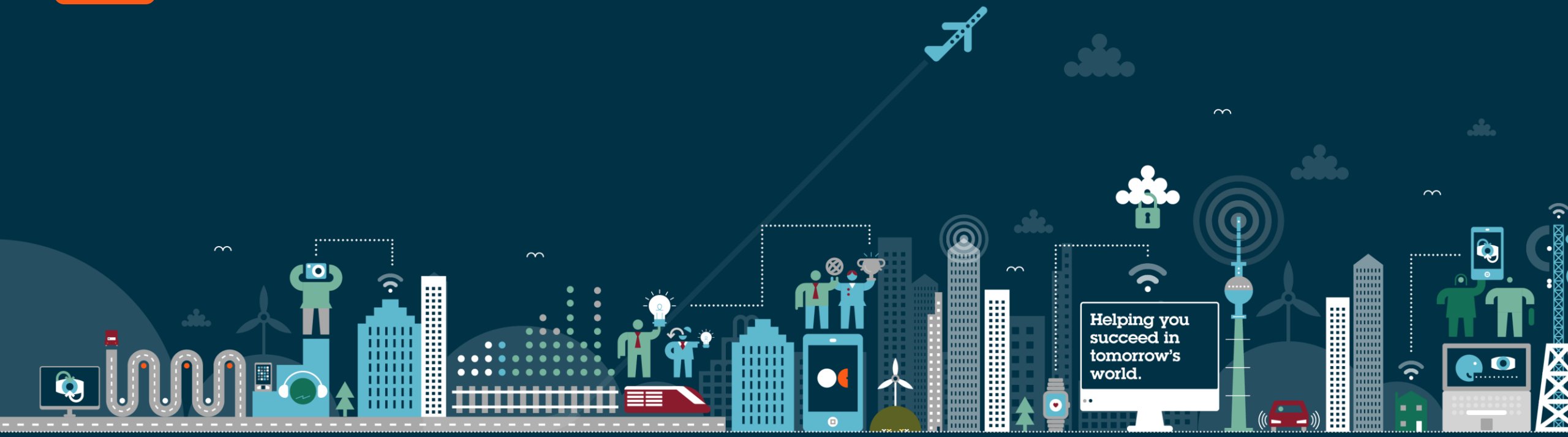
Life sciences are at the fore of preliminary injunction trends emerging from Europe's Unified Patent Court

October 2025

Start



Half of preliminary injunctions granted at first instance on an *inter partes* basis, with invalidity and non-infringement the main points of refusal

The Unified Patent Court (UPC) has now been operational for over two years. In that time, the court has shown itself willing to grant a range of provisional measures, including preliminary injunctions (PIs), orders for the seizure of infringing goods and orders for the preservation of evidence and inspection of premises.

Since the court's operations began, there have been several important decisions that have clarified the criteria that the UPC judges apply when deciding whether to grant provisional measures. Statistics and trends are now emerging indicating how the UPC has applied the Rules of Procedure (RoP) when determining whether to grant PIs.

In short, in order for the court to grant a PI it must be satisfied to a "sufficient degree of certainty" that: (i) the applicant is entitled to commence the proceedings; (ii) the patent is valid; (iii) there is infringement or "imminent infringement"; (iv) there is urgency or that the applicant acted without "unreasonable delay"; (v) the PI is necessary; and (vi) the weighing of the parties' interests favours grant of a PI.

The UPC's emerging case law has begun to give clarity on what these requirements mean – as have the initial statistical trends from the decisions made in the court since it opened in June 2023.

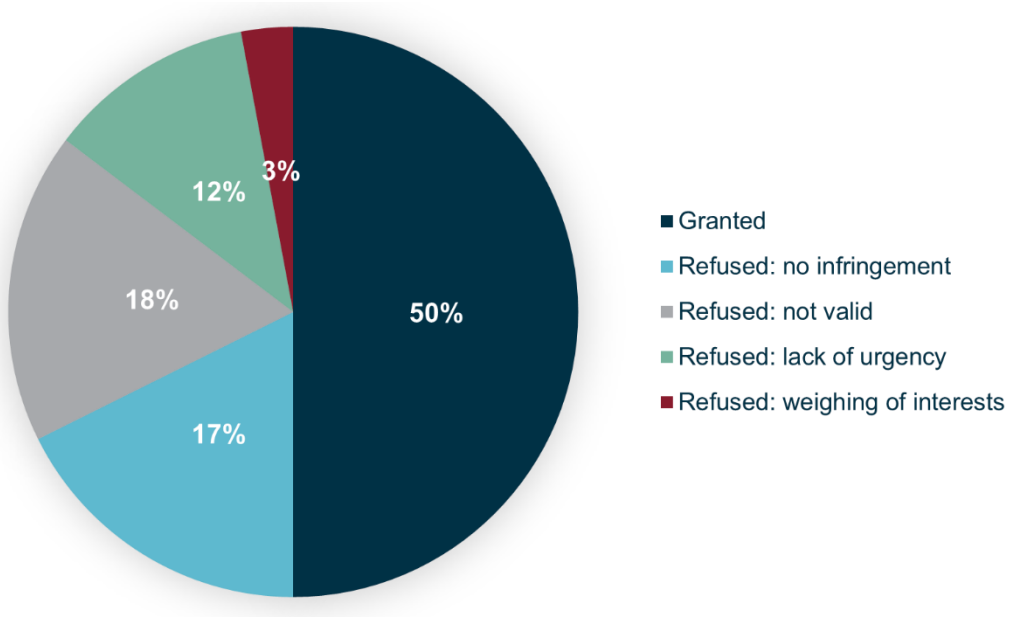
The trends in numbers: first instance *inter partes* decisions

First instance *inter partes* decisions

There have been a total of 34 first instance *inter partes* PI applications so far; of these, the outcome is split evenly, with 17 PIs granted and 17 refused. The majority of refusals were due to there being either an insufficient degree of certainty that the patent was valid or infringed (totalling 70% of the refused PIs). Urgency, or lack thereof, has also been an important factor. Two of the 17 refusals cited more than one reason for the refusal.

The least common factor for refusal of a PI, as a sole factor, is weighing of interests. Although the court has considered this factor a number of times when handing down its decisions, there is only a single PI that has been refused on this ground alone.

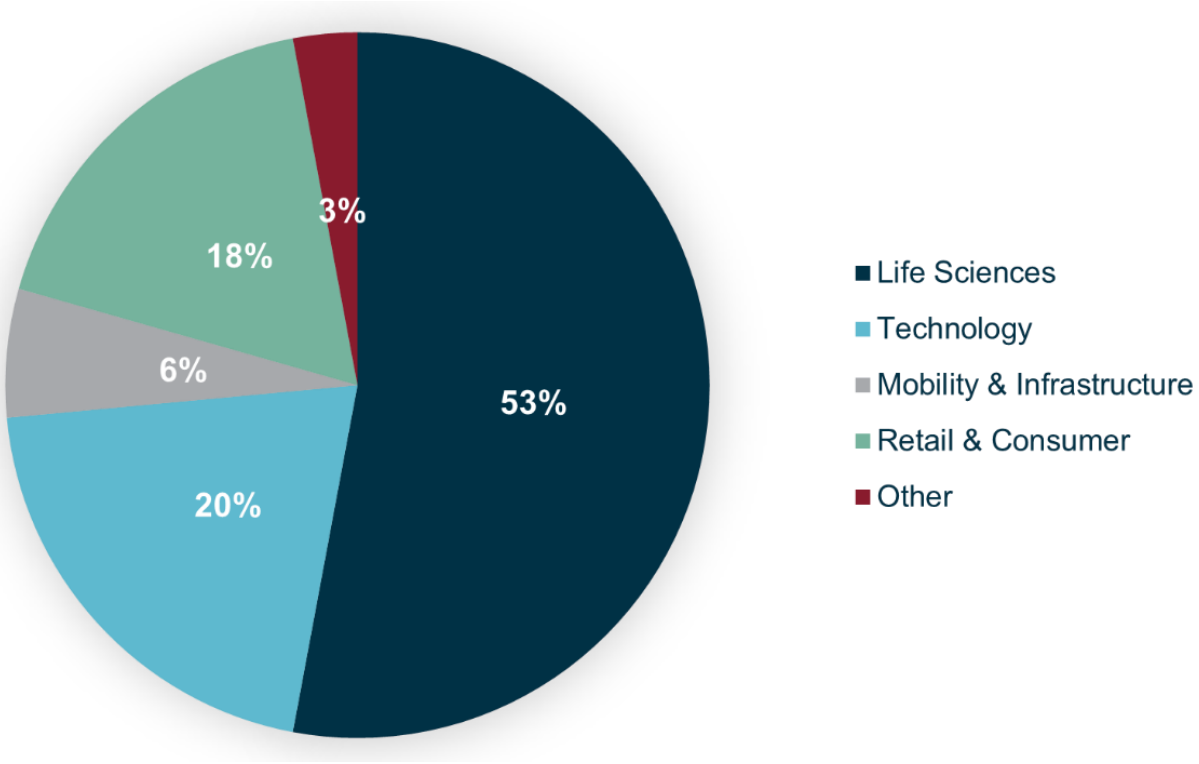
First instance PI decision outcomes

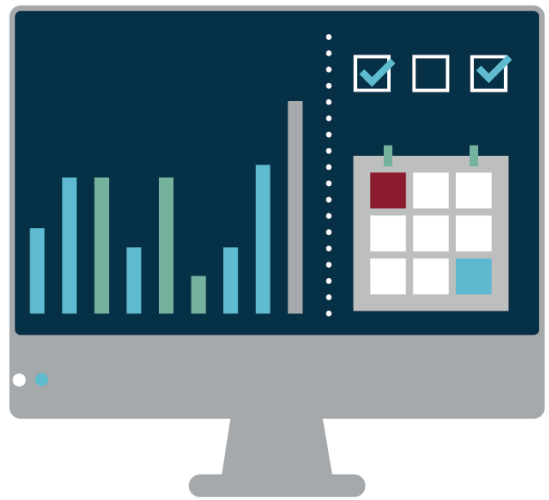


The trends in numbers: first instance PI decisions on a sector basis

First instance PI decisions on a sector basis

Despite concerns that the life sciences sector would not be active in the UPC before its launch, this has proved not to be the case, particularly in the case of PI applications. The sector leads the way with the most PI applications on a sector basis (18).





The trends in numbers: Court of Appeal

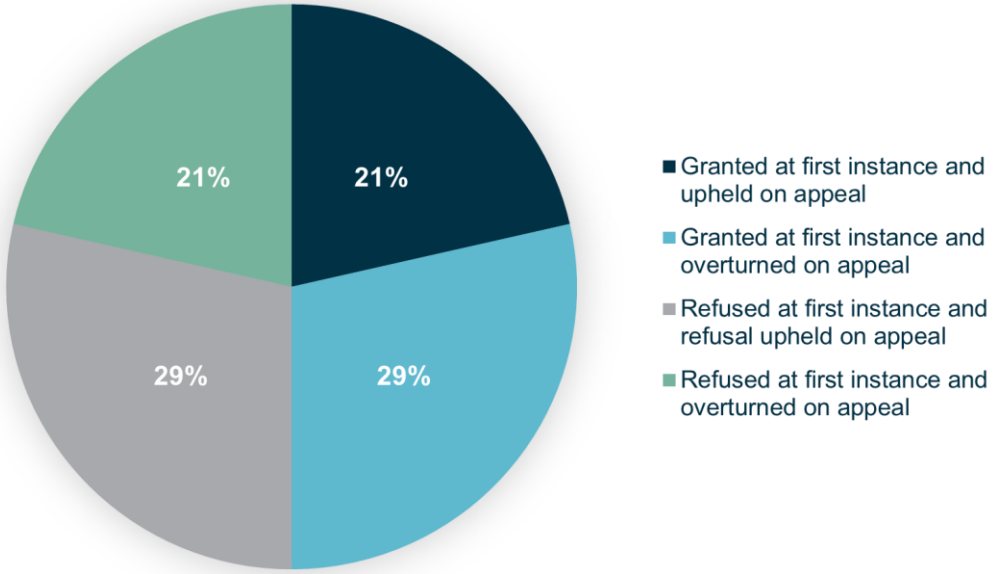
There have been a total of 14 PI decisions from the Court of Appeal, which has shown it is willing to overturn first instance decisions: 50% have been overturned on appeal and 50% upheld.

Whether the Court of Appeal has upheld or overturned a first instance decision has depended on the nature of the first instance decision. Where the first instance court has granted a PI, the Court of Appeal has been prepared to overturn this decision, meaning that overall it has been more likely to deny a PI than grant one.

This willingness to overturn first instance decisions is likely a result of the Court of Appeal's developing jurisprudence: it will be interesting to see whether this overturn rate reduces over time as its decisions clarify and unify the requirements to be applied for a PI. In total, following the Court of Appeal's decision, 42% of PIs have been granted and 58% refused.

There has also been a single case in which the Court of Appeal suspended the effect of a PI granted at first instance pending the appeal, after which the patentee withdrew its entire action. This can be deemed as "granted and overturned", since the Court of Appeal's decision to suspend the effect of the PI likely played a role in the patentee's withdrawal of the action.

Court of Appeal PI decision outcomes



PI requirements: judicial clarification

A sufficient degree of certainty?

Article 62(4) UPCA and Rule 211.2 RoP require a "sufficient degree of certainty" that (i) the applicant is entitled to commence the proceedings, (ii) the patent is valid and (iii) it is infringed or infringement is imminent.

It is now well-established following the Court of Appeal decision in *Nanostring v 10x Genomics* that a "sufficient degree of certainty" requires the court to find the circumstance on the balance of probabilities at least more likely than not. This standard applies to whether the applicant is entitled to commence the proceedings, the validity and the infringement or imminent infringement of the patent.

The burden of proof for establishing entitlement and infringement lies with applicants, whereas for lack of validity it lies with respondents.

However, the court does place limitations on the number of validity arguments that can be presented at this preliminary stage. For example, the Munich Local Division (LD) stated that it was the respondent's responsibility to reduce the case to its three best arguments for the oral hearing – an approach it subsequently adopted in a separate case.

Imminent infringement

What amounts to an "imminent infringement" under Articles 62(1), (4) UPCA and Rule 211.2 RoP has been clarified by the Court of Appeal in *Boehringer Ingelheim v Zentiva*, in which it affirmed the "set the stage" test that was originally set out by the Düsseldorf LD in *Novartis & Genentech v Celltrion.*

What this means is that the question of whether there is imminent infringement is whether the potential infringer has "already set the stage" for infringement to occur, such that it was "only a matter of starting the action" as the "preparations for it have been fully completed".

In the generic pharmaceutical context, merely applying for a marketing authorisation does not amount to imminent infringement, nor does the grant of a marketing authorisation create the required imminence. Completion of national health technology assessment, pricing and reimbursement procedures can amount to an imminent infringement. However, this needs to be assessed on a case-by-case basis, in light of the national regulatory and legislative context and the circumstances of the case.

PI requirements: judicial clarification

Indeed, the Court of Appeal, in reversing the Lisbon LD's first instance decision in *Boehringer Ingelheim v Zentiva*, found that completion of the national health technology assessment, pricing and reimbursement procedures did amount to imminent infringement. The Court of Appeal held that there was nothing to prevent Zentiva from taking part in a public procurement or direct award for the generic (other than its own self-restraint) and therefore the PI was granted.

This outcome can be contrasted with *Novartis & Genentech v Celltrion*, where the Düsseldorf LD held that the stage had not been set and therefore there was no imminent infringement. The Düsseldorf LD did not find that the respondents had already completed all necessary pre-launch preparations. Although the first respondent had obtained a marketing authorisation and there was some promotion of this, the advertising materials did not include a specific timeline, there was no information of any price negotiations nor reimbursement applications by the respondents and samples had not been presented to customers.

Urgency?

Although urgency is not expressly referenced in the UPCA, Rule 211.4 RoP explains that the court shall have regard to any "unreasonable delay in seeking provisional measures". Due to the exceptional nature of provisional measures, urgency is involved in the assessment of whether to grant a PI. When applying this rule, the UPC has been clear that applicants must act promptly once they become aware of the infringing activity. However, they must also assess the evidence to check whether there is a "promising legal action".

The UPC has been clear that applicants for provisional measures must act within two months to be virtually guaranteed a "safe harbour" and satisfy the urgency requirement if the dispute involves more than one UPC member state. While the assessment will always be fact specific, a delay of up to two months should not amount to an "unreasonable delay" if the dispute involves more than one UPC member state.

However, the UPC has been pragmatic regarding what amounts to an "unreasonable delay" and urgency will only be deemed lacking if the applicant has behaved negligently and hesitantly in bringing its claim such that the court must conclude that it is not interested in the timely enforcement of its rights.

PI requirements: judicial clarification

This has resulted in considerable variety in the amount of time in which a delay has been deemed to be insufficiently 'urgent'. For example, in one case, a PI was granted despite a 10-month period between the applicant becoming aware of the infringing activity and the PI application, and, in another decision, the court found that a five-month delay was too long in the circumstances.

Ultimately, the onus is on the applicant to establish that it has not delayed in making its application. When the applicant is silent about the date on which it became aware of the infringement and the court has no way of ascertaining it, the court may rely solely on the date of the alleged infringement when assessing unreasonable delay.

Necessity

According to Rule 206.2(c) RoP, an application for provisional measures must provide reasons why the measures are necessary. It is not enough, on its own, for there to be clear infringement and a high probability of patent validity – the measures must also be necessary. The UPC has tended to consider necessity as intertwined with the weighing of interests/irreparable harm, particularly in the context where there is the potential for direct competition, loss of market share or price erosion.

In cases where there is or is the potential for direct competition or loss of market share, the court has taken this to suggest strongly a kind of irreparable harm that supports the necessity of the measures (for example, see *Dyson v Dreame*, *Insulet v EOFlow*, *Sumi Agro v Syngenta*, *G. Pohl-Boskamp v pharma-aktiva*; *Steros v OTEC).*

If the allegedly infringing conduct has been ongoing and the applicant can wait for the decision in the proceedings on the merits, the Court of Appeal has concluded that provisional measures are not necessary as the proceedings on the merits offer more procedural safeguards.

Weighing of interests

Article 62(2) UPCA and Rule 211.3 RoP provide the court with the discretion to weigh up the parties' interests and take into account "the potential harm for either of the parties resulting from the granting or the refusal of the injunction".

In a number of the early PI decisions, the UPC appeared to give little consideration to the weighing of interests. Indeed, the court specifically held that it is not necessary to weigh the parties' interests if it decides that the patent is not valid or not infringed as the elements of the test for a PI are cumulative.

PI requirements: judicial clarification

However, more recently there have been a number of decisions in which the court has taken weighing of interests into account more fully. When considering this aspect of the test, the court has discretion to consider many factors but the case law shows that there has been a particular focus on "irreparable harm", even though this is not a necessary condition for the grant of provisional measures as the UPCA and RoP only refer to "potential harm".

Therefore, a lack of irreparable harm does not necessarily preclude the grant of a PI, but it has been held to interlink with the above "necessity" requirement, particularly in cases of direct competition and potential market share loss or price erosion.

Prosecution history

Some European national courts are open to hearing arguments in relation to a patent's prosecution history, whereas others are more reluctant. The Court of Appeal has touched on this topic in VusionGroup v Hanshow. This was a decision on a PI application, but the court did not decide whether prosecution history can be taken into account when determining the scope of the patent's protection because it would not have changed the outcome of the case at hand.

In that case, the Court of Appeal upheld the Munich LD's decision that it was not more likely than not, on the balance of probabilities, that the attacked embodiments fell within the scope of the patent and, therefore, there was no infringement. As such, there was no need for the Court of Appeal to consider the prosecution history in its decision.

***Ex parte* PIs**

So far there have only been three reported first instance *ex parte* decisions, but they have all been successful and resulted in a PI being granted. However, there have been instances where the requirements for hearing an application on an *ex parte* basis have not been met and therefore the applications have then been heard on an *inter partes* basis before a decision on whether to grant a PI was made (for example, *Insulet v Menarini* and *Insulet v EOFlow*).

For an application to be heard on an *ex parte* basis, applicants must also explain why the PI should be granted without hearing the respondents. For example, the court has proceeded to grant a PI on an *ex parte* basis if a delay would cause irreparable damage to the applicant.

In considering whether to allow an application to proceed *ex parte*, the court will also consider the nature of any prior correspondence between the parties and any protective letters on file.

PI requirements: judicial clarification

Protective Letters

To protect a respondent against *ex parte* PIs, potential infringers are permitted to file a protective letter with the court to explain why they do not infringe the patent(s) and any arguments as to why the patent(s) is invalid. This is a practice in some countries that are part of the UPC system (for example, Germany). The patentee does not know that a protective letter has been filed; the court will look for one if an *ex parte* PI is sought.

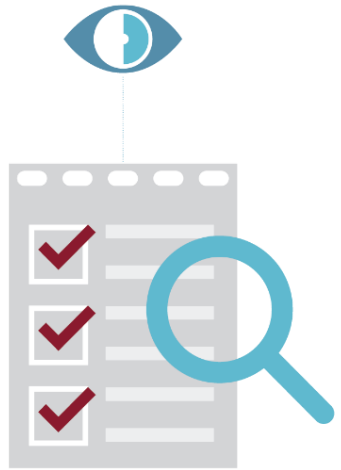
The court has ultimate discretion over how to proceed, but it will take the letter into account. Having a protective letter on file does not guarantee that there will be an *inter partes* hearing, as evidenced in the case of *myStromer v Revolt.*

In the myStromer case, the court granted an *ex parte* PI even though the respondent had filed a protective letter. The letter contained no invalidity arguments and the Düsseldorf LD held that the non-infringement argument in the letter was not convincing.

The court decided that the defendant was therefore unlikely to be able to defend the PI at an *inter partes* hearing. This serves as a warning to potential infringers against filing a protective letter with only weak arguments.

The Düsseldorf LD also assessed the protective letter regime in *Ortovox v Mammut*. Mammut had not filed a protective letter, even though Ortovox had sent a warning letter. The court criticised Mammut for failing to file a letter in these circumstances.

In the absence of a protective letter, the court predicted the arguments that Mammut would put forward based on arguments raised in parallel Swiss proceedings. It concluded that those arguments did not raise any doubts as to validity of the patent and therefore granted the *ex parte* PI.



Osborne Clarke comment

The UPC has shown itself to be an attractive forum in which to bring PI applications and that it is willing to grant them. Decisions can be obtained quickly and the court has also been adaptable in hearing applications of extreme urgency.

Although the Court of Appeal has overturned many first instance PI decisions, now that its jurisprudence is more developed it seems reasonable to expect fewer appeals to succeed. One aspect to continue to watch is whether the importance of weighing the parties' interests, which played little or no role in the court's early decisions, and which still isn't a decisive factor in most decisions, continues to become more important.

Ex parte PI decisions remain few in number – presently, three – but all have been successful. The low number may be due to the protective letter regime and the applicant's additional burden of justifying why a PI should be granted in the absence of allowing the respondent to defend its position. There are also a few cases in which the court has rejected an *ex parte* request, requiring instead an *inter partes* hearing.

The PI regime in the UPC is particularly popular in the life sciences sector, with over 50% of applications having been brought by such patent holders.

More applications have been successful than not, with 10 granted versus eight refused: of those granted, six were Court of Appeal decisions and, of those refused, three were Court of Appeal decisions.

The Court of Appeal's clarity in relation to the test to be applied for whether an infringement is "imminent" also gives patent holders useful guidance for considering whether and when to bring a PI application. The court's acknowledgement that national legislative and regulatory regimes must be considered in deciding whether the "stage has been set" for infringement may lead to forum shopping when deciding in which division a PI application should be brought.

The UPC now has a relatively established body of case law from the Court of Appeal, providing clarity on a number of the elements of the test for the grant of a PI. Although many PI decisions at this stage have been handed down by the German divisions of the UPC, different divisions may consider taking a different approach to the factors where there is less prescriptive guidance from the Court of Appeal and to other factors, such as, expert evidence. This, too, could lead to future forum shopping between the Court of First Instance divisions.

Shereen Younis and James Bruce, trainee solicitors at Osborne Clarke, contributed to this Insight.

Key Contacts

Tim Harris
Partner
United Kingdom

T +44 207 105 7144
tim.harris@osborneclarke.com

Ryan West
Associate
United Kingdom

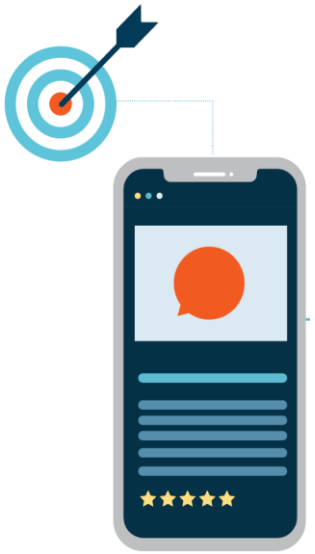
T +442071057651
ryan.west@osborneclarke.com

Matthew White
Senior Associate
United Kingdom

T +44 207 105 7920
matthew.white@osborneclarke.com

Robyn Trigg
Senior Knowledge Lawyer
United Kingdom

T +44 207 105 7338
robyn.trigg@osborneclarke.com



Osborne Clarke is the business name for an international legal practice and its associated businesses. Full details here: osborneclarke.com/verein

These materials are written and provided for general information purposes only. They are not intended and should not be used as a substitute for taking legal advice. Specific legal advice should be taken before acting on any of the topics covered