflicted with ALS: "1. **Diazoxide** or a pharmaceutically acceptable salt thereof for use as a medicament at a daily dose of from 0.15 mg/m2/day to 13.00 mg/m2/day expressed as mg/m2/day of diazoxide free base **in the treatment of a mammal afflicted with amyotrophic lateral sclerosis (ALS)**."

D8 included an example showing that low doses of diazoxide improve survival in a mouse model for AML. The Board of Appeal further noted that the utility of diazoxide in treatment of ALS described in D8 had "not been disproved".

The decisive parts of D8 were claims 8 and 9, which disclosed the combined administration of diazoxide and one or more therapeutic agents useful in the treatment of ALS. Claim 9 of D8 disclosed TUDCA in a list of around forty therapeutic agents, allegedly "useful in the treatment of ALS": "9. Diazoxide or a pharmaceutically acceptable salt thereof for use according to claim 8, wherein the medicament comprises diazoxide and one or more additional therapeutic agents useful in the treatment of amyotrophic lateral sclerosis selected from CK-2017357, olesoxime (TRO19622), arimoclomol, riluzole, tretionin and pioglitazone HC1, AVP-923, memantine, talampanel, **tauroursodeoxycholic acid (TUDCA)**, thalidomide, olanzapine, KNS-760704,

*Case details at a glance*
*Jurisdiction: EPO*
*Decision Level: Board of Appeal*
*Parties: Bruschettini Srl v Ammelburg Moritz*
*Citation: T1941/21*
*Date: 05 June 2024*
*Decision: dycip.com/bruschettini-ammelburg*

*Useful links*
*EP3016654, European Patent Register: dycip.com/ep301665*

*EP2422787, European Patent Register: dycip.com/ep2422787*

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**The claim encompassed the use of TUDCA as a monotherapy to treat ALS**

lithium carbonate, NP001, ONO-2506PO, tamoxifen, creatine monohydrate, coenzyme Q10, YAM80, sodium phenylbutyrate, pyrimethamine, R(+)pramipexole dihydrochloride monohydrate, vitamin E, minocycline, topiramate, gabapentin, AEOL-10150, stem cell injections, SB-509, autologous bone marrow-derived stem cells, ceftriaxone, E0302 (mecobalamin), MCI-186, glatiramer acetate, insulin-like growth factor-1 (IGF-I), ISIS 333611, sNN0029, GSK1223249, brain-derived neurotrophic factor (BDNF) and anti-CD40L antibody."

Based on established case law that a single selection from a list cannot confer novelty, the Board of Appeal held that a composition comprising **diazoxide and TUDCA** for use in the treatment of a mammal afflicted with ALS was **derivable directly and unambiguously** from D8.

Importantly, the Board of Appeal went on to decide that this was also an enabling disclosure. It held that, even if D8 did not provide any in vitro or in vivo experiments with regard to the efficacy of TUDCA in the treatment of ALS, D8 however provided an enabling disclosure for a combination treatment based on diazoxide and TUDCA. Crucially, the Board of Appeal emphasised that the efficacy of diazoxide is supported by experimental data and "had not been disproven".

In accordance with established case law, the Board of Appeal held that the discovery of a new property of a particular ingredient of a known composition (TUDCA in the composition comprising diazoxide and TUDCA, used for a known and identical general purpose, that is, the treatment of a mammal afflicted with ALS) cannot confer novelty. Novelty can only be recognised if this new property is applied in a new use.

Therefore, claim 1 of the main request was found to lack novelty over D8.

## A successful novelty-sufficiency squeeze?

The Board of Appeal appeared to take a strict approach to novelty in this case. In view of the data in the patent, which related to a combination treatment with TUDCA + riluzole + vitamin E, it appears that the Board of Appeal erred on denying novelty in view of a different combination, which was disclosed in the prior art. In different circumstances (for example, if the patent had clearly enabled a monotherapy with TUDCA), it is possible the Board of Appeal would have come to a different conclusion.

For example, the selection of TUDCA from claim 9 of D8 appears to be an arbitrary selection from a very long list. A single selection from a list does not usually confer novelty. However, in the context of a medical use claim in which the successful treatment of the disease is a limiting feature of the claim, it appears arguable whether each and every one of the combinations disclosed could be considered to be an enabling disclosure.

In addition, second medical use claims are formulated based on the wording of Article 54(5) of the European Patent Convention (EPC), which distinguishes between the use of a "substance" or "composition". In D8 the claims only referred to TUDCA in the context of a composition, without any evidence that TUDCA was an active agent in the treatment of ALS. However, the claim at issue referred to a substance (that is, TUDCA or a pharmaceutically acceptable salt thereof), and therefore arguably includes the technical feature that this substance is an active agent in the treatment of ALS. Other boards may have considered this enough to render the claim novel.

In this case it was relatively straightforward for the patentee to render claim 1 novel over D8, such that this attack was not fatal. It appears that no inventive step objection was raised by the opponent starting from D8 and the Board of Appeal did not consider this. It is not clear how the Board of Appeal would have dealt with an inventive step attack starting from the same disclosure.

This case is a reminder that even when considering individual grounds of opposition, a Board of Appeal may nevertheless take into account other grounds. In this case, although sufficiency was not at issue the Board of Appeal appears to have taken this into account, and applied a lenient standard for enablement when assessing the prior art. It appears that this may therefore be considered an example of a successful novelty-sufficiency squeeze in the context of a second medical use claim.

**Author:**
**Nathaniel Wand**

# News from D Young & Co
## Net zero pledge and top tier in Chambers UK

www.dyoung.com/news

We have been working to reduce our our carbon emissions through a number of targeted initiatives, including moving our London office to a building with a BREEAM certification of "excellent". We are therefore delighted to report that we have made a commitment to the CITMA net zero pledge to demonstrate our commitment to making the IP profession more sustainable and environmentally conscious. By making this pledge we commit to taking action to do our part to reduce our contribution to emissions with a number of measures. You can read more about the pledge and our participation on our website: dycip.com/citma-net-zero-pledge

We are also pleased to announce that Chambers UK has ranked D Young & Co as a top tier UK patent and trade mark firm for the 14th consecutive year. We are also very pleased to report that partner Rachel Bateman features as one of only 19 UK individuals featured as 'notable practitioners' in the 2025 guide. We are grateful to our colleagues and clients for their positive feedback to the Chambers' research team: dycip.com/chambers-uk-2025





# UPC caseload insights and trends
## November 2024

The Unified Patent Court (UPC) continues to publish its monthly case load analysis and it is clear that the court remains busy and continues to grow at a determined rate. This article provides insight on filing data and statistics from the UPC up to 30 November 2024.

### Court of First Instance: Munich tops billing

A total of 585 cases have been filed before the UPC First Instance Courts, with 219 infringement actions and a combined 293 revocation actions (including both direct revocation actions and counterclaims for revocation brought during infringement proceedings by separate defendants).

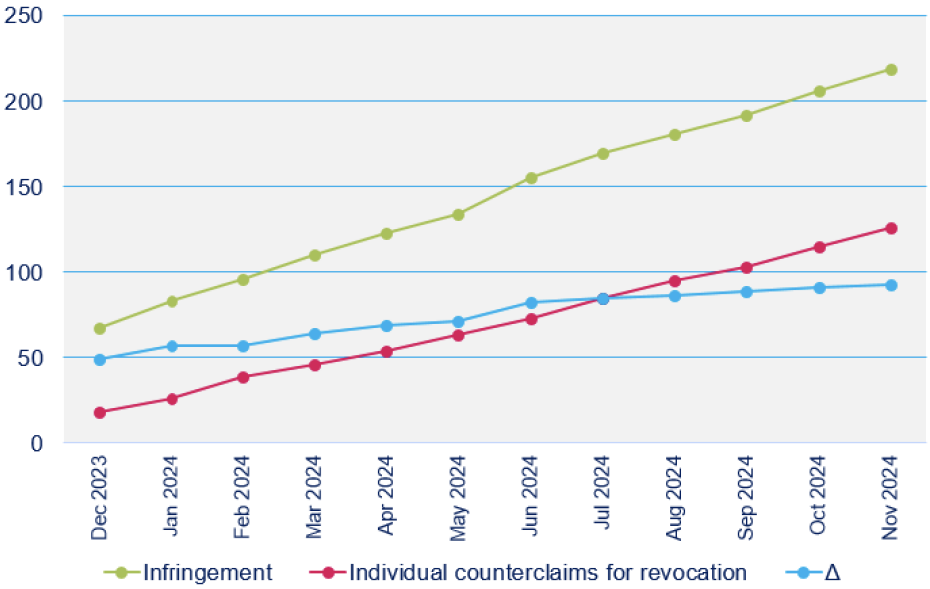
The German courts remain the predominant jurisdiction for cases, with 71% of the total UPC First Instance case load (419). The Munich Local Division continues to stand above the rest with 36% of the total case load (207), although the Düsseldorf Local Division also appears to be popular with litigants, increasing its lead over the Mannheim Local Division and growing at a month-on-month rate of 13% so far in 2024.

The Central Divisions paint a different picture, however, with the Munich Central Division having the smallest case load (6), after the first cases were initiated in October before the Milan Central Division (9). However, the Paris Central Division continues to lead by a significant margin, with 49 cases. This is perhaps not surprising, given the Paris seat of the Central Division hears all cases involving patents in IPC classes B (performing operations, transporting), D (textiles, paper), E (fixed constructions), G (physics) and H (electricity), while the Munich seat hears cases in IPC classes C and F (chemistry, metallurgy, mechanical engineering, lighting, heating, weapons and blasting) and Milan oversees IPC class A (human necessities).

> It is noteworthy that the Milan Central Division has already jumped ahead of Munich in terms of total case load. Furthermore, the findings appear representative of the litigious nature of the respective subject areas.

Taking a closer look at the IPC statistics, human necessity (IPC class A) standalone revocation actions have increased

**Figure 1: Analysis of First Instance Court caseload**



*Useful link*
*Caseload of UPC, November 2024 update (PDF): dycip.com/upc-caseload-nov24*

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substantially in recent months (25), followed by electronics and electrical based cases (IPC class H) in second place (13).

Before the Milan Central Division opened its doors, human necessity cases were allocated to the Paris Central Division, which may explain the Paris Central Division's inflated case load.

On the other hand, electronics and electrical based cases lead the way for infringement actions (84), followed by human necessities with 48 cases. If these trends continue it is expected that the case number growth at the Paris and Milan Central Divisions will continue to outstrip those of the Munich Central Division.

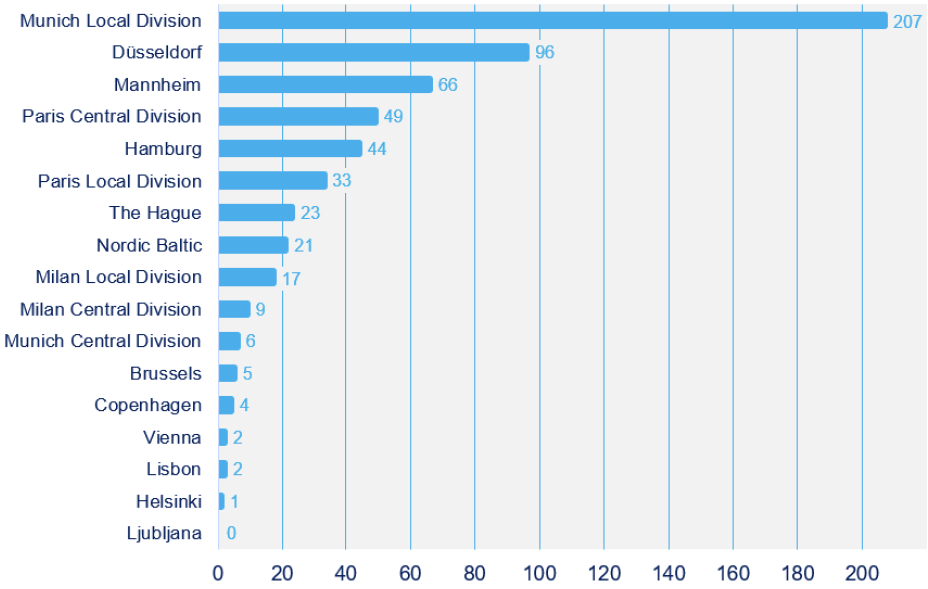
It is clear that the central divisions are still primarily utilised for standalone revocation proceedings, although counterclaims for infringement have also been initiated before the Paris Central Division, the only court to have had this type of action brought before it. However, the overall trend favours cases being heard before the local and regional divisions (89% of total cases).

While the total number of counterclaims for revocation continues to broadly track infringement actions, it appears that revocation counterclaims are not being filed as a matter of course in relation to individual infringement actions. Figure 2, above right, shows the total number of infringement cases are outpacing revocation counterclaims filed against individual infringement actions (as illustrated by the increasing Δ value). It will therefore be interesting to see whether the trend increases in due course.

## Court of Appeal

The UPC Court of Appeal has received 52 appeals by adversely affected parties (under Rule 220.1 of the UPC Rules of Procedure) and 62 appeals against other orders (under Rule 220.2 of the UPC Rules of Procedure). The Court of Appeal has also received its first appeal against a costs decision (under Rule 221 of the UPC Rules of Procedure), in addition to 14 requests for discretionary review, 14 applications

**Figure 2: Infringements v revocation counterclaims**




for suspensive effect, 25 applications for an order for expedition of an appeal and a single application for a rehearing.

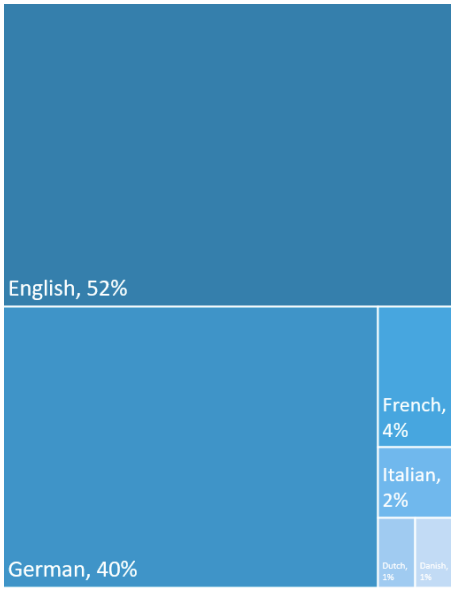
The growth of the Court of Appeal (28% month-on-month) has thus far exceeded that of the Court of First Instance (13% month-on-month) in 2024. This is likely due to the greater number of cases being heard before the First Instance Court that are now open to appeal. Notably, requests for discretionary review have increased nearly five-fold since July 2024, although many of the requests have been dismissed by the Court of Appeal.

## Language of proceedings

English continues to be the predominant language at the UPC Court of First Instance, representing 52% of proceedings, with German representing 40% of cases (see figure 3, right). There is also a new entry to the list of languages used before the court as of October 2024, where Danish appears to be used as the language of proceedings in an infringement action before the Copenhagen Local Division.

Somewhat surprisingly, the proportion of cases being heard in Italian in 2024 has decreased. One may have expected the language to be used more frequently, as

**Figure 3: Language of the total proceedings**




the Milan Central Division began hearing cases, although this has not come to pass.

We will continue to monitor UPC proceedings closely and bring further updates in the coming months.

**Author:**
**Stephen Solomon**

# UPC claim construction
## Recent approaches to claim interpretation

Recent first instance decisions at the Unified Patent Court (UPC) have seen Local Division and Central Division judges apply the Court of Appeal's decisions on claim interpretation. This article compares the approaches taken in three of these decisions.

**Three recent UPC decisions offer insight on approaches to claim construction**

### Background

In NanoString Technologies (Inc, Germany GmbH & Netherlands BV) v 10x Genomics Inc (UPC_CoA_335/2023) the UPC Court of Appeal set out the principles of claim interpretation that have been applied in subsequent first instance decisions. In particular, the UPC Court of Appeal stated 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.

### Koninklijke Philips NV v Belkin GmbH

On 13 September 2024 the UPC Munich Local Division delivered its decision in the Philips v Belkin case in relation to infringement and validity of Philips' patent, which had been declared to be a standard essential patent (SEP) in relation to the Qi wireless charging standard.

The claimed power transmitter receives a request to enter a negotiation phase and confirms the request by transmitting a confirmation "where the confirmation indicates an acceptance or rejection of the request to enter the requested negotiation phase".

The parties disputed whether always accepting the request would satisfy this claim feature. In the corresponding German litigation, the Düsseldorf Regional Court and the Federal Patent Court decided from the wording of the claim that the service sender must be capable of indicating both an acceptance and a rejection. The Munich Local Division of the UPC, however, considered that the summary of invention section of the description disclosed an embodiment where an acceptance is always transmitted, and decided this embodiment was clearly supported by the wording of the claim. Linguistically, because of the "or" wording, the Munich Local Division considered it difficult to justify that the power transmitter must be able to reject a request. Equally, from a technical point of view the court considered the aim of the invention to enable entry into the negotiation phase, not to prevent it, and concluded this embodiment where requests are always accepted to be an optimal realisation of the objective of the patent.

### NanoString Technologies Europe Limited v President and Fellows of Harvard College

On 17 October 2024, the Munich Central Division delivered its decision concerning the revocation action brought by NanoString Technologies against Harvard College's patent directed to a method for detecting a plurality of analytes in a sample.

The parties differed in their definition of the skilled person, with Harvard College arguing the skilled person would only have experience with in situ techniques for detecting biomolecules.

The court did not share this view, deciding that not only did the patent make no fundamental distinction between in vitro and in situ techniques but also that the term "sample" is defined broadly in the patent, and therefore the skilled person would be familiar with both "in vitro" and "in situ" techniques for detecting biomolecules.

NanoString Technologies argued that the description supported the interpretation that

*Case details at a glance*

*Decision level: Court of Appeal, Luxembourg*
*Case: UPC_CoA_335/2023*
*Parties: Nanostring Technologies (Inc, Germany GmbH and Netherlands BV) v President and Fellows of Harvard College and 10x Genomics Inc*
*Date: 26 February 2024 & 11 March 2024*
*Decision: dycip.com/nanostring-10x-coa*

*Decision level: Dusseldorf Local Division*
*Case: UPC_CFI_373/2023*
*Parties: SodaStream Industries Ltd v Aarke AB*
*Date: 31 October 2024*
*Decision: dycip.com/sodastream-aarke*

*Decision level: Munich Central Division*
*Case: UPC_CFI_252/2023*
*Parties: NanoString Technologies Europe Limited v President and Fellows of Harvard College*
*Date: 17 October 2024*
*Decision: dycip.com/nanostring-harvard-college*

*Decision level: Munich Local Division*
*Case: UPC_CFI_390/2023*
*Parties: Koninklijke Philips NV v Belkin (Limited and International)*
*Date: 13 September 2024*
*Decision: dycip.com/koninklijke-philips-belkin*

*Jurisdiction: European Union*
*Decision level: EPO*
*Party: F Hoffmann-La Roche AG*
*Citation: T56/21*
*Date: 04 October 2024*
*Decision: dycip.com/hoffmann-laroche-t5621*

*Related article*
*UPC v EPO: a comparison of claim construction approaches, 06 June 2024: dycip.com/upc-epo-claim-construction*

"a plurality of predetermined sequences" could comprise one predetermined sequence: the relevant paragraph of the description stating "[i]n some embodiments, the nucleic acid label or nucleic acid tag can comprise any number of the pre-determined nucleic acid subsequences, e.g., ranging from about 1...".

The Central Division was not convinced by this argument, and considered this interpretation to be at odds with the wording of the claim and the description as a whole, as well as the prior art.

Equally, the parties were divided as to whether or not a detection reagent stays bound to an analyte throughout the claimed method. The Central Division considered there was nothing in the claimed method or the description, when read in their technical functional context, to require the detection reagent to remain bound throughout the detection or to exclude the same detection reagent to be added before another round of detection is carried out.

**SodaStream Industries Ltd v Aarke AB**

On 31 October 2024 the Düsseldorf Local Division delivered its decision concerning the infringement claim brought by SodaStream against Aarke's "Carbonator Pro" product. The patent in suit related to a device for carbonating a liquid contained in a container with a pressurized gas.

The court reiterated multiple times that the claim is not limited by preferred embodiments, either illustrated in a drawing or from the description, and that these are merely examples provided to give the skilled person context. Rather, the court referred to the description as support for its conclusions on claim interpretation, rather than limitations on the scope of protection.

Aarke argued the term "flask" was limited to a bottle-like receiving unit fulfilling the intended function of effective anti-burst protection, and had a literal meaning as a small container, usually with a wide base and a narrow neck. The court ruled the skilled person doesn't consider the literal meaning of the claimed terms, but rather uses the context of the patent claim as a whole.

The court's interpretation of the disputed claim features was based largely on the technical function each feature performs. For example, "flask" was construed as a component that fulfils the objective of receiving a container containing liquid, rather than limited to any particular shape. Equally, the court found the skilled person would interpret the interlocking connection between the filling head and the receiving flask as being part of the solution to overcoming the identified limitations of the prior art, namely that the prior art locking mechanism may not be sufficiently strong to protect the components of the device in the event of an empty bottle failure.

**Discussion**

Each of these decisions use the principles set out by the UPC Court of Appeal as the starting point for considering claim interpretation. Further, each decision begins with a detailed discussion on the technical background and knowledge of the skilled person, as the skilled person's understanding of the objective of the invention was critical in all three judgments to determining the scope of the claims.

While the Munich Local Division considered the claims should be interpreted so as to include all the embodiments presented in the description as forming part of the claimed invention, the Munich Central Division discounted one embodiment in the description from its claim interpretation as being contradictory to the claim wording. The Munich Local Division did consider this point, stating that elements of the description and the drawings that provide an irresolvable contradiction with the claims should not be used to determine the subject matter of the patent. Equally, if elements of the description are presented as not being in accordance with the invention, they are not to be used to determine the subject matter of the patent.

The Düsseldorf Local Division seemingly took a broader interpretation that the claim features should be interpreted based on their technical function, and that the embodiments in the description are used for context and to provide support for the claim interpretation.

Interestingly, there was no technically qualified judge on the panel and the invention was in the mechanical field. We wait to see whether this is an approach more broadly applied in other fields and/or UPC divisions.

As seen in these decisions, the content of the description is critical to understanding the scope of the claims at the UPC.

Adaptation of the description to the subject matter of the granted claims has been a hot topic at the European Patent Office (EPO) in recent years. In October 2024 the EPO Board of Appeal, in T56/21, stated that not only should the granted claims be clear in themselves, adapting the description to match the subject matter of claims reduces the reservoir of technical information that could be used in national courts to determine the protection conferred by the patent. The EPO Board of Appeal also decided there was no legal basis for requiring the description be adapted to match allowable claims of more limited subject matter.

> In view of these recent UPC and EPO decisions applicants should consider that, unless elements of the description are explicitly presented as not forming part of the claimed invention or are contradictory to the subject matter of the claims, such elements are likely to be used to determine the subject matter of the patent in the event of court proceedings at the UPC.

**Author:**
**Andrew Cockerell**

# T1809/20
# Preferable patent language

*Case details at a glance*
*Jurisdiction: European Union*
*Decision level: EPO*
*Parties: Novartis AG v Oetke, Cornelia, Hoffmann Eitle, Weinzierl, Gerhard & MorphoSys AG*
*Citation: T1809/20*
*Date: 06 June 2024*
*Decision: dycip.com/t-1809-20-epo*

In T1809/20 the European Patent Office (EPO) Board of Appeal revoked a patent for added matter because claim 1 of the main and sole auxiliary request comprised multiple selections at differing levels of disclosed "preference" without any pointer present in the application as filed for combining preferences of different levels.

## Background

EP2513134B1 claimed "A method of producing a purified antibody", which included a step of washing with a wash solution comprising a number of ranges. During opposition, Novartis AG (the patentee) filed a main request that further defined a range for the pH of the wash solution.

In its decision, the Opposition Division rejected the arguments of the opponents in relation to added matter, sufficiency and inventive step, and allowed the claims of the main request. Appeals were filed against the decision of the Opposition Division, which included the successful attacks relating to added subject matter that led to the revocation of the patent.

## Disclosure of the application as filed

Focusing on the disclosure relating to the wash solution, claim 1 of the main request required a combination of selections including:

1. the concentration of arginine or arginine derivative in the wash solution.
2. the concentration of the non-buffering salt in the wash solution.
3. the pH of the wash solution being greater than 8.0.

For feature (1), the application as filed disclosed a concentration of "**between** 0.05 M and 2.0 M [...] **more preferably between** 0.05 and 0.85 M [...] **most preferably between** 0.1 and 0.5 M" (emphasis added). Claim 1 of the main request recited the intermediate preferred range ("more preferably") of these three originally disclosed levels of preference.

For feature (2), the application as filed disclosed a concentration "typically is between 0.1 and 2.0 M…, or between 0.5 M and 1.5 M,… or between 1 M and 2 M". Hence,

**Claim 1 comprised multiple selections at differing levels of disclosed "preference**

the application as filed disclosed a broad range and two sub ranges, with claim 1 of the main request reciting the broad range.

For feature (3), the application as filed disclosed "the pH of the one or more wash solutions is greater than 8.0, **preferably** at least 8.1, **more preferably** at least 8.5 and even more preferably at least 8.9" (emphasis added). Claim 1 of the main request recited the broadest preferred range ("is greater than 8.0") of the multiple levels of preference for the pH value.

## Decision of the Board of Appeal

The Board of Appeal identified that feature (1) "unmistakably" related to an intermediate level of preference, while features (2) and (3) related to the selection of the broadest disclosed ranges. The Board of Appeal then concluded that the main request was not allowable because "the combination of the features… is based on multiple selections at different levels of preference without any pointer being present in the application as filed for these selections".

For the auxiliary request, the claimed wash solution defined a combination of the most preferable range of feature (1), one of the sub-ranges of feature (2), and a pH range for feature (3) having a lower limit corresponding to the intermediate level of preference described as more preferable.

The proprietor argued that basis for the combination was provided by examples disclosed in the application as filed. The Board of Appeal agreed for features (1) and (3) because the examples disclosed values representative of the limits of these claimed ranges, but not for feature (2), because the relevant values in the examples fell within both the broader and more specific ranges, and hence could not be used to distinguish between these ranges.

## Conclusion

This case demonstrates that the amendments relating to features disclosed with increasing levels of preference should be treated with a degree of caution, and reinforces the importance of clear and unambiguous pointers for combinations for the assessment of Article 123(2) of the European Patent Convention (EPC).

In line with this decision, the use of preferable language is not sufficient in and of itself to provide a pointer to every permutation of described features, and importantly it is not possible to simply amend down each separate list in order of preference until a novel and inventive claim is arrived at.

This creates a problem in that suitable basis in an application may require the explicit linking of different features with multiple levels of preference, which leads to a significant burden when drafting and the potential ballooning of specifications if all permutations are described. Furthermore, this could create potential issues in which all permutations are equally pointed to, and hence the skilled person is not pointed to any particular combination over any other.

A pragmatic approach may therefore be needed in which advantageous synergistic combinations of related features are identified and defined at the drafting stage to provide suitable fall-back positions.

**Author:**
**Toby Willis**

# CRISPR patents revoked
## Applicant associated with Nobel Prize winners voluntarily withdraws

*Case details at a glance*
*Jurisdiction: EPO*
*Decision level: Boards of Appeal*
*Parties: Ipsen Bioinnovation Ltd v Allergan Inc*
*Citation: T2229/19*
*Date: 06 October 2023*
*Decision: dycip.com/t-2229-19*

*Useful links*
*EP2800811 revoked, 27 November 2024: dycip.com/ep2800811*

*EP3401400 revoked, 27 November 2024: dycip.com/ep3401400*

The University of California, the University of Vienna, and Emmanuelle Charpentier, applied for European patents relating to the use of CRISPR in eukaryotes. Patents EP2800811 and EP3401400 were initially maintained by the European Patent Office (EPO) at first instance in opposition. Both patents (which include Jennifer Doudna and Emmanuelle Charpentier among the inventors) contained broad claims covering almost any method of modifying a target DNA using a CRISPR-Cas 9 system. These very broad patents originated from a provisional application filed in May 2012 (P1), shortly before the ground-breaking discovery was published in the journal "Science" in June 2012.

However, it was later determined by the EPO that P1 left out an important detail. This detail was added in a second provisional application filed in October 2012 (P2), after the Science publication, as essential for CRISPR-Cas 9 binding and cleavage.

The universities' initial success in Europe was temporary, as the opposition decisions were, unsurprisingly, appealed. Oral hearings were scheduled for October 2024 and the Board of Appeal released preliminary opinions considering both patents invalid on several grounds.

In particular, the Board of Appeal considered that the claims were not entitled to priority, and the preliminary opinion was therefore that the claims lacked novelty and inventive step in view of the Science publication from June 2012. The Board of Appeal was also of the preliminary opinion that the patents were not sufficiently disclosed because they lacked information on important technical features, meaning that a person skilled in the art could not work the invention.

In October 2024, in response to the preliminary opinions, the representatives acting on behalf of the universities in the appeal proceedings filed lengthy submissions in which they withdrew their approval of the texts of the two patents, thereby revoking two of their own foundational patents and bringing the appeal proceedings to an end.

The universities argued that the revocations were necessitated by "serious procedural concerns" with the Board of Appeal's approach in recent case law (T2229/19) which, if followed, they believed would violate its right to be heard. In T2229/19 the Board of Appeal held as inadmissible a request to delete two dependent claims solely on the grounds that, although the deletion would have addressed all the objections considered so far, the deletion would not prima facie overcome the Board or Appeal's preliminary opinion on a different, yet to be discussed issue, namely sufficiency of disclosure. In the universities' view, issues raised in preliminary opinions should be allowed to be addressed by filing new claim sets that delete the problematic claims from the patent, an approach the universities say was historically routinely allowed by the Board of Appeal. However, according to the universities, in T2229/19 the Board of Appeal deviated from this practice by rejecting a claim set filed in similar circumstances on the basis that it would not *prima facie* overcome the Board of Appeal's opinion on a different issue, without allowing the parties to make any arguments on that point. The universities considered that there was a "non-negligible risk" that the Board of Appeal would take this same approach and reject their claim requests without allowing them to properly make their case: "The Patentees cannot be expected to expose the Nobel Prize-winning invention protected by the present patent to the repercussions of a decision handed down under such circumstances, when other members of this family (such as e.g., EP3597749) are still at a stage where the Patentees can procedurally ensure that they will ultimately be fully heard by the Board on all substantive issues."

The opponents have described the universities' request for revocation as a strategy to prevent an unfavourable final decision from being issued, and to mitigate effect of such a negative decision for the universities' other pending patents. The opponents considered the universities' concerns about T2229/19 as merely an attempt to distract from the deficiencies of the patents identified by the Board of Appeal. They argued there would be nothing improper about the Board of Appeal rejecting the universities' proposed claim sets, as it was the universities' choice not to file them sooner (the problematic issues being in play since the outset of proceedings).

This latest update in the CRISPR patent story creates additional uncertainty for those trying to navigate the highly complex CRISPR IP landscape, and for those already paying licensee fees to these dominant patents in order to secure use of this technology. It also prompts patentees to carefully consider their strategy for filing auxiliary claim sets at an early stage of proceedings.

**T2229/19 raises uncertainty for those navigating the complex CRISPR IP landscape**

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# UPC preliminary measures
## Emerging trends

Preliminary measures, including injunctions and seizure of goods, covering all of the Unified Patent Court (UPC) participating member states are a powerful tool for patentees. As a counterbalance, potential infringers are permitted to file protective letters, which, whilst not eliminating the risk of a preliminary injunction, have the potential to prevent a preliminary injunction being issued *ex parte*. We explore in this article some of the trends emerging from the case law.

### Urgency requirement

The emerging case law shows that patentees need to act promptly once they become aware of infringing activity. If a patentee does not act promptly then the preliminary measures are unlikely to be granted.

There has been some differing case law on how quickly an applicant must act in this regard. For instance, in Ortovox v Mammut (UPC_CFI_452/2023) it was held that the applicant has one month in which to act once an applicant has all the knowledge and documents that reliably enable a promising legal action. However, in Dyson v SharkNinja (UPC_CFI_443/2023) it was held that the applicant has two months in which to act. This has been confirmed in Hand held Products v Scandit, in which the court noted that, because the application for the preliminary injunction was filed on the same day that registration of unitary effect took place, it was clear that the applicant had treated the matter with the necessary urgency.

Interestingly, in Ericsson v ASUSTek, Arvato and Digital River (UPC_CFI_317/2024) it was acknowledged that the requirement of "urgency" for preliminary injunctions is not explicitly expressed in the Unified Patent Court Agreement (UPCA), but it was noted that the exceptional nature of provisional measures requires the court to be convinced of the urgency involved, and that this process is fact driven. The court stated that an applicant is expected to be diligent in seeking a remedy against an alleged infringer, and an unreasonable delay in initiating proceedings could lead to a finding that the urgency is lacking. It was held that the burden is on the applicant to show that it has not delayed unnecessarily. In particular, the applicant must provide the court with information of the moment when they became aware of the infringement. If the applicant is silent about that date and the court has no way of ascertaining it, the court may solely rely on the date of the alleged infringement for the assessment of unreasonable delay.

In this case, the court found that the applicant had failed to provide sufficient temporal elements enabling the court to assess the applicant's diligence in initiating proceedings. Consequently, the application for provisional measures was dismissed. The court noted that the requirements for granting preliminary injunctions (validity of the patent, imminent infringement, urgency and the balance of interests) are cumulative, allowing the court not to address them all if one is not satisfied. Nevertheless, despite finding that the requirements of urgency was sufficient to dismiss the request, the court still looked at validity and infringement and held that *prima facie* the patent was valid and infringed.

Additionally, in Valeo v Magna (UPC_CFI_347/2024) the court discussed the one-month period of Ortovox v Mammut and held that there is "no fixed deadline" by which an applicant must submit its application for provisional measure; the question is always whether the applicant's conduct as a whole justified the conclusion that the enforcement of its rights is not urgent.

> These decisions may not mean that an application made after two months automatically fails, but it seems highly likely that persuasive reasons will be needed to show why the delay is reasonable.

### Limitations on examination of validity

Emerging case law not only shows that validity may be considered in requests for preliminary measures, but that the number of validity attacks should generally be reduced to the three best arguments. Moreover, as it is the responsibility of the defendant to challenge the presumption of validity, it is therefore the defendant's responsibility to select the three arguments (see Hand Held Products v Scandit (UPC_CFI_74/2024), which confirms the decision in Dyson v SharkNinja). Further, Hand Held Products v Scandit confirms that that there can be several realistic starting points for inventive step attacks.

> The UPC seems willing to move away from the European Patent Office's (EPO) inventive step approach of "most promising starting point".

Additionally, the court noted in Valeo v Magna that no conclusions can be drawn from the general revocation rates of patents: only validity of the patent in suit is relevant.

### Imminent infringement will be considered

Prior to Novartis and Genentech v Celltrion (UPC_CFI_166/2024) it had been unclear if the UPC was responsible for imminent infringement at all, and the defendants in this case used this point as a line of argumentation. However, this decision makes it clear that the UPC does cover it, and it sets out some useful guidelines for the pharmaceutical industry.

In this case, the defendants had developed a biosimilar and obtained a marketing authorisation for it. Back in 2022 they had publicly announced that they intended to launch the product in Europe in 2024 and, after the grant of marketing authorisation in May 2024, they issued another press release announcing their plan to rapidly expand its market share.

The court stated that imminent infringement may be characterised by certain circumstances which suggest that

*Useful links*

*UPC_CFI_452/2023, 11 December 2023 (PDF): dycip.com/upc-cfi-452-2023*

*UPC_CFI_443/2023, 21 May 2024 (PDF): dycip.com/upc-cfi-443-2023*

*UPC_CFI_74/2024, 27 August 2024 (PDF): dycip.com/upc-cfi-74-2024*

*UPC_CFI_317/2024, 15 October 2024 (PDF): dycip.com/upc-cfi-317-2024*

*UPC_CFI_347/2024, 31 October 2024 (PDF): dycip.com/upc-cfi-347-2024*

*UPC_CFI_166/2024, 06 September 2024 (PDF): dycip.com/upc-cfi-166-2024*

*UPC_CFI_177/2023, 18 October 2023 (PDF): dycip.com/upc-177-2023*

## How urgently should patentees act when requesting a preliminary injunction at the UPC?

infringement has not yet occurred, but that the potential infringer has already set the stage for it to occur. These circumstances must be assessed on a case-by-case basis with the burden lying with the applicant. The court held that the question to be answered is whether the defendant's conduct leads to the conclusion that they are more likely than not to enter the market during the patent term. Further, the court considered that an offer is sufficient if it creates a demand for the product which the offer is likely to satisfy. This would be an advertisement in which the defendant would be able to supply a potential order, for a specific price, in compliance with regulatory measures.

The court held that customers familiar with the practices of the pharmaceutical industry are likely to regard statements about future market entry as "vague announcements" when regulatory measures, pricing and reimbursement conditions have not been finalised. In order for an infringement to be imminent, all pre-launch preparations must be completed such that an offer can be made at any time. As the advertisement did not show any specific timeline, and there was no information about price negotiations or reimbursements, nor were samples presented to potential customer, the court held that it could not find the defendants had completed all pre-launch preparation. Therefore, the application for provisional measures was rejected. The court additionally held that, due to the lack of infringement, it did not have to decide on the likelihood of validity.

### Protective letters & ex parte hearings

Protective letters are effectively a pre-emptive statement of defence: they may set out why a product or process does not infringe a patent, and/or contain arguments as to why the patent is invalid, and set out the reasons why any future application by the patentee for provisional measure should be rejected by the UPC. Protective letters may be filed with the UPC at any time, by any person, for a small fee (currently €200). The protective letter has effect for a period of six months, which is extendible upon payment of a fee (currently €100). Protective letters are not made public, so a patentee would not be aware of one until they make an application for a preliminary injunction.

In myStomer v Revolt (UPC_CFI_177/2023) the patentee applied for an *ex parte* preliminary injunction the day after a trade fair in which Revolt had exhibited its bike and provided an order form. Revolt had already filed a protective letter a few days before the trade fair. In the protective letter Revolt argued exhaustion and denied infringement. However, as noted by the court, there were no invalidity arguments in the letter. The court dismissed the exhaustion arguments as they had already been considered and dismissed by the Swiss Court. The court further considered that Revolt had not significantly denied infringement. Therefore, the court considered it appropriate and justified to grant the preliminary injunction on the same day of the request without summoning that parties to an oral hearing.

It seems that if a court does not find a protective letter persuasive, it may exercise its discretion and order a preliminary injunction without hearing the alleged infringer.

### Key takeaways

The UPC is a proving to be a popular venue for preliminary injunctions. While case law is still developing, a key emerging trend is the need for patentees to act urgently when requesting a preliminary injunction.

The UPC has shown that it is willing to consider validity in requests for preliminary injunctions, but it seems the number of attacks generally should be limited to the best three. Further, there may be several realistic starting points for inventive step attacks.

There has been less case law relating to protective letters, nevertheless, it seems that courts may still be willing to carry out *ex parte* hearings if they find a protective letter unpersuasive.

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# UPC recoverable costs
## Factors influencing the value of a revocation action

*Useful links*

*Unified Patent Court Agreement, 2013/C 175/01:*
*dycip.com/upca-2013-c17501*

*UPC Rules of Procedure (PDF):*
*dycip.com/upc-rulesofprocedure*

*UPC guidelines for the determination of the court fees and the ceiling of recoverable costs, 24 April 2023 (PDF):*
*dycip.com/upc-court-fees-23*

Recent orders of the Court of First Instance of the Unified Patent Court (UPC) Central Division (Paris Seat) indicate the factors a court may take into account when deciding upon the value of a revocation action (through the value of a patent to be revoked) and which band of recoverable costs is to be applied.

The legal background relating to the payment of costs during revocation actions stems from Article 69(1) of the Unified Patent Court Agreement (UPCA). This article indicates that: "Reasonable and proportionate legal costs and other expenses incurred by the successful party shall, as a general rule, be borne by the unsuccessful party, unless equity requires otherwise, up to a ceiling set in accordance with the Rules of Procedure." Article 69(1) is supported by Rule 152(2) of the UPC Rules of Procedure, which outlines that: "The Administrative Committee shall adopt a scale of ceilings for recoverable costs by reference to the value of the proceedings. The scale may be adjusted from time to time."

### Scale of ceilings for recoverable costs (November 2024)

| Value of the proceeding (€) | Recoverable costs ceiling (€) |
|---|---|
| Up to & inc. 250,000 | Up to 38,000 |
| Up to & inc. 500,000 | Up to 56,000 |
| Up to & inc. 1,000,000 | Up to 112,000 |
| Up to & inc. 2,000,000 | Up to 200,000 |
| Up to & inc. 4,000,000 | Up to 400,000 |
| Up to & inc. 8,000,000 | Up to 600,000 |
| Up to & inc. 16,000,000 | Up to 800,000 |
| Up to & inc. 30,000,000 | Up to 1,200,000 |
| Up to & inc. 50,000,000 | Up to 1,500,000 |
| More than 50,000,000 | Up to 2,000,000 |

Rule 152(2) indicates that in order to determine the ceiling for recoverable costs an assessment of the value of proceedings must be undertaken. The UPC has issued guidelines for the determination of the court fees and the ceiling of recoverable costs, in which section II.2.b dictates that: "(1) The value of a counterclaim for revocation or of a revocation action should be determined having regard to the value of the patent to be revoked."

The guidelines therefore indicate that in order to evaluate the value of the proceedings and subsequently determine the ceiling for recoverable costs, the value of the patent to be revoked must be taken into account. This can be based on the factors we will discuss below as well as consideration of the value of an appropriate license fee. Of course, it might be difficult for a claimant to determine the value of the patent if they are not able to see licence details, and this might mean that they are deprived of a key indicator to elevate the value of recoverable costs. It is not clear whether a claimant could force a defendant to disclose such information, but the guidelines indicate that an appropriate license fee can be calculated based on the turnover of the parties for the remaining lifetime of the patent.

In its order, the court applied this legal background, observing the requirement for an assessment of the value proceedings (by the value of the patent to be revoked) in order to ultimately deduce the ceiling for recoverable costs. Relevant factors indicated by the court for assessing the value of a patent are:

- The remaining lifetime of the patent;
- The number of UPC and non-UPC states in which the patent is validated;
- The value of the relevant market (in this case, the court took account of the fact that no information was provided by the defendant as to products falling under the patent sold in UPC member states, but considered the value of the global market relevant to the patent in suit as evidenced by the claimant and the defendant);
- The presence of pending opposition proceedings;
- The timing of the revocation action filing (in this case, the defendant decided to file the revocation action before EPO opposition proceedings were completed, suggesting heightened patent value, despite the fact that the defendant had not opposed the patent in suit before the EPO); and
- The claimant's area of practice (in this case, the court noted that the defendant operated in the same field as the patent in suit such that patent revocation would potentially increase their freedom to operate).

The court noted that in this case these factors speak for an elevated patent and/or action value, such that the lowest band for recoverable costs cannot be applicable. However, the court also noted that the claimant did not appear to put into practice the patented technology in the contracting member states such that the value of proceedings must reside in one of the lower bands.

Interestingly, the court also emphasised that the assessment of the value of proceedings must be made based on the filing party's objective interest at the time of filing the action, and that therefore circumstances arising after the time of filing the action are not to be considered. This, in theory, means that a claimant should not be able to take into account the strength and contents of a defendant's counter arguments when putting forward a value of the proceedings. However, in this case the claimant was allowed to change their position, with the court indicating that the original selection of a value of proceedings by the claimant was not relevant since nothing in UPC Agreement or Rules of Procedure suggests this is binding, and the initial indication was only subjective and acted as a starting point for discussions.

It is not currently clear to what extent invoking one of these factors would raise or lower the value of the patent and thus increase or decrease the recoverable costs ceiling. However, it would seem to be the case that providing specific evidence concerning the value and use of products covered by the patent in suit is an important factor in elevating the value of the litigation and thus the recoverable costs to be awarded.

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In this webinar Simon O'Brien and Nathaniel Wand discuss T1437/21 (novelty and inventive step of treating a patient subpopulation in view of prior art of a phase 3 clinical trial), T1941/21 (inventive step over clinical trial protocol and novelty over combination therapy) and T0197/22: (insufficieny of a first medical claim).

### UPC case caw, observations & analysis

As use of the Unified Patent Court and case law starts to build, we will be running a series of regular webinars dedicated to analysing the court's decisions, providing you with our most up to date statistics, practical observations and analysis.

Our November 2024 UPC webinar was presented by Rachel Bateman, Samuel Keyes and Lawrence King and is now available to view on demand on our website: dycip.com/upc-patent-nov24

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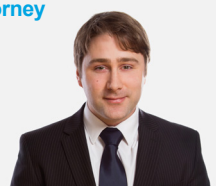

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