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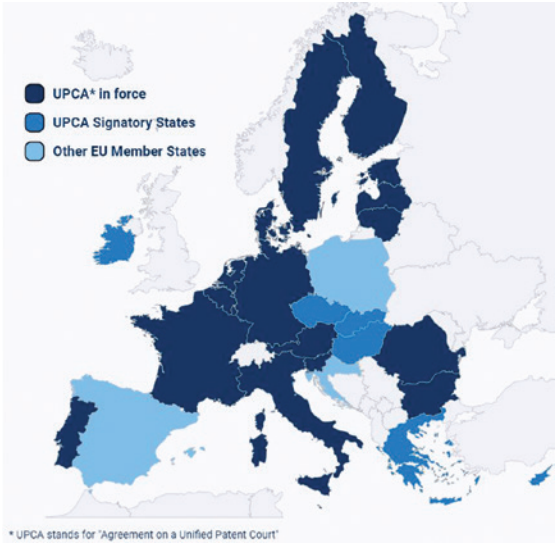

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Francisco Javier García Pérez

The UPC's Reach Beyond Its Borders: Jurisdiction over Infringements Occurring in Spain (*Dyson v. Dreame*)

On 14 August 2025, the Unified Patent Court's Hamburg Local Division issued a final order (case UPC_CFI_387/2025 [the "Order"]) concluding that the UPC may join acts infringing the Spanish national part of a European patent, even though Spain is not a UPCA Contracting Member State. The decision hinges on the interplay between the Brussels I Recast Regulation's jurisdictional rules, the UPC's status as a "common court," and – critically – the role of an EU-based authorised representative as both "anchor defendant" and intermediary. Building squarely on the Court of Justice's ruling in *BSH Hausgeräte v. Electrolux*, it reshapes expectations – or, at least, sparks an intense and strategic debate – about forum, reach and strategy in pan-European enforcement.

The patent in question (EP 3 119 235) relates to a curling attachment for hair appliances. The claimant markets the "Airwrap"; the defendants' accused products include "Dreame Airstyle" and "Dreame Pocket" (older "curling attachments") and newer "Airstyle Pro" and "Pocket Neo" ("staggered curling attachments"). The patent is valid in the UPCA Member States and Spain.

Defendant 1, a Hong Kong manufacturer, ran country-specific websites, showing availability in several EU markets, including Spain. Defendant 2, a German distributor, managed the German market and shipped to selected EU states. Defendant 4, a Swedish affiliate, handled sales in Sweden. Defendant 3, a German company, was the EU authorised representative listed on product packaging – an indispensable intermediary for electronics sales in the EU under the GPSR (Regulation 2023/988) and the Market Surveillance Regulation (Regulation 2019/1020).

The UPC's Hamburg panel found that infringement was more likely than not for the older products, but not for newer variants. However, the focus here is on the question of jurisdiction.

The Order concludes that the UPC's international jurisdiction is established "in accordance with Regulation (EU) No 1215/2012" (Art. 31 UPCA), and Art. 71a–71d of Brussels I recast integrate the UPC as a "common court". There are three possible routes for the Court:

Firstly, Art. 4(1) Brussels I recast establishes jurisdiction at the domicile of EU-based defendants. For UPC purposes, this provision allows for consolidated actions to be taken across all UPCA territories where the European patent is valid, with the territorial scope being governed by Art. 34 UPCA.

Secondly, Art. 7(2) Brussels I recast, taken together with Art. 71b(2), provides jurisdiction, regardless of the defendant's domicile, where "the harmful event occurred or may occur" in a UPCA Member State. This underpins UPC jurisdiction over non-EU manufacturers for infringements in UPCA Contracting Member States.

Thirdly, – and crucially, in the Court's opinion, for determining jurisdiction over infringements that took place in Spain in the case at hand –, Art. 8(1) Brussels I recast allows for claims to be joined if they are closely connected. This means that proceedings against multiple defendants can be brought in the forum of any one defendant's domicile, thus

avoiding irreconcilable judgments. The Order applies Art. 8(1) to reach a non-EU manufacturer for alleged infringements in Spain by using an EU-based authorised representative as the necessary anchor.

For UPCA Member States, the UPC asserted jurisdiction against the Hong Kong manufacturer under Art. 7(2)/71b(2), and against the EU domiciled defendants under Art. 4(1), with Art. 34 defining the territorial scope of the orders.

In this case the UPC could not rely on Art. 34 UPCA – as Spain is not a UPCA Member State. Jurisdiction required a close connection under Brussels I recast and plausible allegations of infringing acts in Spain.

The UPC carefully acknowledged precedents that caution against bootstrapping separate national infringements merely because companies belong to the same group (ECJ, 13 July 2006, C-539/03, *Roche Nederland BV and Others v. Primus and Goldenberg*); the close connection in this case hinged on the authorised representative's statutory duties, which enabled EU market access.

Crucially, the EU authorised representative provided the Art. 8(1) anchor, because the claims were closely connected and the representative's mandated role under EU law created a legally necessary link to the manufacturer's distribution activities in Spain and elsewhere.

That regulatory framework was pivotal. The authorised representative must verify that EU declarations of conformity and technical documentation have been drawn up, cooperate with the relevant authorities, and ensure corrective action is taken. The UPC reasoned that these legal tasks are pre-marketing obligations intrinsic to making products available in the EU. In short, without an authorised representative, a non-EU manufacturer cannot lawfully distribute its products. This indispensable role made the representative both an intermediary subject to injunction in UPCA territory (Art. 63(1), second sentence UPCA; Art. 9(1)(a) Enforcement Directive) and the anchor defendant for the purposes of Art. 8(1) Brussels I recast.

In substantive terms, the Order concludes that an injunction against Spain's authorised representative could not be based on the UPCA. The UPC instead relied on Spain's implementation of the Enforcement Directive – Art. 71(2) of the Spanish Patents Act – authorising measures against intermediaries whose services are used for infringements. That bridged jurisdiction and relief: the representative's services were integral to the distribution process, the measures were objective and proportionate, and Spanish law supports the granting of interlocutory injunctions against intermediaries. By contrast, the Order rejected the idea of Spanish jurisdiction over the German distributor and Swedish affiliate, as there were no plausible facts tying them to Spain.

The Order is neither a claim to universal UPC jurisdiction nor an invitation to forum shop through group concatenation. Rather, it is a careful application of Brussels I recast and the Enforcement Directive to contemporary EU product rules. The UPC's restraint – requiring plausible Spanish acts of infringement, refusing Spanish jurisdiction where none were demonstrated, and providing relief against intermediaries via national law – underscores that this is an incremental widening of jurisdiction based on EU private international law and the ECJ's guidance.

For practitioners, the takeaways are clear: map the compliance chain; identify the representative; assess country-specific offers; and precisely invoke the Art. 8(1) connection. The message for businesses is also clear: the authorised representative is not just an administrative contact point – it could be considered as a jurisdictional and injunctive fulcrum for EU market access.

The Order is one of the first court decisions to apply the UPC's "long-arm" in Spain. However, it is still too early to determine its scope and practical implications, and case-by-case analysis is crucial. The debate about the application of UPC decisions in Spain seems far from settled.

The Role of Urgency and Proportionality in Preliminary Injunction Proceedings in Patent Cases in Romania

Ana-Maria Baciu*/Ileana Nicolescu-Decsei**

Urgency and proportionality play a significant role in the way Romanian courts assess preliminary injunctions in patent litigation. This article examines how these principles, despite not being formalized as standalone requirements, interact with the codified prerequisites for injunctive relief, as reflected in recent Romanian case law.

I. Preliminary injunctions in intellectual property disputes in Romania

In Romania, preliminary injunctions relating to intellectual property are primarily governed by Law No. 64/1991 on patents, alongside the Romanian Civil Procedure Code and Government Emergency Ordinance No. 100/2005 on the enforcement of industrial property rights (GEO no. 100/2005). The latter transposes Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (Directive 2004/48/EC).

Either the right holder or any person authorized to exercise the intellectual property right with the right holder's consent may request a preliminary injunction. The claimant must credibly demonstrate that the intellectual property right is subject to an actual or imminent unlawful act that poses a risk of damage that would be difficult to repair.

1. Nature, scope and enforceability of provisional measures

Courts may only order provisional and reversible measures. The most common requests include the provisional cessation of the alleged infringement and measures to preserve evidence, as well as requiring either party (claimant or defendant) to post a bond to secure potential damages if the injunction or defense is later found to be unjustified.

In terms of enforceability, the measures ordered through a preliminary injunction take effect immediately upon publication of the decision and are enforceable. However, upon request and payment of appeal bond, the appellate court can suspend their enforcement until the appeal is resolved.

In order to maintain the effect of the preliminary injunction, an infringement claim must be filed either before or shortly after the request for provisional measures is made. If no such claim is pending when the injunction is granted, the court will set a deadline of up to 30 days for the claimant to submit the main infringement action. Failure to submit the main infringement claim within this period means the preliminary measures become ineffective.

2. Jurisdiction and limitations of judicial review

The preliminary injunction procedures involve two jurisdictional stages: first instance and appeal. Each stage results in a binding and enforceable decision. The court competent to rule on a preliminary injunction is the court with jurisdiction over the merits of the case at first instance, *i.e.* the Tribunal in the territorial jurisdiction of the defendant's domicile.

It is important to note that Romania does not have specialized patent courts and that judges usually lack technical background. Consequently, during preliminary injunction proceedings, courts are not in a position to rule on the validity of the patent or the infringement itself. Instead, they perform a preliminary assessment of the appearance of validity and the likelihood of infringement without engaging in a full technical or substantive analysis. This is particularly important since preliminary injunction proceedings are not compatible with lengthy evidence-taking, such as an expert report; thus, the orders are usually based on the arguments and written evidence produced by the parties.

3. Prerequisites for granting a preliminary injunction

When assessing a request for a preliminary injunction, the court must consider the following closely connected aspects:

- The *prima facie* existence of the allegedly infringed right. The claimant must prove that they are the holder or are exercising the holder's rights in relation to a valid title, even if the title is facing challenges.
- The *prima facie* existence of an imminent or actual infringing act, *i.e.* a credible indication that the defendant is engaged in, or is likely to imminently engage in, conduct that infringes the claimant's intellectual property rights.
- The measures must be provisional and reversible, *i.e.* limited in time pending the resolution of the case on the merits.
- The existence of damage that would be difficult to repair. The claimant must demonstrate that they would suffer such damage in the absence of the requested measures. This may consist of pecuniary or non-pecuniary damage, including material losses and other losses resulting from the infringing acts (*e.g.* loss or reduction of customers or reputation).
- Non-prejudgment of the merits. Preliminary injunction proceedings must not result in a decision on the merits of the case. The court should only assess whether provisional measures are justified based on a summary examination of the facts and legal arguments. If the claimant's request cannot be resolved through such a limited assessment—*i.e.* if it requires an in-depth analysis of the specific conditions examined in the main action—the application for a preliminary injunction should be dismissed.

The following sections will examine the requirements of urgency and proportionality, which, although not formally

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established by law as prerequisites for granting preliminary injunctions, play an important role in the court's assessment.

II. Urgency

1. Presumed, but verified nonetheless

Preliminary injunction proceedings are characterized by their speed and procedural efficiency. They are designed to address situations that require immediate judicial intervention to prevent harm that would be difficult or impossible to repair later.

The urgency is reflected in several procedural particularities. For example: the preliminary injunction is immediately enforceable upon publication. Deadlines for summoning the parties may be shorter than in ordinary proceedings, and in some cases the court may rule without summoning the parties at all. The court must render a decision within 24 hours of the hearing, and the written reasoning must be issued within 48 hours of the ruling.

Apart from the procedural urgency, both case law and legal doctrine emphasize that the combined interpretation of the legal framework[1] leads to the conclusion that the requirement for urgency in granting a preliminary injunction is presumed to be met in cases involving infringed or allegedly infringed patents. This requirement is closely linked to the nature and extent of the alleged harm.

However, this presumption does not prevent the defendant from challenging the existence of urgency at any stage of the proceedings, including on appeal. In other words, the urgent nature of the requested measure must be substantiated until a final decision is issued on the application for the preliminary injunction.

Moreover, although the Romanian legal framework does not explicitly link urgency to the timing of the application, courts usually consider whether the claimant acted promptly. Specifically, the time elapsed between the occurrence (or awareness) of the alleged infringement and the filing of the application may influence the court's assessment of urgency.

Any significant delay without valid justification may be interpreted as tacit acknowledgment that urgent intervention is not required. In other words, once the claimant becomes aware of the actual or imminent infringement, they are expected to act without undue delay. Remaining passive for an extended period may undermine the alleged harm.

However, procedural passivity does not always result in the dismissal of a preliminary injunction. For example, the delay may have represented a reasonable amount of time for the claimant to research and document the infringement or carry out correspondence with the defendant before involving a court. A new element may also have arisen that justified recourse to the procedure in question.

2. Diverging views on urgency

Regarding the condition of urgency, the Bucharest Tribunal stated in a 2020 decision[2] that the requirement for urgency in granting a preliminary injunction is presumed to be met in cases involving infringed or allegedly infringed industrial property rights, pursuant to Art. 9 GEO no. 100/2005. The court reasoned that the urgency stems from the need to protect a right that would be harmed by delay, specifically, the claimant's apparent exclusive right under the patent. This assessment was based on the practical difficulties of quantifying future damages resulting from the continued commercialization of the allegedly infringing products.

Importantly, the Tribunal did not consider the fact that the allegedly infringing product had been on the market for over seven years to be an impediment to granting the injunction. Instead, it emphasized that the patent had been assigned to the claimant in 2018, seemingly justifying the claimant's recent legal action. However, the Bucharest Court of Appeal overturned this decision on appeal,[3] questioning whether the urgency requirement had truly been met, given that the allegedly infringing product had been on the market for around eight years.

The Court of Appeal found that this context suggests that the potential harm to the defendant, if the preliminary injunction is granted but the infringement is not confirmed, would be greater than the harm the claimant might suffer if the defendant is allowed to continue the allegedly unlawful activity. In contrast, the claimant would have an easier path to compensation, including through monetary damages (which had already been requested in the main action), whereas the defendant would face greater difficulty in reversing the effects of an unjustified injunction, especially given that the existence of the alleged infringement remained unclear. In the absence of clear evidence of a *prima facie* infringement and of any particular urgency justifying a risky provisional measure, the court allowed the appeal and dismissed the request for a preliminary injunction.

In a 2021 decision,[4] the Bucharest Court of Appeal overturned the reasoning of the Bucharest Tribunal, acting as the court of first instance, with respect to the urgency requirement for granting a preliminary injunction. More precisely, the Bucharest Tribunal initially rejected the requested preliminary injunction, finding, among other things, that the urgency requirement had not been met. The Tribunal relied on the fact that the defendants began marketing activities relating to the allegedly infringing products (IQOS and HEETS products) as early as 2016, and that the claimants had been aware of these activities well before filing for a preliminary injunction in 2021. Moreover, based on evidence submitted by the defendants, the claimants had previously attempted—unsuccessfully—to stop similar situations arising in other jurisdictions. In this context, the Tribunal concluded that the passage of time did not support a finding of urgency.

The Court of Appeal disagreed with this reasoning. It noted that the patent had been granted by the European Patent Office on 10 July 2019, and that the Romanian Patent

1 Art. 9 of Government Emergency Ordinance No. 100/2005 and Art. 979(1) and (2) of the Civil Procedure Code.
2 RO-Tribunalul București, 26 June 2020, 673/2020 – Apivirol Forte.
3 RO-Curtea de Apel București, 18 September 2020, 1101/2020 – Apivirol Forte.
4 RO-Curtea de Apel București, 27 April 2021, 711/2021 – IQOS.

Office had published information regarding its validation in Romania on 30 January 2020. Given these circumstances, the Court of Appeal accepted the appellant's argument that they could not have acted with reasonable chances of success before 30 January 2020. Although the appellants waited an additional ten months before filing the injunction request in November 2020, the Court of Appeal took into account the complexity of the case and held that this delay did not undermine the matter's urgency. Consequently, the Court of Appeal concluded that the timing of the claimant's filing did not rebut the presumption of urgency.

In a more recent case from 2024,[5] the Court of Appeal overturned the first instance ruling and granted a preliminary injunction concerning a medicinal product. The Court of Appeal found that the legal prerequisites for issuing a preliminary injunction had been met, and provided noteworthy reasoning regarding the requirement of urgency. Specifically, the court held that urgency had been demonstrated despite the defendant's claim that the patent holder had been aware of their preparatory activities as early as 2022. Instead, the court emphasized that the relevant factor was the product's actual market entry in 2023, a fact that the defendant did not contest.

Romanian case law shows that, although urgency is usually assumed in patent preliminary injunction cases, this assumption is not absolute and can be challenged depending on the particular facts and procedural context of each case. The key conclusion is that claimants should not unnecessarily delay preparing and filing their application, as such delays can undermine the urgency, and implicitly the necessity, of the measures they seek to establish. Additionally, actual market entry is increasingly regarded as the defining moment to assess urgency, often carrying more weight than prior knowledge of preparatory activities.

III. Proportionality

Although the proportionality requirement is not explicitly stated in the legal provisions governing preliminary injunctions in the field of intellectual property, it follows from Art. 3(2) GEO no. 100/2005, as well as recital 25 and Art. 3(2) of Directive No. 2004/48/EC. GEO no. 100/2005 transposes the latter and must be interpreted in light of it.

Although case law on this subject is rather scarce, it seems that Romanian courts typically evaluate whether the impact of the measure is justified and proportionate in relation to the harm it aims to prevent and the potential harm it could cause to the defendant. This involves balancing the interests of both parties in light of the requested measures and the circumstances of the case. Case law shows that, when carrying out the proportionality test, courts generally weigh the claimant's apparent valid title and apparent infringement against the consequences of granting a preliminary injunction that might later be deemed unjustified.

Current case law shows that, when there are significant challenges to the appearance of the right and/or infringement, Romanian courts consider the parties' financial strength and business scale to be relevant factors. Typically, courts examine factors such as turnover, the number of employees, and the estimated sales of the allegedly infringing products. These factors help the court to assess whether the provisional measures would cause serious and difficult-to-remedy harm to the defendant, and whether the claimant could recover any potential damages after a final decision on the merits.[6]

In a generic versus innovator dispute, the Bucharest Tribunal took the interests of patients in accessing more affordable medication into account when conducting a proportionality analysis. However, the Court of Appeal did not uphold this reasoning and granted the preliminary injunction. Despite the patent being challenged, the appellate court held that the presumption of validity prevails and that the assessment of damages should primarily focus on the harm suffered by the patent holder. While the court acknowledged the potential harm to the defendant and loss of benefits for third parties (such as patients), it emphasized that the patent holder is rewarded with a temporary monopoly as a result of their innovation. Therefore, the requirement for damages is intended to safeguard that exclusive right.[7]

IV. Closing remark

The principles of urgency and proportionality are playing an increasingly important role in how Romanian courts assess preliminary injunctions in patent cases. Judges must strike a careful balance between protecting the claimant's intellectual property rights and avoiding the potentially irreversible impact that provisional measures could have on the defendant's business, or even broader public interests.

Although urgency is generally assumed in intellectual property disputes, recent case law has confirmed that this presumption is not bulletproof. Delays in filing can cast doubt on the need for immediate court intervention. At the same time, although still a developing concept in Romanian jurisprudence, proportionality requires courts to weigh the strength of the claimant's case against the possible economic or societal consequences of granting an injunction.

The takeaway from this growing body of case law is clear: claimants must be vigilant and act without undue delay, while courts must continue to consider the risk of disproportionate harm in the context of each case's specific circumstances.

5 The decision is not currently available on public case law databases.
6 RO-Curtea de Apel București, 27 April 2021, 711/2021 – IQOS.
7 The decision is not currently available on public case law databases.

The Role of Urgency and Proportionality in Preliminary Injunction Proceedings in Patent Cases in the UK

Pete Damerell*/Daniel Down**/Adam Mackinnon***

The key focus of the Courts of England and Wales when considering applications for preliminary injunctions is an assessment of the extent to which the parties would suffer damage (which could not be adequately compensated) in the period prior to a decision on the merits if a preliminary injunction was, or was not, granted, rather than the merits of the parties' arguments on infringement and validity. If the patentee could be adequately compensated in damages if a preliminary injunction is not granted but the respondent is later held to infringe a valid patent following the trial on the merits, no preliminary injunction will be granted. Conversely, if the respondent would be adequately compensated under a patentee's cross-undertaking in damages if a preliminary injunction is granted, but the respondent is held not to infringe a valid patent following the trial on the merits, then a preliminary injunction should normally be granted. However, if neither party would be adequately compensated in damages in these scenarios, then the Court will consider where the 'balance of convenience' lies to decide whether or not to grant the preliminary injunction. As explained below, factors such as urgency and proportionality form part of this 'balance of convenience' assessment. Where these factors are balanced and it is therefore not possible to determine which course is likely to cause the least irremediable prejudice to the parties, the Court will preserve the *status quo*.

Most preliminary injunction applications are made on an *inter partes* basis. However, *ex parte* applications may be made in situations with extreme urgency (with any injunction granted usually only being for a short period, a matter of days, until an *inter partes* hearing can be held). Urgency is therefore an especially important factor in that scenario.

I. Legal principles governing preliminary injunctions

1. Legal basis

The Courts have the power to grant a preliminary (or 'interim') injunction to restrain a party from infringement pending a trial on the merits where it appears to the Court to be "just and convenient"[1] to do so. Injunctions are a discretionary remedy and the Court has a wide discretion, although the Court follows established principles that have been developed through case law. As a condition of granting a preliminary injunction, the applicant will be required to give a cross undertaking in damages (to ensure that the respondent is compensated for any damage that it suffers if the patent is ultimately held not to be infringed, including for the reason that it is invalid).

In practice, the overwhelming majority of preliminary injunctions are granted in the context of disputes between pharmaceutical originators and generic manufacturers. There are numerous cases which have considered the nature of the regulation and pricing restrictions in this market, and held that the originator may suffer unquantifiable damage that cannot be adequately compensated if a preliminary injunction is not granted but the patent is held to be valid and infringed following a trial on the merits. Preliminary injunctions in other contexts are rare.

2. The *American Cyanamid* guidelines

The principles governing the grant of an interim injunction in a patent infringement action have been developed through case law. The decision of the House of Lords (the precursor to the UK's Supreme Court) in *American Cyanamid*[2] is the leading authority governing the grant of interim injunctions. The Court explained as follows:

"The object of the interlocutory injunction is to protect the plaintiff against injury by violation of his right for which he could not be adequately compensated in damages recoverable in the action if the uncertainty were resolved in his favour at the trial; but the plaintiff's need for protection must be weighed against the corresponding need of the defendant to be protected against injury resulting from his having been prevented from exercising his own legal rights for which he could not be adequately compensated under the plaintiff's undertaking in damages if the uncertainty were resolved in the defendant's favour at the trial. The Court must weigh one need against another and determine where 'the balance of convenience' lies."

These principles have been distilled into a series of sequential questions often referred to as the *American Cyanamid* guidelines:

1. The first question, which asks "whether or not there is a *serious question to be tried*", represents a threshold test regarding the underlying claim (i.e. the claim for patent infringement). The applicant does not need to demonstrate a "probability" of success, nor set out a "*prima facie* case", to meet this standard. The question is simply whether it can be shown that the claim is "not frivolous or vexatious", i.e. that the applicant has a "real prospect of succeeding" in the underlying claim. The Court's role at this stage is not to grapple with more complex issues as to the facts or law in dispute, to prevent the interim hearing descending into an undesirable mini-trial. This is evidently a relatively low bar, whereby relief will only be refused on this *prima facie* basis to very weak causes of action.
2. Next, the Court will consider: (i) whether "*damages* would be *an adequate remedy*" for the applicant if the preliminary injunction sought was not granted and the applicant subsequently succeeded at trial; and (ii) whether

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1 Section 37(1) Senior Courts Act 1981.
2 American Cyanamid Co v Ethicon Ltd [1975] R.P.C. 513.

the respondent would, in fact, "be in a financial position to pay it". If the applicant cannot demonstrate that they will suffer irreparable or unquantifiable harm, no interim injunction should be granted, regardless of the strength of the applicant's case.

However, if damages are held not to be an adequate remedy for the applicant, the Court should consider whether, on the contrary hypothesis (that the respondent was to ultimately succeed at trial) the respondent would be adequately compensated under the applicant's undertaking as to damages for the loss that the respondent would have sustained by being injuncted in the period between the successful application and trial. If damages under the cross-undertaking would be an adequate remedy and the applicant is in a financial position to pay them, there would be no reason, based on this ground, to refuse an interim injunction.

3. Where there is doubt as to the adequacy of the respective remedies in damages available to either party, or both, "the question of the *balance of convenience* arises". The relevant factors and their weight will vary from case to case. Where these factors appear evenly balanced, measures will generally be taken to *preserve the status quo*.

3. The current approach to *American Cyanamid* – still fit for purpose?

A question that remains unanswered is whether the Court should continue to apply the *American Cyanamid* guidelines sequentially and independently (as historically they have been), or whether they should be considered together in a holistic manner.

The impetus for this discussion comes from the Supreme Court of Ireland's decision in *MSD v Clonmel*[3], which concerned an attempt to prevent the sale of a generic version of Merck's "bad" cholesterol-reducing Inegy medicine in infringement proceedings, where a less mechanistic and more flexible approach to the *American Cyanamid* questions was taken. The Court held that if they were "not applied with some degree of flexibility, it can have a distorting effect". By way of example, the Court found that the adequacy of damages for both the applicant and respondent (point 2 above) forms part of the consideration of the balance of convenience (point 3 above) rather than a separate and distinct obstacle for the applicant to overcome.

However, the English Courts have yet to resolve this question. Following the English Court of Appeal's decision in *Neurim v Generics*[4] (in the context of a second medical use patent for a compound to improve restorative sleep in insomnia patients), an appeal to the Supreme Court against the decision to refuse an interim injunction was lodged on the basis that the English courts should adopt a similar approach to the Supreme Court of Ireland. A three-judge panel of the UK Supreme Court (Lords Kerr, Lloyd-Jones, Kitchin JJ SC) ultimately denied the application for permission to appeal, since the timing of any appeal would effectively render it nugatory. However, the UK Supreme Court did agree that there was a public interest in hearing the question of whether the English courts should approach the *American Cyanamid* questions more holistically:

"The panel considered that there is a point of law of public general importance touching on the question whether the four-stage test outlined by Lord Diplock in American Cyanamid Co v Ethicon Ltd [1975] AC 396 should be applied in a rigid and strictly sequential manner or whether a more overarching and flexible approach to the issues adumbrated by Lord Diplock would be appropriate – cf. the observations of Lord Goff in R v Secretary of State for Transport ex p. Factortame Ltd (No 2) [1991] 1 AC 603.

The panel decided, however, that permission should not be given in this case. Prominent among the reasons for this decision was the imminence of the trial in the action."

The reasons for refusal of permission to appeal have no strict precedential value, however. More recently, the English Court of Appeal has indicated that it remains bound by the House of Lord's decision in American Cyanamid and therefore it is not open to it to follow the alternative approach advocated by the Supreme Court of Ireland. For example, it stated in *Astrazeneca AB, Astrazeneca UK Limited v Glenmark Pharmaceuticals Europe Limited* that "it is not open to this Court to follow the Irish Supreme Court in MSD v Clonmel because we are bound by American Cyanamid."[5]

The Court of Appeal's statement suggests that it is likely to require a further appeal to the UK Supreme Court before this question can be resolved with any certainty. Any future shift in the approach to the *American Cyanamid* questions could have corresponding implications for the considerations of urgency and proportionality, which, as explained in Sections II and III below, tend to be considered as part of the final question of the 'balance of convenience'.

II. Urgency

1. Unreasonable delay generally impermissible, but no strict requirement

In the UK, there is no standalone, strict or formal requirement under the *American Cyanamid* guidelines or otherwise which requires an applicant to bring an application for a preliminary injunction within a set period of time. Nevertheless, the concept of 'urgency' does exist and is addressed by reference to any 'delay' by the applicant in seeking the preliminary injunction. Accordingly, the general rule is that a preliminary injunction will not usually be granted if the applicant has unreasonably delayed in seeking to obtain such relief. This is because, in general, delay is regarded as being suggestive of a less acute need for an immediate injunction. In addition, the longer the period of time in which the respondent has allegedly infringed the applicant's rights, the greater the risk that the grant of an interim injunction would cause even greater prejudice to the respondent if it was subsequently overturned at a later stage of the proceedings.

3 Merck Sharp & Dohme Corp v Clonmel Healthcare Ltd [2019] IESC 65.
4 Neurim Pharmaceuticals (1991) Ltd v Generics (UK) Ltd [2022] EWCA Civ 699.
5 [2025] EWHC 748 (Pat).

The same standard applies to patent cases as any other request for a preliminary injunction[6] – the general requirement for the claimant to "come promptly" applies:

"Now I am *not aware*, having regard to patents, that there is *any substantial ground of distinction between an interlocutory injunction upon a patent right and upon any other*. The principles appear to me to be *substantially the same*; and the general rule of the court is that *a person who comes to ask for that remedy*, which is granted with despatch and for the purposes of protecting rights until the trial, *should come promptly*" (*emphasis added*).[7]

In English practice, the issue comes into play as just one of the multitude of factors which are taken into account by the Court when assessing the final question of *American Cyanamid*, namely where the "balance of convenience" lies (i.e., after the questions of serious of issue to be tried and adequacy of damages have already been assessed). Though not necessarily decisive, the English Courts have held that "the delay in bringing the application is a powerful factor against the grant of an injunction".[8]

Therefore, although there is no strict requirement and it does not automatically negate the award of a preliminary injunction, any unreasonable delay by the applicant in seeking the preliminary injunction can be an important factor to be considered by the Court when weighing up its discretion.

Overall, the position is aptly summarised by Lionel Bently and Sir Richard Arnold: "[i]nterim injunctions are *likely* to be denied on the basis of delay" (*emphasis added*).[9]

2. How much delay is too much?

In line with the Court's flexible approach to the consideration of delay in the framework of the *American Cyanamid* principles, there is also no specific amount of delay which will prevent an applicant from obtaining a preliminary injunction. Instead, this will vary depending on all the circumstances of the individual case and the prejudice that would be caused to each party by the award or refusal of a preliminary injunction.[10] However, there are some cases that provide a limited amount of guidance.

In the 1975 decision of *Radley Gowns Ltd v Costas Spyrou* (in the context of an alleged breach of copyright concerning the production of patterned dresses), a two-month delay (in and of itself) was not fatal to an application for a preliminary injunction.[11] In that case, a delay of six weeks before sending a letter of action had been adequately explained by the claimants' "not unnatural preoccupation with Christmas trade" and that in the absence of any evidence that the defendant had materially changed his position for the worse on the strength of the subsequent two months' delay (before starting the claim), that was held not to be of such a serious order that the claimants should be refused the relief sought.

A more recent decision by the Patents Court of England and Wales in *Bayer v Aspire*[12], which concerned the pharmaceutical rivaroxaban (an oral anticoagulant to prevent blood clotting), led to the grant of a preliminary injunction despite there having been "a degree of delay" on the part of both the claimant and the defendant, as evidenced by their various correspondence and exchanges of evidence leading up to a hearing.

It is therefore clear that there is no hard and fast rule and, as set out further below, the Court will consider the circumstances of any such delay when exercising its discretion.

3. Circumstances of the delay

In addition to the length of the delay, the circumstances of any such delay are also likely to be relevant to the Court's decision making. If the delay cannot be reasonably justified, it will usually lead to an application for a preliminary injunction failing.[13]

In one (19th century!) case, a delay was acceptable because the applicant's solicitors had advised the applicant to wait until the respondent was in a financial position to manufacture the allegedly infringing products.[14]

In another case, the respondent's own conduct forced a delay by refusing to engage with the applicant by providing requested samples prior to the launch of the allegedly infringing products.[15] In such a scenario, the Court held that the applicant should not be penalised for a delay that was entirely of the respondent's making. Generally, where the applicant's delay has not prompted any change in the respondent's conduct, it will be given less prominence by the Court when assessing the balance of convenience.

Furthermore, any delay which relates to persons who are not parties to the application in question is not a ground for refusing an injunction, if there has been no delay in proceeding against the respondent.[16]

However, it is not sufficient for an applicant to seek to justify delay on the basis that there are multiple infringers and it is not practical to seek a preliminary injunction against each and every one.[17]

6 By way of example, delay has in recent years been considered to be an important factor within the balance of convenience test in the context of employers' applications for interim injunctions to restrict the activities of former employees (and therefore protect confidential information).
7 North British Rubber Co v Gormully and Jeffery Co (1894) 12 R.P.C. 17.
8 AAH Pharmaceuticals Ltd v Pfizer Ltd [2007] EWHC 565 (Ch). In this case, the Court had already held that the issue of the strength of the claimant's case and the damage which could flow from a grant or refusal of an injunction were considerations which led to refusal of the injunction (and therefore the issue of delay was not conclusive).
9 Injunctions in Patent Law, Trans-Atlantic Dialogues on Flexibility and Tailoring, pp. 261–290.
10 Monsanto Co v Stauffer Chemical Co (N.Z.) [1984] F.S.R. 559 at 572.
11 [1975] FSR 455.
12 Bayer Intellectual Property GmbH v Aspire Pharma Ltd [2024] EWHC 711 (Pat).
13 Blinkx UK Ltd v Blinkbox Entertainment Ltd [2010] EWHC 1624 (Ch). In this case, a delay of nearly two years resulted in the application for a preliminary injunction being refused, and the Court had regard to the fact that the respondent's business had grown substantially in the intervening period between the claimant becoming aware of the alleged breach and the application being filed.
14 United Telephone Co v Equitable Telephone Association (1888) 5 R.P.C. 233.
15 Leo Pharma A/S v Sandoz Ltd [2008] EWHC 541 (Pat).
16 Pneumatic Tyre Co v Warrilow (1896) 13 R.P.C. 284.
17 Bovill v Crate (1865) L.R. 1 Eq. 388.

4. Urgency in *inter partes* versus *ex parte* applications

Whereas typical *inter partes* applications are granted on notice and generally run at least until the determination of a corresponding merits action, *ex parte* applications for a preliminary injunction may in exceptional emergency cases be granted immediately without notice to the respondent, generally lasting only a few days until an *inter partes* hearing takes place.

In an *ex parte* context, the applicant must justify why the application is urgent. Generally, this will be because it can show that the respondent would take advantage of any notice, or because any delay (to allow the scheduling of an *inter partes* hearing) would cause further damage.

For *ex parte* applications, the applicant has a duty of "full and frank" disclosure. Where an urgent injunction is sought *ex parte*, the Court places a high degree of trust in the applicant to give an accurate and complete summary of the facts, not merely those supporting its case. The applicant must avoid misleading the Court by any act or omission and must disclose all relevant facts, whether helpful or harmful to the application.

5. Trial expedition as an alternative to an interim injunction

It is worth noting that the Patents Court Guide, which applies to proceedings in the Patents Court, explains[18] that: "[a]pplicants for interim remedies (in particular, interim injunctions) and respondents are encouraged to consider whether an expedited (speedy) trial would better meet the interests of justice". It further explains that, depending on the circumstances, "varying degrees of expedition are possible. Some cases may warrant extreme expedition, others a lesser degree".

There have been a number of cases where a preliminary injunction to restrain patent infringement was refused in circumstances where an expedited trial was instead ordered.[19,20] Therefore, even where an applicant acts without *any* delay upon becoming aware of an actual or imminent infringement of its rights and seeks a preliminary injunction from the Court on an urgent basis, this alone will not necessarily be sufficient to secure the relief sought if there is a prospect of obtaining a merits decision (and therefore a final injunction) within a reasonable time period. The logic for this approach has been that damages in the short period will be quantifiable (usually, in the pharmaceutical context, because the period of time is insufficient for sales of the generic product to lead to changes in the pricing scheme for the originator product).

Conversely, the grant of an interim injunction is, in itself, a factor which can be taken into account when the Court is weighing up whether to grant an expedited trial or not (although it does not follow from the fact that a preliminary injunction has been granted in an intellectual property case that an expedited trial should follow as a matter of course).[21]

6. Preliminary injunctions for patent applications?

In limited circumstances, the Court may grant a preliminary injunction to restrain rival products from entering the market *prior* to the grant of a patent (and therefore inherently before any infringing acts could possibly occur). This issue arose for the first time before the English courts relatively recently in *Novartis v Teva*[22] in which the defendants had received a marketing authorisation for the pharmaceutical drug fingolimod which is used to treat multiple sclerosis, and the claimants were seeking to prevent them from entering the market pending a merits decision despite the patent-in-suit (to a dosing regimen) not having yet been granted.

However, while the jurisdiction of the English Courts to grant this type of relief has been established, this circumstance is unlikely to arise very frequently. To date it has only applied in situations *after* the European Patent Office has indicated that the patent will be granted, but *before* the formal procedure for grant has completed (i.e., that the grant of the patent has become certain and a mere formality). Accordingly, the case was exceptional in that there could be no doubt that the patent was going to be granted, or as to the form in which it was going to be granted. In such cases, the usual principles under *American Cyanamid* are to be applied to determine whether a preliminary injunction should be awarded. In this case, despite holding that it could grant a preliminary injunction, the Court did not do so on the facts of the case.

III. Proportionality

1. No formal proportionality test – a discretionary remedy

As with urgency, there is no specific proportionality test set out in the framework of the *American Cyanamid* guidelines. However, the proportionality (or otherwise) of granting a preliminary injunction is inseparably wrapped up within the 'adequacy of damages' and 'balance of convenience' stages of the test. Ultimately, as discussed above, a preliminary injunction is a discretionary remedy, which is only granted where it is "just and convenient"[23] to do so. This necessarily involves an assessment of whether the award of the remedy would be equitable to the parties.

2. Adequacy of damages

Lord Hoffmann explained in *National Commercial Bank*[24] that in practice it is often hard to tell whether either damages or the cross-undertaking will be an adequate remedy, and the Court has to engage in trying to predict whether granting or

18 See paragraph 12.7.

19 Neurim Pharmaceuticals (1991) Limited and another v Generics UK Limited and another [2020] EWCA Civ 793. In this case, the short period between the hearing of the application for the interim injunction and the hearing on the merits (only four months) was held to make a price spiral causing uncompensatable damage less likely.

20 See also Evalve, Inc. and others v Edwards Lifesciences Limited [2019] EWHC 1158 (Pat), in which the Court refused to grant a preliminary injunction in favour of Evalve, which had already succeeded in an application for expedition of the merits proceedings. As a consequence of this earlier application, Evalve was also ordered to pay the costs of the application for a preliminary injunction. In this case, there was a seven-month period between the application for preliminary injunction and the expedited trial.

21 See for example Floyd J (as he then was) in Warner-Lambert Company LLC v Teva UK Ltd & Ors [2011] EWHC 2018 (Ch).

22 Novartis AG and another v Teva UK Ltd and others [2022] EWHC 959 (Ch).

23 Section 37(1) Senior Courts Act 1981.

24 National Commercial Bank Jamaica Ltd v Olint Corp Ltd [2009] UKPC 16; [2009] 1 W.L.R 1405 at [17].

withholding an injunction is more or less likely to cause irremediable prejudice (and to what extent). The Court should take whichever course seems likely to cause the least irremediable prejudice to one party or the other.

However, a key reason that the grant of a preliminary injunction is rare in the UK is that the Court usually finds that applicants can be adequately compensated for in damages. For example, for many years it was accepted in most cases that a generic drug launch would lead to a price spiral and therefore cause irreparable harm to an applicant. Some recent judgments, such as *Neurim v Generics*[25], have made clear that this cannot be assumed, and must be established on the facts of each case.

The situation can become even more complex in circumstances where multiple products may be available to treat a particular disease. In a very recent example, Boehringer Ingelheim (BI) sought a preliminary injunction against Dr Reddy's to prevent it from launching a generic version of empagliflozin, an SGLT2 inhibitor licensed for the treatment of type 2 diabetes, heart failure and kidney disease. By the time of the hearing, Dr Reddy's was the only generic company in a position to launch. However, an alternative product dapagliflozin is also authorised to treat type 2 diabetes in the UK and, earlier this year, the patent covering dapagliflozin was declared invalid by the Patents Court and the Court of Appeal, with permission to appeal to the Supreme Court being refused. In response, numerous generic dapagliflozin products were launched, leading to its reimbursement price dropping significantly and the NHS issuing guidance recommending *inter alia* that empagliflozin patients be proactively switched to dapagliflozin.

On this basis, Dr Reddy's contended that a corresponding decline in the empagliflozin market would make it commercially unattractive for third parties to launch such products and damages would be an adequate remedy for BI on the basis that there would be no price spiral. However, the Judge disagreed that the decline would be so fast or as significant and there was in fact a considerably risk of other generic entrants before the merits trial with a knock-on impact on jobs, product pipeline and partnership programs. Accordingly, the Judge went on to consider the remaining limbs of the *American Cyanamid* test and ultimately awarded the interim injunction.[26]

3. Balance of convenience and the *status quo*

Assuming that damages would not be an adequate remedy, the Court must consider the adequacy of the applicant's cross-undertaking in damages. If there is no adequate remedy for either side, the Court must consider all other relevant factors and the 'balance of convenience'. If the balance of convenience favours neither party, the Court should preserve the *status quo*.

Although it is not a formal requirement, there is a general expectation for manufacturers of generic pharmaceuticals to initiate a revocation claim to 'clear the way', and a failure to do so has historically led to generic manufacturers falling on the wrong side of the balance of convenience.[27] To that end, the English Courts have tended to find[28] that in cases between a pharmaceutical patentee and a generic manufacturer, the balance of convenience lies with granting a preliminary injunction, since the damage incurred by the patentee will be greater. This is particularly the case when one considers the damage to goodwill caused by dropping prices to compete with generics and then attempting to raise them again following the grant of a permanent injunction. The question is ultimately fact-specific. Although some practitioners have speculated that some recent case law[29] suggests that the general presumption (i.e., that the patentee will suffer greater damage than their counterparty) may not be as reliable as previously thought, this appeared to carry considerable weight in the very recent decision of *Dr Reddy's v Boehringer Ingelheim* discussed above. Having found that damages would not be an adequate remedy for either party and that the case was not one in which the size or likelihood of the unquantifiable harm, or the uncertainties in assessing it, could be seen to be greater for one party than the other, the Court had firmly in mind that the *status quo* favours the grant of the injunction. Dr Reddy's had offered no evidence to explain its conduct of the litigation in the context of effectively clearing the path, despite pointing to BI's alleged 'patent thicket' which made clearing the way a 'practical impossibility'. In particular, it was not permitted to rely on what was described as an entirely foreseeable change in the empagliflozin market (arising from the genericisation of dapagliflozin in a decision earlier this year) to justify a change in its plans.

Another example of a scenario in which a respondent to an application for a preliminary injunction was on the right side of the balance of convenience, notwithstanding that it had failed to clear the way in a medical device context, arose in *Evalve v Edwards Lifesciences*.[30] Here, the respondent offered to limit its marketing activities before a merits decision to ten implantations (of a prosthetic device designed to repair leaking mitral valves) in two hospitals. In such circumstances, the balance of convenience favoured refusal of the preliminary injunction. However, this could equally be argued to amount to a decision that the award of a preliminary injunction would be disproportionate.

25 Neurim Pharmaceuticals (1991) Ltd v Generics (UK) Ltd [2022] EWCA Civ 699.

26 Dr Reddy's Laboratories (UK) Limited v Boehringer Ingelheim International GmbH [2025] EWHC 2834 (Pat).

27 SmithKline Beecham Plc and others v Apotex Europe Ltd and others [2006] EWCA Civ 658 and AstraZeneca AB and another v Glenmark Pharmaceuticals Europe Limited [2025] EWCA Civ 480.

28 See a summary of some cases following this principle in Cephalon Inc v Orchid Europe Ltd, [2010] EWHC 2945 (Pat) at [49].

29 For example, AstraZeneca AB and another v Glenmark Pharmaceuticals Europe Limited [2025] EWHC 748 (Pat). However, this decision was overturned on appeal, where the Court of Appeal held that "it is proper for a court to take into account, when considering the balance of the risk of injustice and deciding to preserve the status quo, that the generic company could have 'cleared the path' for its launch by bringing proceedings for revocation of the patent sufficiently far in advance".

30 Evalve, Inc. and others v Edwards Lifesciences Limited [2019] EWHC 1158 (Pat).

The Case Law of the Unified Patent Court from 1 August to 30 November 2025

Yasmine Azzaoui*

This report provides an overview of the case law delivered by the UPC between 1 August and 30 November 2025. During this period, the Court continued to refine key aspects of substantive and procedural law. Notably, the Court of Appeal issued two important decisions in November providing initial guidance on the assessment of inventive step. The decisions reviewed illustrate the Court's ongoing efforts to harmonize approaches across divisions. Although the considerable number of decisions rendered makes it difficult to ensure complete exhaustiveness, we hope this overview will be a helpful resource.

I. Substantive law

1. Applicable law

The Munich Local Division[1] had to reconcile earlier German nullity proceedings with a UPC counterclaim for revocation relating to the same patent. The Court applied res judicata in a state-specific and ground-specific manner: for Germany, it declined to revisit novelty and inventive step already decided by the German court but accepted that it could still assess sufficiency of disclosure because this ground had not been raised nationally. For the other UPC states designated for the EP (France, Italy, Romania), the Court carried out its own validity assessment on all grounds.

The Court of Appeal[2] recalled that while national law is a source of law under Art. 24 UPCA, it is for the parties themselves to establish the relevant facts and evidence concerning the content and application of national law.

2. Infringement

The Mannheim Local Division[3] held that where the defendant disputes the implementation of a claim feature, the claimant must provide sufficiently specific facts concerning the design of the attacked embodiment. The degree of substantiation required depends on the level of detail with which the implementation is contested.

The Court of Appeal[4] confirmed that the concept of "offering" in Art. 25(a) UPCA must be interpreted autonomously and in an economic sense. It includes acts occurring prior to contract formation that may divert business from the patent proprietor and does not require a legally binding offer. A mere product presentation, including an invitation to submit an offer, may suffice.

The Mannheim Local Division[5] held that where a patented product is designed so that its components can be assembled at the place of use without the addition of further items, the offering or supply of all such components already constitutes direct infringement under Art. 25(a) UPCA. It further stated that when a patented product consists of at least two coordinated components intended, by their design, to be assembled into the patented product without additional items, the sale of a single such component may amount to direct infringement if the possibility of assembling the remaining components is indicated or is otherwise apparent.

a) Claim construction

The Munich Local Division confirms the approach already taken by the Court of Appeal of the UPC in *Nanostring v. 10xGenomics* decision held on 26 February 2023 and consider that the interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used but rather, the description and the drawings must always be taken into account as aids to the interpretation of the claim. However, this does not mean that the patent claim serves only as a guideline and that its subject matter may extend to what the patent proprietor has contemplated from a consideration of the description and drawings. These principles for the interpretation of a patent claim apply equally to the assessment of the infringement and the validity of a European Patent.[6]

The Court of Appeal[7] recalled that, as a general principle of claim construction, any product or process described in the patent specification as an embodiment is normally regarded as falling within the scope of the claims. This presumption may, however, be displaced where the specification, read as a whole, clearly teaches the skilled person that a disclosed embodiment is not actually claimed, such as where the embodiment merely illustrates a technical specification that is not addressed by the claimed teaching.

The Düsseldorf Local Division[8] held that the scope of protection of a device claim generally extends to embodiments that contain the claimed structural features even if they do not fully achieve the technical function or advantage described in the patent, and that it would be incompatible with adequate protection to limit the claim to embodiments that realize such functions or advantages.

In *Amgen v. Sanofi*,[9] the Court of Appeal clarifies that the interpretative value of a dependent claim for construing the main claim is context-specific, and that where the dependent

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1 UPC-LD Munich, 15 October 2025, UPC_CFI_114/2024 and UPC_CFI_448/2024.
2 UPC-CoA, 13 August 2025, UPC_CoA_446/2025 and UPC_CoA_520/2025.
3 UPC-LD Mannheim, 9 October 2025, UPC_CFI_132/2024.
4 UPC-CoA, 3 October 2025, UPC_CoA_534/2024, UPC_CoA_19/2025 and UPC_CoA_683/2024.
5 UPC-LD Mannheim, 12 September 2025, UPC_CFI_338/2024.
6 UPC-LD Munich, 1 August 2025, UPC_CFI_54/2024 and UPC_CFI_396/2024.
7 UPC-CoA, 25 November 2025, UPC_CoA_464/2024, UPC_CoA_530/2024, UPC_CoA_21/2025, UPC_CoA_457/2024, UPC_CoA_532/2024, UPC_CoA_27/2025, UPC_CoA_458/2024 and UPC_CoA_533/2024.
8 UPC-LD Düsseldorf, 31 October 2025, UPC_CFI_630/2025.
9 UPC-CoA, 25 November 2025, UPC_CoA_528/2024 and UPC_CoA_529/2024; a more detailed analysis of the UPC's case-law concerning inventive steps will be published in one of the next EPLP issues.

claim merely adds an additional feature without providing a more specific technical characterization of the main claim, it generally cannot be used to draw conclusions that narrow or define the scope of the main claim. In the context of claims drafted in medical-use format, the Court holds that therapeutic efficacy is an inherent claim feature: the claimed product must be objectively suitable for the stated medical use, meaning that the treatment must produce a meaningful, clinically perceptible improvement in the patient's condition. The fact that neither the claim wording nor the description specifies a minimum therapeutic effect does not alter this requirement, since the obligation stems not from the literal claim language but from the legal implications of the medical-use claim format itself.

b) Imminent infringement

The Court of Appeal[10] held that neither the filing of a marketing authorization application by a generics company nor the grant of such authorization constitutes an imminent infringement. By contrast, the completion of national procedures for health technology assessment, pricing and reimbursement may amount to imminent infringement, depending on the national regulatory framework and the circumstances of the case. The Court rejected a request for an order to communicate information in case of an alleged imminent infringement because there was no indication that the requested information existed, nor any showing that it was reasonably necessary for advancing the requesting party's case.

c) Doctrine of equivalence

The Hague Local Division[11] stated its preference for a harmonized approach to equivalence within the UPC, drawing on the doctrines applied across Contracting Member States. It emphasized that equivalent patent infringement is excluded where there is no technical-functional equivalence: where the substituted means do not perform essentially the same function to achieve essentially the same result. Conversely, a finding of equivalence requires that the variant performs the same function as the claimed element, with essentially the same result. The Court also noted that protection cannot extend to what is not novel or inventive over the prior art, in line with Art. 1 of the Protocol on the interpretation of Art. 69 EPC and established national doctrines. In the absence of an alternative test proposed by the parties, and referring to its reasoning in *Plant-e v. Arkyn*, the Court applied the same equivalence test.

The Paris Local Division[12] discussed indirect infringement under Art. 26 UPCA and Art. 69 EPC and its Protocol, noting the need for a harmonised approach within the UPC. Referring to prior UPC case law, the Court applied the first step of the equivalence test, namely whether the modified or substituted means essentially perform the same function to achieve essentially the same effect.

The Paris Local Division[13] recalled in another case that, under Art. 24 UPCA, the applicable sources of law include the EPC and Art. 2 of the Protocol on the Interpretation of Art. 69 EPC, which requires due account to be taken of elements equivalent to those indicated in the claims. Referring to earlier UPC case law from the Paris, Mannheim and Brussels Local Divisions, the Court held that, in the absence of agreement between the parties on the applicable national test, a harmonized UPC approach must be adopted. It therefore applied the first step of the equivalence analysis: whether the modified (or substituted) means essentially perform the same function to achieve essentially the same effect.

d) Defences

aa) Prior use

The Munich Local Division[14] gave a detailed application of Art. 28 UPCA (right based on prior use). It emphasized that the content and scope of the prior-use right are determined by the relevant national law and are strictly territorial. Applying German law, the Court found prior use because the defendant had, before the priority date, both developed and commercially offered sintering pastes with parameter values clearly inside the amended claim range, and had committed itself to continuing these formulations. The LD accepted that the defendant did not need to have understood the parameter values in patent terms; it was enough that the technical conditions of the claim were objectively fulfilled and that the defendant pursued the same technical effect.

bb) Market abuse

The Munich Local Division[15] held that the defendants' antitrust defense was unsubstantiated, finding that the factual material presented did not meet the threshold required to assume market abuse under Art. 102 TFEU. While the defendants argued that the patented technology constitutes a de facto industry standard whose control by three major companies allegedly enables exclusionary practices and discriminatory licensing, the Court observed that these assertions were supported only by forecasts and speculative market projections rather than verifiable data. The Court emphasized that assessing market dominance requires a concrete definition of the relevant market, identification of market participants and evidence of actual market power. During oral proceedings, the defendants themselves acknowledged that their key market-share chart for 2024 onwards was only a forecast lacking valid figures. The Court further noted that none of the additional documents submitted demonstrated current dominance or supported the allegation of coordinated exclusion. Given the absence of sufficiently substantiated facts, the Court rejected the request for production of documents and held that no dominant-market-position argument could be upheld on the basis of the evidence presented.

3. Remedies

a) Injunctions

aa) Proportionality

The Paris Central Division[16] stated that while a general injunction to restrain future infringements is the normal reme-

10 UPC-CoA, 13 August 2025, UPC_CoA_446/2025 and UPC_CoA_520/2025.
11 UPC-LD The Hague, 11 September 2025, UPC_CFI_479/2025.
12 UPC-LD Paris, 1 August 2025, UPC_CFI_363/2024.
13 UPC-LD Paris, 24 October 2025, UPC_CFI_612/2024.
14 UPC-LD Munich, 15 October 2025, UPC_CFI_114/2024 and UPC_CFI_448/2024.
15 UPC-LD Munich, 28 November 2025, UPC_CFI_425/2024 and UPC_CFI_751/2024.
16 UPC-CD Paris, 20 October 2025, UPC_CFI_189/2024 and UPC_CFI_434/2024.

dy where infringement is found, it retains discretion to refuse an injunction where such measures would be disproportionate or unduly detrimental to the interests of third parties. It further held that selecting certain treatment options from among those available to medical practitioners does not in itself constitute a relevant public interest, and that the fact that a particular device has been chosen does not imply that adequate treatment could not be provided with other available products.

The Court of Appeal[17] held that measures such as recall, removal from distribution channels and destruction constitute the normal consequence of a finding of infringement under Art. 64 UPCA, implementing Art. 10 of Directive 2004/48. These measures may only be withheld if disproportionality is established. The Court emphasized that proportionality under Art. 64(4) UPCA must consider the seriousness of the infringement, the infringer's willingness and ability to render the products non-infringing, and the interests of third parties. The burden that recall or removal may place on the infringer does not, in itself, justify refusing such measures.

In *Edwards v. Meril*,[18] the Court of Appeal reiterates that a successful infringement action normally entitles the right holder to a permanent injunction, since Art. 62 UPCA obliges the Court to prohibit continued or threatened infringement unless special circumstances justify refusal. Such an exception may arise where granting an injunction would fail to comply with the proportionality requirements of Art. 3 of the Enforcement Directive, particularly the obligation that remedies remain proportionate. In assessing proportionality, both for injunctive relief and corrective measures, the Court may consider not only the parties' interests but also those of third parties, including patients.

bb) Instigators, co-perpetrators and accomplices

The Court of Appeal[19] stated that injunctions under Art. 63 UPCA may be directed at instigators, co-perpetrators and accomplices. A company director cannot be considered a "third party" vis-à-vis their own company for the purposes of Art. 63 UPCA and Art. 11 of Directive 2004/48. The Court confirmed that personal injunctions against company directors require evidence that the director consciously participated in the infringing acts with awareness of their unlawful nature. Reliance on legal advice negating infringement may, in principle, prevent the required awareness from being established.

cc) Deadline for enforcement of the measures

The Court of Appeal[20] noted that where no deadline is set in the injunction or decision, it is for the claimant to set an appropriate deadline when notifying its intention to enforce the measures, in accordance with R. 118.8 RoP.

b) Determination of damages and compensation

The Court of Appeal[21] recalled that a request for an order to lay open books forms part of the procedure for the determination of the amount of damages and compensation, which is governed by Chapter 4 of Part 1 RoP (see R. 131.1(c) and R. 141 to 144 RoP). A party filing such a request is liable for both the fixed fee and the value-based fee for the determination of damages.

4. Validity

a) Priority

The Düsseldorf Local Division[22] held that the term "same invention" in Art. 87 EPC requires that the skilled person be able to derive the claimed subject-matter directly and unambiguously from the earlier application as a whole, using common general knowledge. The LD noted that this corresponds to the disclosure standard applied for added matter.

b) Novelty

The Milan Local Division[23] held that an invention forms part of the state of the art when it is found clearly, integrally, directly and unambiguously in a single piece of prior art and is identical in its constituent elements, in the same form, with the same arrangement and the same features. This applies equally to novelty attacks based on a single item of prior use made available to the public.

In assessing novelty, the Milan Central Division[24] confirms that the skilled person will generally not derive precise dimensions or quantitative limitations from schematic drawings unless such information is directly and unambiguously taught.

c) Inventive step

The Paris Central Division[25] stated that the assessment of inventive step requires: (i) identification of the objective technical problem on the basis of the patent specification; (ii) identification of the state of the art at the time of the invention, represented by one or more realistic starting points; and (iii) determination of whether the skilled person would have arrived at the claimed invention without inventive skill. The Paris CD indicated that a holistic approach, considering the invention as a whole, may be appropriate. It noted that a realistic starting point is one addressing the same or similar technical problem, even if the cited document does not disclose all the features of the challenged patent but provides the basis for developing the inventive idea.

The Milan Local Division[26] stated that, in assessing inventive step, the technical problem must be derived from effects directly and causally related to the technical features of the claimed invention. An effect cannot be used in formulating the technical problem if demonstrating that effect requires additional information not available to the skilled person, even after considering the content of the patent application.

17 UPC-CoA, 3 October 2025, UPC_CoA_534/2024, UPC_CoA_19/2025 and UPC_CoA_683/2024.
18 UPC-CoA, 25 November 2025, UPC_CoA_464/2024, UPC_CoA_530/2024, UPC_CoA_21/2025, UPC_CoA_457/2024, UPC_CoA_532/2024, UPC_CoA_27/2025, UPC_CoA_458/2024 and UPC_CoA_533/2024.
19 UPC-CoA, 3 October 2025, UPC_CoA_534/2024, UPC_CoA_19/2025 and UPC_CoA_683/2024.
20 UPC-CoA, 3 October 2025, UPC_CoA_534/2024, UPC_CoA_19/2025 and UPC_CoA_683/2024.
21 UPC-CoA, 1 October 2025, UPC_CoA_681/2025.
22 UPC-LD Düsseldorf, 15 October 2025, UPC_CFI_115/2024 and UPC_CFI_377/2024.
23 UPC-LD Milan, 27 October 2025, UPC_CFI_178/2024 and UPC_CFI_432/2024.
24 UPC-CD Milan, 27 November 2025, UPC_CFI_613/2024.
25 UPC-CD Paris, 20 October 2025, UPC_CFI_189/2024 and UPC_CFI_434/2024.
26 UPC-LD Milan, 27 October 2025, UPC_CFI_178/2024 and UPC_CFI_432/2024.

The Mannheim Local Division[27] held that invoking common general knowledge ("CGK") for a subset of features is insufficient unless the specific combination relied upon is itself part of the CGK. When alleging that the skilled person would arrive at a particular design based on known principles and CGK, it must be shown that the skilled person would reach that design without applying inventive skill.

The Düsseldorf Local Division[28] stated that the skilled person is generally accustomed to selecting suitable materials for a given purpose from those known to be appropriate. Choosing a material from a limited range of options available to the skilled person does not usually require special expertise and is not regarded as inventive.

The Court of Appeal has rendered two decisions outlining its assessment of inventive step.

First, in *Edwards v. Meril*,[29] the Court sets out a detailed framework for assessing inventive step under Art. 56 EPC, emphasizing that the analysis must begin with identifying the objective technical problem from the skilled person's perspective at the priority date, interpreted in light of the patent specification as a whole. While approaches to inventive step vary across EPC member states (ranging from the EPO's problem-solution approach to more holistic methods applied in jurisdictions like Germany and the UK), the Court underscores that these methodologies serve only as guidelines and should normally converge toward the same result when correctly applied. The burden of alleging and proving invalidity lies with the party challenging the patent (Art. 54 and 65 UPCA; R. 44(e)-(h) and 25.1(b)–(d) RoP), though the Court notes that determining the relevance of factual circumstances remains a matter of law. Building on its earlier guidance in *Nanostring v. 10x Genomics*, the Court explains that the state of the art must be assessed by comparing the claims (viewed in the context of the description and drawings) with what the invention contributes over the prior art, while avoiding hindsight by ensuring that the formulation of the problem does not presuppose the claimed solution. A realistic starting point is any prior-art disclosure that would have been of interest to the skilled person seeking to solve the objective problem, and multiple realistic starting points may exist. The relevant field of technology includes both the field directly addressed by the patent and any neighboring fields where similar problems arise and of which the skilled person would reasonably be aware. The skilled person is presumed to have no inventive ability or creativity and will progress from a realistic starting point only when prompted by explicit teachings in the prior art or by routine development. A claimed solution is therefore obvious if the skilled person would (rather than merely could) have arrived at it when attempting to solve the objective problem. Finally, an inventive step does not require demonstrating that the invention improves on prior-art solutions; it may also reside in proposing a non-obvious alternative to known approaches.

Second, in *Amgen v.* Sanofi, the Court of Appeal[30] emphasized that a reasonable expectation of success (distinct from a mere hope of achieving the desired outcome) is required for a finding of obviousness. This expectation must be grounded in the skilled person's rational scientific appraisal of the available facts before embarking on the research path leading to the claimed invention. The likelihood of success varies with the maturity of the technical field: where the field is unexplored or characterized by significant technical or practical uncertainties, the threshold for expecting success is higher, making obviousness less likely. Conversely, the stronger and more explicit the pointer in the prior art toward the claimed solution, the lower the threshold for establishing such an expectation. The Court added that contemporaneous research efforts by other teams do not, by themselves, evidence a reasonable expectation of success; parallel work may equally indicate exploration driven by scientific curiosity rather than predictable outcomes. When the patentee credibly substantiates uncertainties or technical difficulties, the burden shifts to the party alleging obviousness to demonstrate that these obstacles would not have deterred the skilled person.

The Munich Local Division[31] reiterated that, when assessing inventive step, the court must avoid any retrospective evaluation of the invention; even where common general knowledge is invoked, the skilled person must still have a motivation, based on the prior art, to arrive at the claimed solution. The Court also held that, in revocation proceedings, if the claimant elects not to challenge certain granted claims, both the court and the defendant are bound by that chosen scope of attack.

d) Added matter

In assessing whether there is an impermissible extension of subject matter, the Munich Local Division[32] notes that the fact that there is not a single example, Figure or embodiment disclosed in the application as filed having all of the features of granted claim 1, in the combination as claimed, is as such not decisive for the question of whether an amendment introduces added matter. At the end of the day, only the disclosure of the application as a whole to the skilled person is decisive. That being said, the fact that the application as filed in this case has a completely different claim set compared to the patent as granted, lists more than 1000 "embodiments" without a clear hierarchical structure (the expression "in some embodiments" is used more than 1000 times, leading to an astronomical number of potential combinations), spread out over more than 300 pages, and includes 64 (elaborate) Figures is indeed a relevant factor for the assessment of whether the skilled person would deduce the subject matter of the amended claims from the application as filed. Under these circumstances, the isolated disclosures of a number of features in several embodiments is not to be equated to a direct and unambiguous disclosure of the combination of said features. Claiming a combination of seemingly individually disclosed features, without the application providing the skilled person

27 UPC-LD Mannheim, 9 October 2025, UPC_CFI_132/2024.
28 UPC-LD Düsseldorf, 15 October 2025, UPC_CFI_115/2024 and UPC_CFI_377/2024.
29 UPC-CoA, 25 November 2025, UPC_CoA_464/2024, UPC_CoA_530/2024, UPC_CoA_21/2025, UPC_CoA_457/2024, UPC_CoA_532/2024, UPC_CoA_27/2025, UPC_CoA_458/2024 and UPC_CoA_533/2024.
30 UPC-CoA, 25 November 2025, UPC_CoA_528/2024 and UPC_CoA_529/2024; a more detailed analysis of recent UPC case law concerning inventive step will be featured in a future issue of EPLP.
31 UPC-CD Munich, 20 November 2025, UPC_CFI_836/2024.
32 UPC-LD Munich, 1 August 2025, UPC_CFI_54/2024 and UPC_CFI_396/2024.

with any guidance to do so, boils down to artificially creating an embodiment which constitutes added matter.

The Court of Appeal[33] held that, to determine whether there is an extension of the added-matter, the Court must identify what the skilled person, applying an objective and filing-date-based assessment and using their common general knowledge, would derive directly and unambiguously from the application as a whole, including implicitly disclosed subject-matter. In the case of a divisional patent, this requirement applies both to the originally filed parent application and to the PCT application that later entered the regional phase and forms the basis of the divisional. The subject-matter of the granted claim must therefore not extend beyond either disclosure. This was also confirmed in the *Amgen v. Sanofi* case held by the Court of Appeal.[34]

The Munich Local Division[35] held that where an international application is not drafted in an EPO official language, the content of the resulting European application is determined primarily through the translation filed at entry into the European phase; this translation is not a mere formality but defines the application in the language of the proceedings for the purposes of examination and for assessing compliance with Art. 123(2) EPC. Since it is in the applicant's own interest that the examination be conducted on the basis of an accurate disclosure, the applicant-filed translation may generally be presumed to truthfully reflect the content of the international application. Third parties and the Court may therefore rely prima facie on the translation as published by the EPO when assessing added matter. If the patent proprietor claims that the translation is inaccurate, the burden lies on them to prove its incorrectness.

e) Sufficiency of disclosure

In examining sufficiency, the Court of Appeal[36] recalls that the disclosure must be assessed on the basis of the patent as a whole (claims, description and drawings) through the eyes of the skilled person with its common general knowledge at the filing or priority date. The central question is whether that skilled person can reproduce the claimed invention without inventive step and without undue burden; sufficiency exists where the specification enables at least one way of carrying out the invention, including for functionally defined features, which require disclosure of a single technical concept for performing the claimed function. The Court further emphasizes that, for claims defined by functional language, the patent need not describe how to realize every conceivable embodiment within the functional definition: fair protection demands that undisclosed variants achieving the same effect, and which the skilled person could obtain from the disclosure, also fall within the claim. The mere unavailability of certain embodiments does not defeat sufficiency provided that suitable embodiments can be derived. A reasonable degree of trial and error is acceptable and does not amount to undue burden. The burden of presenting and proving a sufficiency objection rest with the party alleging invalidity.

II. Procedural law

1. General topics

a) Service of pleadings

The Hamburg Local Division[37] clarifies that an authorization given to a lawyer to act in provisional-measures proceedings does not automatically extend to representation in a subsequent infringement action concerning the same patent. Even if the two proceedings are legally connected, they remain procedurally distinct, and counsel must hold a separate, explicit mandate for the infringement action. Because the mandate for provisional measures does not carry over, the representative who acted for the defendant in the earlier PI proceedings is not authorized to accept service of the Statement of Claim in the later infringement action. Service on such counsel would therefore be procedurally ineffective unless the party expressly grants new authority.

Where the defendant's statutory seat, central administration, and principal place of business are located outside UPC territory, service of the Statement of Claim must normally follow the procedure under R. 274 RoP, rather than being attempted through the defendant's former PI representative.[38]

b) Parties to the proceedings

The Milan Central Division[39] holds that the notion of a "concerned" party under Art. 47(6) UPCA must be interpreted broadly: any person or entity potentially assessing their freedom to operate in the technical field of the patent has standing to bring a revocation action.

The Court of Appeal[40] held that an intervener may not take actions or make submissions that contradict the party they support; accordingly, an intervener cannot oppose that party's withdrawal of its appeal. Procedural steps by an intervener are admissible only insofar as they serve the supporting party's requests, as the intervener has no independent procedural standing. If the supported party leaves the proceedings, such as by settling and withdrawing its appeal, the intervention becomes inadmissible and the intervener's own appeal becomes moot under R. 360 RoP. As to costs, the intervener is generally treated in the same way as the principal party they support.

c) Late filing

The Mannheim Local Division[41] stated that a defendant cannot normally be expected to defend against an assertion of indirect infringement introduced for the first time during the oral hearing. In such circumstances, the assertion is considered too late to be admitted.

On the contrary, the Paris Local Division[42] held that an indirect infringement allegation based on equivalence, raised just after the statement of defense, was not late-filed. It considered that the allegation did not alter the claimant's procedural strategy and that the defendant had the opportunity to

33 UPC-CoA, 2 October 2025, UPC_CoA_764/2024 and UPC_CoA_774/2024.
34 UPC-CoA, 25 November 2025, UPC_CoA_528/2024 and UPC_CoA_529.
35 UPC-CoA, 5 November 2025, UPC_CoA_762/2024 and UPC_CoA_773/2024.
36 UPC-CoA, 25 November 2025, UPC_CoA_528/2024 and UPC_CoA_529.
37 UPC-LD Hamburg, 25 August 2025, UPC_CFI_688/2025.
38 UPC-LD Hamburg, 25 August 2025, UPC_CFI_688/2025.
39 UPC-CD Milan, 27 November 2025, UPC_CFI_613/2024.
40 UPC-CoA, 27 November 2025, UPC_CoA_70/2025.
41 UPC-LD Mannheim, 9 October 2025, UPC_CFI_132/2024.
42 UPC-LD Paris, 1 August 2025, UPC_CFI_363/2024.

respond in the rejoinder. The equivalence claim was therefore admissible.

The Hague Local Division[43] also held that the claimant's equivalence arguments, raised for the first time in its reply, were admissible. Although the defendant objected that the arguments were late by pointing out that equivalence had already been relied upon in earlier UK proceedings and that the claimant should therefore have pleaded it in the Statement of Claim, the Court confirmed that adding an equivalence argument does not constitute an amendment of the party's case under R. 263 RoP and does not require judicial leave. The Court considered that the reply merely responded to the defendant's Statement of Defence and remained within the framework of the literal-infringement case set out in the Statement of Claim. It further found it understandable, in light of the pending UK judgment at the time of filing, that the claimant did not advance equivalence earlier. The defendant suffered no unreasonable prejudice, having had an opportunity to respond in writing and orally, and having already debated the issue in parallel UK proceedings. The Court therefore accepted the equivalence arguments in the reply.

The Hamburg Local Division[44] confirmed that challenges to the validity of the patent must be introduced in strict compliance with the Rules of Procedure, meaning they must be filed together with the counterclaim for revocation. It is therefore not permissible for a party to advance a new validity attack (such as an objection of lack of inventive step) during the oral hearing based solely on documents already present in the proceedings.

d) Further exchanges of written pleadings

The Court of Appeal[45] dismissed the discretionary review request under R. 220.3 RoP, holding that the Mannheim Local Division had not manifestly erred in refusing leave for an additional written submission under R. 36 RoP. The Court emphasized that further exchanges of pleadings lie within the judge-rapporteur's discretion and must be assessed in light of procedural efficiency, particularly the objective that first-instance infringement proceedings reach oral hearing within one year. Given the advanced stage of the written procedure, the scheduling of the oral hearing for 9 October 2025, and the applicant's delay (waiting four months after the release of the allegedly infringing AI Stack feature and five weeks after its last regular submission) the refusal to allow a late brief could not be regarded as manifestly wrong. The Court further held that the impugned order had no final or irreparable impact on the applicant's rights, noting that the applicant remained free to initiate separate actions concerning newly released products, thereby excluding any risk of res judicata for factual or legal matters not encompassed within the present proceedings. Finally, the applicant had failed to show that the matter raised a fundamental question of law warranting appellate intervention to ensure consistency in the interpretation of the Rules of Procedure; the strict conditions for discretionary review were therefore not met.

2. Jurisdiction

The Court of Appeal[46] held that R. 19.1 RoP contains an exhaustive list of admissible grounds for objections, including objections to jurisdiction. Alleged violations of Art. 47(2) CFR or Art. 6 ECHR do not fall within these grounds and cannot support an objection under R. 19.1 RoP. The Court further stated that the allocation of competences to the UPC under Art. 31 and 32 UPCA, read with the Brussels I Regulation, does not affect the division of tasks between the CJEU and national courts under Art. 19 TEU and 267 TFEU. It also confirmed that the Administrative Committee was empowered, by analogy with Art. 87(2) UPCA, to designate Milan as the section of the Central Division replacing London.

a) Local jurisdiction

The Court of Appeal[47] confirmed that R. 19.5 RoP applies mutatis mutandis to applications for provisional measures, allowing a referral to the competent division when efficiency and urgency so require. Where a local division considers a competence-based defence to be well-founded and the applicant has designated another competent division for provisional measures, the case must be referred accordingly. Competence under Art. 33 UPCA is an internal UPC matter and is not governed by the Brussels I Recast Regulation. No hierarchy exists between competence based on the place of infringement (Art. 33(1)(a) UPCA) and competence based on the defendant's residence or principal place of business (Art. 33(1)(b) UPCA). To establish competence under Art. 33(1)(a), it is sufficient that infringing acts (such as offers or the ability to obtain the alleged infringing products via a website accessible in the relevant Contracting Member State) are shown. The determination of competence should not require a full evaluation of disputed facts that also relate to the merits; instead, the court conducts a summary appraisal based on the parties' allegations and any available evidence.

b) Cross-border jurisdiction

The Hamburg Local Division[48] held that the UPC has jurisdiction irrespective of the defendant's domicile for patent infringements committed in a UPC Member State, pursuant to Art. 71b(2) in conjunction with Art. 7(2) Brussels I Recast. The Court further stated that international jurisdiction for alleged infringement of the national part of a European patent outside UPCA countries requires at least a plausible allegation of infringing acts in the relevant country.

c) Multiple defendants

Where a defendant is not domiciled or active in the Member State of the local division but belongs to the same corporate group as other defendants and the challenged embodiments are the same, the claims are closely connected within the meaning of Art. 8(1) Brussels I Recast[49]. Non-EU manufacturers must appoint an Authorized Representative in the EU for product safety and market surveillance regulations, and that such a representative plays an indispensable role in product distribution. As a result, an Authorized Representative may act as an anchor defendant under Art. 8(1) Brussels I Re-

43 UPC-LD The Hague, 18 November 2025, UPC_CFI_187/2024 and UPC_CFI_507/2024.
44 UPC-LD Hamburg, 5 November 2025, UPC_CFI_461/2024 and UPC_CFI_718/2024.
45 UPC-CoA, 1 September 2025, UPC_CoA_805/2025.
46 UPC-CoA, 6 October 2025, UPC_CoA_288/202, UPC_CoA_290/202 and UPC_CoA_291/202.
47 UPC-CoA, 28 November 2025, UPC_CoA_317/2025 and UPC_CoA_376/2025.
48 UPC-LD Hamburg, 14 August 2025, UPC_CFI_387/2025.
49 UPC-LD Hamburg, 14 August 2025, UPC_CFI_387/2025.

cast and may be subject to injunctive relief under Art. 63(1) UPCA[50].

In the case of a request for provisional measures, the Hague Local Division[51] confirmed its jurisdiction over both defendants, Menarini and Sinocare. For Menarini, jurisdiction was straightforward because it had commenced commercial supply of the accused CGM system in the Netherlands. As regards Sinocare, which is established outside the UPC territory, the Court held that jurisdiction could nonetheless be asserted under Art. 71b(2) Brussels I Recast in conjunction with Art. 7(2). The LD found sufficient connecting factors because Sinocare and Menarini had publicly announced a coordinated strategy for the European launch of the product, and because the accused iCan CGM App developed by Sinocare was made available for download and use in the Netherlands. These elements indicated that alleged infringing acts occurred, or were intended to occur, within the UPC Member State, thereby establishing international jurisdiction over both defendants.

The Court of Appeal[52] recalled that the concept of the "same parties" of Art. 33(4) UPCA must be understood as requiring the parties to be identical. There may be such a degree of identity between the interests of two legal entities that a judgment delivered against one of them would have the force of res judicata as against the other. In such a situation, the entities must be considered to be one and the same party for the purposes of the application of Art. 33(4) second sentence UPCA. Then, the Court confirmed the competence of the Central Division to hear the direct revocation action brought by Meril Italy, holding that Art. 33(4) UPCA requires strict identity of parties and cannot be triggered merely because companies within the same corporate group share aligned commercial interests; since Meril India, Meril Germany and Meril Italy are distinct legal entities, the pendency of infringement actions against some of them did not preclude a separate revocation action by another.

3. Recognition of national decisions

The Court of Appeal[53] held that the recognition of national judgments under Art. 36 Brussels I Recast remains unaffected by Art. 34 UPCA. Art. 34 concerns only the territorial reach of UPC decisions and does not modify the res judicata effects of decisions of national courts within their own territory.

4. Language of the proceedings

The Hamburg Local Division[54] rejected a request for simultaneous interpretation of the oral hearing from German into Polish. The Court applied Art. 51(2) UPCA and R. 109 RoP, noting that interpretation may be ordered where appropriate, subject to a two-step assessment developed in earlier case law: (i) whether interpretation is warranted for the hearing, and (ii) whether the related costs should form part of the recoverable costs. The Court held that interpretation was not appropriate for the defendants in this case: the companies concerned were German, Austrian or Danish, and the individuals identified were not statutory representatives, with some not being employees of the defendants. The Court also found no basis to impose the associated costs on the proceedings. It noted that the parties remain free under R. 109.4 RoP to arrange their own interpreter at their own expense.

5. Procedural confidentiality (including access to files)

In assessing the admissibility of a request for access to written pleadings and evidence, the Munich Local Division[55] confirms that a request is "reasoned" when it (i) identifies the documents sought and (ii) states the purpose of access with sufficient clarity for the Judge-Rapporteur to perform the Art. 45 UPCA balancing. No heightened substantive requirement exists. Educational or general public-interest reasons suffice, in particular once proceedings are closed. Because the infringement and revocation proceedings had been withdrawn and were therefore concluded, the Court emphasizes that the public's general interest in accessing written pleadings and evidence normally outweighs party-specific interests, even where no decision on the merits has been issued. The Court notes that access supports transparency and public monitoring of judicial activity. The opposing parties argued that the applicant law firm was hiding its true motives because the claimant had recently initiated new litigation on the same patent. The Court rejects this argument: there is no proof of concealed motives, and even if the applicant advised clients on the patent, such an interest would increase, not decrease, the legitimacy of access. The Court clarifies that only written pleadings and evidence fall within R. 262.1(b). Court orders or CMS notifications are not covered and therefore excluded. Access must respect previously issued confidentiality orders and pending confidentiality requests. Since the applicant did not file a R. 262.3 request to challenge confidentiality, the Court holds that only the redacted versions submitted by the parties can be disclosed. Personal data under GDPR must also be redacted. To ensure confidentiality, the Court orders the parties to upload redacted pleadings and evidence to a secure data room. This mirrors practice in Mannheim and Düsseldorf.

6. Access to hearing recordings under R. 115 RoP

The Mannheim Local Division[56] partially granted Amazon's request under R. 115 RoP by allowing its representatives to listen to the audio recording of the 14 November 2025 oral hearing at the Düsseldorf Local Division but rejected the request to produce a complete transcript with the assistance of a stenographer. The Court held that R. 115 provides for listening access only, not full transcription, and emphasized that neither the UPCA nor the Rules of Procedure contemplate the creation or circulation of verbatim transcripts, particularly not for use outside UPC proceedings. It found that a transcript would undermine the confidentiality regime jointly requested by the parties, risk uncontrolled dissemination of sensitive content in foreign jurisdictions, and contradict the legislative intent reflected in both the drafting history and the

50 UPC-LD Hamburg, 14 August 2025, UPC_CFI_387/2025.
51 UPC-LD The Hague, 22 October 2025, UPC_CFI_587/2025.
52 UPC-CoA, 25 November 2025, UPC_CoA_464/2024, UPC_CoA_530/2024, UPC_CoA_21/2025, UPC_CoA_457/2024, UPC_CoA_532/2024, UPC_CoA_27/2025, UPC_CoA_458/2024 and UPC_CoA_533/2024.
53 UPC-CoA, 3 October 2025, UPC_CoA_534/2024, UPC_CoA_19/2025 and UPC_CoA_683/2024.
54 UPC-LD Hamburg, 1 September 2025, UPC_CFI_461/2024 and UPC_CFI_718/2024.
55 UPC-LD Munich, 26 August 2025, UPC_CFI_487/2025.
56 UPC-LD Mannheim, 27 November 2025, UPC_CFI_936/2025.

ECJ model on which R. 115 is based. The Court also noted that extensive participation by multiple counsel (including US and UK lawyers) during the hearing ensured adequate note-taking, eliminating any necessity for a transcript. It further warned that private, non-authoritative transcripts could generate disputes over accuracy and improperly influence subsequent proceedings. Accordingly, access to the audio was authorized under controlled conditions, while all other requests, including for leave to appeal, were denied.

7. Measures to preserve evidence

a) Ex parte measures under Art. 60 UPCA and R. 192 et seq. RoP

The Milan LD[57] held that for granting *ex parte* measures under Art. 60 UPCA and R. 192 et seq. RoP (including inspection, preservation of evidence and seizure) the assessment must be carried out at the time of the request and does not require concrete proof of imminent destruction of evidence; a plausible statistical possibility of alteration is sufficient. It stated that the procedural correctness of the patentee's urgent request must be assessed with regard to the patent invoked before the LD and the circumstances relevant to its validity, and that references to the prosecution history of a corresponding US patent are irrelevant. Role of expert evidence.

The Mannheim Local Division[58] clarified the standard applicable to the review of an *ex parte* order to preserve evidence. It emphasized that R. 197.3 RoP serves as a fundamental safeguard to ensure that the party affected by the *ex parte saisie* has the opportunity to exercise the right to be heard guaranteed by Art. 60(6) UPCA and Art. 7(1) of the Enforcement Directive 2004/48/EC. Accordingly, the Court must assess the request for review by considering all arguments and facts raised for the first time by the respondent, as expressly required by R. 197.3 RoP. The Court further explained that this review entails determining whether, in light of the newly presented material, the *saisie* order could still have been granted ex ante. If not, the order must be revoked or modified. The Court must also decide whether such revocation has retroactive effect, rendering past enforcement unlawful, or only prospective effect, preventing further execution without invalidating measures already taken.

b) Standard of review

The Bussels Local Division[59] clarified the scope and standard of review under R. 197.3 RoP, holding that review proceedings require a double assessment. The Court must first reassess whether the *ex parte* order to preserve evidence/for inspection was rightly granted on the basis of the facts and evidence before the Court (or reasonably known to the applicant) at the time of issuance, taking into account the applicant's duty of candor under R. 192.3 RoP. It must then assess whether the order should be confirmed, modified or revoked in light of all facts and evidence submitted in review proceedings under R. 194.3(b) RoP, which involves a substantive examination of the conditions of Art. 60(1) and (3) UPCA and of the scope of the original order.

The Court emphasized that the relevant reference date for both assessments is the date of the original order, whether granted *ex parte* or, hypothetically, *inter partes*. The review does not address the execution of the order nor the evidence actually gathered; such matters belong to later stages of PI or merits proceedings.

The Court reiterated that the purpose of an order to preserve evidence/inspection is to allow an applicant who has presented "reasonably available evidence" of infringement to obtain further, non-public information needed to substantiate infringement allegations. The preserved material must enable the applicant to evaluate whether to pursue provisional measures (in light of R. 211.4 RoP), to initiate proceedings on the merits (R. 13.1(l)(i) RoP), or to refrain from litigation if the evidence is insufficient.

The Court clarified that the statutory requirement that infringement be "about to be infringed" in Art. 60(1), 60(3) UPCA sets a standard different from "urgency" or "unreasonable delay" under the RoP and from "threatened infringement" under R. 13.1(l)(i) RoP. The applicant must show a plausible and concrete future risk of infringement, whose duration depends on the case's circumstances.

Finally, when experts are appointed under an order to preserve evidence/inspection, their task is limited to filtering the obtained material and selecting information that may assist in proving or disproving infringement of the patent-in-suit.

8. Provisional measures

In proceedings for provisional measures, the Paris Local Division[60] limited the length of the respondent's written submissions. The respondent had filed a 473-page objection in reply to a 30-page application. The Court held that such volume was not appropriate in expedited proceedings and ordered the respondent to file a condensed objection of no more than 70 pages, and the applicants to file a reply limited to 40 pages. The order reflects the Court's management of proportionality and procedural efficiency in provisional measures proceedings.

a) Reasonable delay

The Hague Local Division[61] rejected the defendants' allegation of undue delay and held that the applicants had acted promptly. After the grant was published on 2 April 2025, applicants ordered the defendants' cabinets, waited for delivery, examined them, sent a cease-and-desist letter on 19 May 2025, and filed the Statement of Claim on 28 May 2025. The fact that applicants were aware from 23 December 2024 that the patent would be granted did not make the delay unreasonable. Even assuming applicants could have ordered the cabinets earlier, the overall delay remained under two months from publication of the grant, excluding time for an attempted out-of-court settlement. The LD therefore found no undue delay.

In another case held by the Hague Local Division[62], the Court also found that the applicant had not acted with un-

57 UPC-LD Milan, 27 October 2025, UPC_CFI_127/2025.
58 UPC-LD Mannheim, 2 October 2025, UPC_CFI_636/2025.
59 UPC-LD Brussels, 12 November 2025, UPC_CFI_407/2025 and UPC_CFI_408/2025.
60 UPC-LD Paris, 17 September 2025, UPC_CFI_697/2025.
61 UPC-LD The Hague, 11 September 2025, UPC_CFI_479/2025.
62 UPC-LD The Hague, 22 October 2025, UPC_CFI_587/2025.

due delay. The updated version of the accused app, which was necessary to assess the allegedly infringing functionality, only became available on 21 April 2025, and the relevant products were obtained shortly thereafter. The request for provisional measures, filed on 27 June 2025, was therefore made within a reasonable period. The LD held that earlier awareness of the forthcoming grant of the patent did not impose an obligation to act sooner, and that the steps taken between availability of the app and the filing of the application demonstrated sufficient diligence to satisfy the urgency requirement.

On the contrary, in another case, the Hague Local Division[63] dismissed the application for provisional measures on the ground that Cilag had acted with unreasonable delay. Although the applicant became aware of the defendant's involvement with the allegedly infringing cartridges in November 2024, it waited until late April 2025 to file its request. The Court held that the applicant should have realized the potential extent of infringement and related market impact much earlier, and that later developments could not revive urgency. As urgency was lacking, the Court did not examine the remaining defenses. The LD explained in its reasoning that an applicant whose conduct already indicates that it is not in a hurry, cannot expect assistance in the form of an order for provisional measures. Given that the main proceedings at the UPC are (to be) concluded within a little over one year, a patent holder who acts with unreasonable delay, shall not be allowed to jump the queue.

The Paris Local Division[64] rejected the application for provisional measures brought by Merck against Viatris on the grounds that Merck had acted with unreasonable delay. The LD first cited the Hague LD's reasoning, and considered the question, in the context of a generic product: at what point was or should the person who purchased the rights have been informed of an event that could justify an application for interim measures? In this case, the rights to the marketing authorization on which the application for provisional measures is based were repurchased by the Defendant during the same period when the administrative procedure for authorizing the generic product to be placed on the French market was ongoing. The Court identified the publication of the price and reimbursement rate for the generic medicine as the decisive moment rendering market entry sufficiently concrete for the purchaser of the rights to be aware, or to be expected to be aware, of a potential infringement. The various stages of the administrative process (including the marketing authorization obtained in November 2024, the internal communications indicating imminent launch, and the listing of the product for reimbursement) were all elements from which the purchaser, acting with due diligence, should have recognized the imminence of the generic's entry onto the market. The Court also observed that the acquisition of the relevant exploitation rights by Merck in July 2024 necessarily implied a due-diligence obligation to familiarize itself with regulatory developments affecting the authorized product, including any pending applications for generics. Against this background, the Court considered that Merck either knew or should have known of the risk of generic entry several months before it acted.

Given that Merck waited until the end of July 2025 to file its application, the Local Division held that this delay of approximately eight months from the decisive administrative publication was incompatible with the requirement of urgency under R. 211.4 RoP. The Court concluded that such inaction amounted to an unreasonable delay, independently justifying the rejection of the request for provisional measures, without the need to proceed to a full assessment of infringement or the balance of interests.

The Hague Local Division[65] considered the balance of interests and concluded that the applicants' interests outweighed those of the defendants. Applicants faced irreparable harm through price erosion and loss of market share, particularly as the patented washing-machine cabinets constituted their only product and market position had to be built from scratch. Defendants, by contrast, offered many other furniture items, making the impact on their business and reputation relatively limited. Any potential damages if the injunction were overturned were also considered modest and could be mitigated by imposing a security.

b) Appointment of a technical judge

The Düsseldorf Local Division[66] ordered the involvement of an additional technically qualified judge in the preliminary injunction proceedings. The LD recalled that provisional measures require a sufficiently secured presumption of validity under Art. 62(4) UPCA and R. 211.2 RoP, meaning that the panel must be able to form a reliable view on the patent's validity. Because the defendant challenged not only infringement but also validity, the LD considered it appropriate to strengthen the panel with technical expertise. Although R. 34 RoP mentions the appointment of a technically qualified judge only in the context of main proceedings, the Court noted that Art. 8(5) UPCA allows such appointment in any procedure, including interim measures. The Court also emphasized that, in likely future main proceedings (particularly if a counterclaim for revocation is filed) a technically qualified judge would be required. Early appointment was therefore considered useful to ensure that the additional judge could familiarize himself with the case and support the reporting judge as needed.

c) Evidence

The Düsseldorf Local Division[67] held that where the defendant specifically contests the applicant's factual submissions, the applicant must provide facts sufficient to give the Court the level of certainty required for granting provisional measures; further evidentiary measures such as expert reports are normally inappropriate in interim proceedings. The LD added that the burden of presentation and proof regarding facts relevant to lack of validity rests with the defendant.

d) Prior arts and accuracy of the translations

The Düsseldorf Local Division[68] held in the case of PI proceedings that if both parties file translations of a prior-art document and disagree on the accuracy, it is for the defendant to substantiate why the applicant's translation is incorrect;

63 UPC-LD The Hague, 29 August 2025, UPC_CFI_374/2025.
64 UPC-LD Paris, 21 November 2025, UPC_CFI_697/2025.
65 UPC-LD The Hague, 11 September 2025, UPC_CFI_479/2025.
66 UPC-LD Düsseldorf,4 August 2025, UPC_CFI_550/2025.
67 UPC-LD Düsseldorf, 31 October 2025, UPC_CFI_630/2025.
68 UPC-LD Düsseldorf, 31 October 2025, UPC_CFI_630/2025.

failing that, the Court will base its decision on the applicant's translation.

e) Inadmissibility of auxiliary requests

The Munich Local Division[69] holds that, in proceedings for provisional measures under Art. 62 UPCA, auxiliary requests that rely on an amended or alternative claim formulation departing from the granted version are generally inadmissible, as they seek to cure existing doubts regarding validity and cannot provide a reliable basis for interim relief. Where the patent proprietor considers it necessary even on an auxiliary basis to amend the claims, this is a strong indication that the patent in its granted form is likely invalid. In such circumstances, the Court cannot be "sufficiently convinced" of the validity of the granted claims, so an application for urgent relief based on the granted version must as a rule be rejected.

f) Remedies

The Hague Local Division[70] granted an information order only insofar as necessary to prevent further infringement. Requests aimed at gathering information for the calculation of damages, such as prices and numbers of cabinets sold, were refused for lack of urgency or necessity.

The Court of Appeal[71] explains that potential future changes to products on the market do not justify delaying proceedings under R. 211.4 RoP. In addition, an interim award of costs may be granted in favour of either party in provisional-measures proceedings. Interim cost awards allow the successful party to recover part of its costs on a provisional basis pending separate and final cost proceedings under R. 150 et seq RoP. Because representation costs typically form the bulk of recoverable costs, an interim award up to half the applicable ceiling is generally appropriate, even though broader costs may ultimately be recoverable under R. 151(d) RoP. Different considerations may apply where the parties have submitted or agreed on detailed cost specifications during the proceedings.

9. Revocation actions and amendments to the patent in issue

The Court of Appeal[72] upheld the First Instance's discretionary assessment under R. 49.2, 50.2 and 30.2 RoP, emphasizing that amendments may be admitted if they could not reasonably have been filed earlier and if their admission does not prejudice the opposing party's right to be heard; the Court of First Instance has a margin of discretion in this respect.

10. Application to annul a decision of the Office to reject a request for unitary effect

The Court of Appeal[73] clarified that R. 91 RoP, which governs interlocutory revision before the EPO, does not apply to accelerated actions brought against decisions issued by the EPO under R. 97 RoP concerning the rejection of a request for unitary effect. The Court held that such challenges fall within the exception regime of R. 85(2) RoP, given the strict procedural structure of R. 97: a three-week period to file a request for annulment (R. 97.1), the registrar's obligation to transmit the request to the standing judge "as soon as possible", and a further three-week period for the judge to decide (R. 97.4). The Court emphasized that R. 97 constitutes a *lex specialis*, and that actions seeking annulment of an EPO decision rejecting unitary effect must therefore proceed exclusively under the procedural timetable and mechanisms specifically set out in R. 97 RoP.

11. Costs

The Milan Central Division[74] held that costs related to enforcement proceedings fall outside the scope of R. 151 RoP, which governs the allocation of costs in the main proceedings. The Court emphasized that the wording of R. 150 RoP does not permit the recovery of costs incurred after the publication of the decision, as the UPC system deliberately separates the merits phase from the costs phase to facilitate efficient cost settlement. While the costs decision logically depends on the outcome of the merits, it cannot extend to costs accrued after proceedings are terminated, and enforcement-related expenses must therefore be excluded from any costs award.

a) Security for costs

In the case of an *ex parte* measures to preserve evidence, the Milan LD[75] explained that, under R. 196.3 and 196.6 RoP, the security to be provided as a condition for enforcement must be proportionate to potential damages and litigation costs. Damages related to seizure cannot be equated with the sale price of a vehicle but only with the lost marginal profit, and only costs arising during the evidence-gathering phase may be considered, projecting future costs of potential main proceedings would unduly hinder access to judicial protection.

In the case of an application for provisional measures, the Hague Local Division[76] was sufficiently convinced that it was more likely than not that the patent would be found valid and infringed in the main proceedings. Preliminary relief was therefore necessary and proportionate. A preliminary injunction was granted, subject to a security of €25,000, taking into account that the applicants are an SME and the minor impact on defendants' overall sales. A recall was also ordered for cabinets sold since 2 April 2025, to address past infringement; given its potentially more disruptive nature, the Court imposed an additional €75,000 security for enforcement.

b) Representation costs

The Hamburg Local Division[77] held that recoverable representation costs must be reasonable and proportionate under Art. 69(1) UPCA, meaning costs that were necessary for the legitimate objective of the proceedings. It stated that the assessment must be objective and rational, considering whether the expenses were appropriate for the conduct and outcome of the case. The Court emphasized that proportionality focuses on the amount of costs incurred: they must not be dispro-

69 UPC-LD Munich, 17 October 2025, UPC_CFI_692/2025.
70 UPC-LD, The Hague, 11 September 2025, UPC_CFI_479/2025.
71 UPC-CoA, 28 November 2025, UPC_CoA_317/2025 and UPC_CoA_376/2025.
72 UPC-CoA, 25 November 2025, UPC_CoA_464/2024, UPC_CoA_530/2024, UPC_CoA_21/2025, UPC_CoA_457/2024, UPC_CoA_532/2024, UPC_CoA_27/2025, UPC_CoA_458/2024 and UPC_CoA_533/2024.
73 UPC-CoA, 16 September 2025, UPC_CoA_796/2025.
74 UPC-CD Milan, 15 October 2025, UPC_CFI_773/2025 and UPC_CFI_774/2025.
75 UPC-LD Milan, 27 October 2025, UPC_CFI_127/2025.
76 UPC-LD The Hague, 11 September 2025, UPC_CFI_479/2025.
77 UPC-LD Hamburg, 1 August 2025, UPC_CFI_123/2024.

portionate in view of the value in dispute, the significance of the case, its complexity, and the prospects of success. The LD referred to earlier UPC case law confirming that recoverability depends on the necessity of the measures and the relevance of the costs to the effective enforcement or defense of rights.

The Munich Local Division[78] stated that UPC representatives have a duty to represent their clients effectively, and that the decision to involve several representatives for hearings or preparatory meetings, each with a specific role, is to be regarded as reasonable and proportionate. Given the complexity of the case and the overall amount in dispute, the necessity of multiple representatives and their mode of participation did not require detailed examination when calculating reimbursable travel costs.

The Paris Local Division[79], ruling on recoverable representation costs following its merits decision of 1 August 2025, applied R. 118.5 and 152 RoP and reaffirmed that recoverable costs must be reasonable, proportionate and assessed within the framework of the Administrative Committee's ceiling. Although the successful party sought reimbursement of € 51,912.33 and argued that the ceiling should not apply for reasons of equity, the Court found that the case presented no particular complexity, the patent was technically straightforward, and no procedural conduct by the opposing party justified raising the ceiling. It also noted that the only evidence submitted (a global accounting certificate) did not allow identification of any unnecessary or disproportionate expenses. Conversely, the Court rejected the losing party's request to reduce the ceiling on the basis of financial hardship, holding that financial difficulties arising from insolvency proceedings cannot justify lowering costs, since the party chose to litigate and had to anticipate the risks of defeat. The Court therefore fixed recoverable representation costs at the ceiling of €38,000 and ordered that this amount be entered as a claim in the insolvency proceedings.

The Court of Appeal[80] recalled that under Art. 69(1) UPCA and R. 150(2) RoP, a successful party cannot obtain an interim award exceeding 50 % of the applicable ceiling of recoverable representation costs set by the Administrative Committee pursuant to R. 152.2 RoP.

c) Appeal fees

The Court of Appeal[81] held that the fixed appeal fee under R. 228 RoP, and any value-based fee corresponding to the infringement action, must be paid for each appeal, even where multiple appeals between the same parties raise identical issues.

d) Distribution of costs between parties

The Hague Local Division[82] held that where a patent is upheld only in a form that is not alleged to be infringed, the patentee must bear the costs of the counterclaim for revocation. However, if the counterclaim seeks revocation of claims not asserted against the counterclaimant and those claims are revoked, a cost compensation is appropriate depending on the circumstances.

The Munich Local Division[83] held that the mere fact that a counterclaim for revocation is inherently linked to an infringement action, and is typically filed by the defendant to defend the patent's validity in the infringement proceedings, does not justify imposing the costs of the revocation counterclaim on the claimant when the infringement action is withdrawn and the defendant subsequently withdraws the counterclaim. The LD stated that in such a situation the defendant is to be regarded as the unsuccessful party for the purposes of Art. 69(1) UPCA, since the sought remedy (revocation of the patent) was not achieved.

e) Reimbursement of the court fees following a settlement agreement

The Brussels Local Division[84] held that, once the parties have reached a settlement agreement and confirmed it under R. 365(1) RoP, they are entitled to reimbursement of the court fees already paid, taking into account the fees still outstanding. This applies pursuant to R. 370(9)(c) RoP and, subsidiarily, R. 370(9)(e) RoP. The Court further stated that the Rules of Procedure do not limit its discretion to adopt a pragmatic approach to the payment and reimbursement of court fees, particularly when a mediation process is ongoing between the parties.

f) Confidentiality

The Milan Local Division[85] ruled that the agreed amount of legal costs cannot be kept confidential, as that amount does not in itself reveal the company's financial capacity, commercial strategy, or the importance of the patent as a corporate asset.

g) Applications for determination of costs

The Munich Local Division[86] confirmed that an application for a cost decision constitutes summary proceedings, giving the judge-rapporteur broad discretion regarding the procedure to be followed and the assessment of whether the costs claimed were actually incurred and are reasonable and proportionate. The judge-rapporteur noted disagreement with an earlier Brussels order of 25 July 2025 (UPC_CFI_131/2025). The Court held that the extent of scrutiny must itself remain reasonable, and that marginal cost items may be awarded at the judge-rapporteur's discretion. Procedural obligations of the parties

12. Front-loaded procedure

a) Identification of the most promising documents

The Milan Local Division[87] held that when a party submits a large number of novelty and inventive-step attacks, only those

78 UPC-LD Munich, 17 October 2025, UPC_CFI_404/2025 and UPC_CFI_405/2025.
79 UPC-LD Paris, 30 October 2025, UPC_CFI_803/2025.
80 UPC-CoA, 25 November 2025, UPC_CoA_464/2024, UPC_CoA_530/2024, UPC_CoA_21/2025, UPC_CoA_457/2024, UPC_CoA_532/2024, UPC_CoA_27/2025, UPC_CoA_458/2024 and UPC_CoA_533/2024.
81 UPC-CoA, 6 October 2025, UPC_CoA_288/202, UPC_CoA_290/202 and UPC_CoA_291/202.
82 UPC-LD The Hague, 13 August 2025, UPC_CFI_327/2024.
83 UPC-LD Munich, 27 October 2025, UPC_CFI_127/2024, UPC_CFI_482/2024 and UPC_CFI_29/2025.
84 UPC-LD Brussels, 7 October 2025, UPC_CFI_216/2024 and UPC_CFI_556/2024.
85 UPC-LD Milan, 23 October 2025, UPC_CFI_497/2024 and UPC_CFI_571/2024.
86 UPC-LD Munich, 17 October 2025, UPC_CFI_404/2025 and UPC_CFI_405/2025.
87 UPC-LD Milan, 23 October 2025, UPC_CFI_497/2024 and UPC_CFI_571/2024.

identified by the challenging party as the (most) promising will be assessed on the merits. The remaining attacks will not be examined, since an unmanageable volume of objections prevents the LD from organizing the proceedings efficiently in line with the principles of proportionality and speed; and if the most promising attacks do not affect the validity of the claim(s), the others are assumed not to do so either.

b) Substantiation of arguments in the case of an amendment of the patent

The Hamburg Local Division[88] held that front-loading does not require all evidence to be filed with the initial pleading and that the registered proprietor need not prove entitlement unless challenged, with ownership documents admissible if submitted without undue delay. Amendments to the patent under R. 263 RoP must generally be admitted, and defendants may introduce corresponding new prior-art documents and inventive-step objections, provided they are raised no later than the reply to the defence to the counterclaim. Objections first raised at the oral hearing require leave. Claimants who amend the patent must fully substantiate compliance with patentability requirements, and defendants' new validity attacks in response are not late.

13. Deadlines

The Munich Local Division[89] granted in part the claimant's request to extend the deadlines for the infringement reply, the reply to the revocation counterclaim and any amendment application. Although both parties agreed to the extension, the Court held that R. 9.3 RoP allowed an extension only until 5 September 2025, not until the requested date of 9 September 2025. An extension beyond 5 September would cause subsequent deadlines to fall on a weekend and automatically shift under R. 301.1 RoP, thereby interfering with preparation for the interim hearing. The LD therefore extended the deadlines only to 5 September 2025.

14. Penalty orders

The Court of Appeal[90] sets out an extensive clarification of the UPC framework governing penalty payments under Art. 82 UPCA and R. 118.8, 354.3 and 354.4 RoP, emphasizing at the outset that a penalty may be imposed either directly in the operative part of the decision on the merits or, where not done initially, through a separate penalty order, and that such an order is independently appealable without requiring an appeal against the underlying merits decision.

a) Compliance with penalty orders

The Court of appeal[91] explains that for reasons of legal certainty, the decision on the merits should in principle set the period for compliance; however, where the merits decision is silent, the successful party may notify the defendant of a compliance period, which the defendant must challenge immediately if considered unreasonable, as the competent court (either the division of first instance under R. 354.4 or, where the merits decision originated from the Court of Appeal, the Court of Appeal itself) will ultimately determine the appropriate period with retrospective effect. The Court further stresses that a penalty may only be enforced if a specific penalty order exists (mere references to penalties in the grounds of a judgment or in an enforcement notice are insufficient) and that the party seeking enforcement must request a penalty order from the issuing court under R. 354.4, which retains exclusive competence to assess compliance with its own injunctions. Turning to evidentiary burdens, the Court states that the defendant bears the responsibility of demonstrating timely and full compliance with the injunction, while the claimant may, at the merits stage, request clarification of the evidence necessary to prove compliance; confidentiality objections relating to compliance evidence must also be raised during the merits proceedings. The Court clarifies the moment at which compliance periods begin: for provisional measures, the period starts at the moment the defendant becomes aware of the decision; for decisions on the merits, it begins upon service. On translation obligations, the Court interprets R. 118.8 RoP narrowly, holding that only the operative orders to be enforced require translation, and that penalty orders enforceable under R. 354.4 are not subject to this requirement.

b) Translation requirements

The Court of Appeal[92] confirms that an enforcement notice under Art. 82(4) UPCA may be validly served through the CMS under R. 275–276 RoP, and that such service is equivalent to the service of written pleadings under the UPC procedural rules.

15. Default judgment

The Milan Local Division[93] clarified the conditions for issuing a default judgment under Art. 37 UPCA and R. 277 and 355 RoP. The Court must verify that service of the statement of claim complied with R. 277 RoP, that the defendant failed to act within the prescribed time limit, and that the claimant's factual submissions substantiate the requested relief; the defendant's procedural inactivity does not prevent the court from deciding. Under R. 271 RoP, service of the statement of claim is valid even without the annexes referred to in the document, provided that the content of the introductory pleading enables the defendant to understand the facts of the case and to exercise its rights. Annexes generally serve an evidentiary function and are not an indispensable part of the introductory pleading within the meaning of R. 271 RoP and Regulation (EU) 1784/2020. R. 171.2 RoP reflects the principle that unchallenged facts are deemed acknowledged, but this principle applies only to an actively participating party and not to a defendant in default, for whom the court must always verify proper notification of the proceedings. Default remains a neutral procedural circumstance and, when statutory conditions are met, cannot justify paralyzing the proceedings. Lastly, R. 355.2 RoP sets the evidentiary standard applicable to default judgments, in conjunction with Art. 54 UPCA, excluding any automatic granting of the claim by reason of default alone; the claimant must prove the facts underlying the requested relief to a level sufficient to justify the measures sought.

The Düsseldorf Local Division[94] held that when the steps taken to serve an application for provisional measures are

88 UPC-LD Hamburg, 28 October 2025, UPC_CFI_555/2024.
89 UPC-LD Munich, 1 September 2025, UPC_CFI_848/2024 and UPC_CFI_612/2025.
90 UPC-CoA, 14 October 2025, UPC_CoA_699/2025.
91 UPC-CoA, 14 October 2025, UPC_CoA_699/2025.
92 UPC-CoA, 14 October 2025, UPC_CoA_699/2025.
93 UPC-LD Milan, 19 November 2025, UPC_CFI_802/2024.
94 UPC-LD Düsseldorf, 28 November 2025, UPC_CFI_449/2025.

deemed sufficient under R. 275.2 RoP, including the issuance of an invitation to file an objection under R. 209.1(a) RoP, the proceedings may continue even if the defendant does not respond. If no objection is filed within the court-set deadline, the Court may decide the application for provisional measures on the basis of the applicant's submissions alone, issuing a regular order in the PI proceedings. This approach aligns with earlier UPC case law confirming that a defendant's failure to lodge an objection permits the Court to proceed to a decision by default

16. Appeal

a) Scope of the appeal

The Court of Appeal[95] noted that allegations of continued non-compliance occurring after the penalty order are outside the scope of the appeal, which is confined to assessing whether the order was justified at the time it was issued. Under R. 354.4 RoP, any claim that the addressee of an injunction or penalty order has subsequently failed to comply must be brought before the same Local Division that issued the order, which retains exclusive competence to determine further enforcement measures or additional penalties. As the order under appeal originated from the Mannheim Local Division, only that division may examine new facts relating to post-order conduct, whereas the Court of Appeal may disregard such material in the appeal proceedings.

b) Standard of review

The Court of Appeal[96] held that a change of claim through the introduction of a subsidiary claim will be refused where it broadens the claim beyond what was previously asserted and no explanation is given as to why it could not have been submitted earlier with reasonable diligence. The Court further stated that, on appeal, a party may refer to statements made during the first-instance oral hearing, provided that such references do not misrepresent the case or the facts, in accordance with R. 284 RoP.

c) Suspensive effect

The Court of Appeal[97] clarifies the strict procedural preconditions for obtaining suspensive effect under R. 223 RoP. It stresses that no application for suspensive effect is admissible unless an appeal has first been lodged, as required by R. 223.1 RoP read with Art. 74 UPCA. Even in situations of extreme urgency, where R. 223.4 RoP allows a party to apply "at any time", the Court underlines that this exception presupposes the prior filing of a Statement of Appeal under R. 224.1 RoP and payment of the appeal fee in accordance with R. 228 RoP and filing the Grounds of Appeal is not required at this stage (R. 224.2 RoP). Because the applicant had not yet filed an appeal or paid the appeal fee, no pending appeal existed and the applicant therefore lacked any legal interest in seeking suspensive effect. The Court rejects reliance on earlier decisions where the appeal and the application for suspensive effect had been lodged on the same day, finding those precedents inapplicable. The application was accordingly held inadmissible, without prejudice to the applicant's right to reapply once a valid appeal has been lodged.

The Court of Appeal[98] rejected Sun Patent's application for suspensive effect against the Paris Local Division's order granting three VIVO employees access to highly confidential information (HCI), finding the application admissible but unfounded. While R. 223.5 RoP states that appeals under R. 220.2 RoP have no suspensive effect, the Court held, by reference to Art. 74 UPCA, that a party may still request suspensive effect in exceptional circumstances, consistent with earlier case law (ICPillar v ARM; NUC v Warmcook). However, Sun Patent failed to show that the appeal would become pointless if the three designated employees obtained access. The Court emphasized that the order already subjects those employees to strict use-limitation obligations and to penalty payments in case of breach, and Sun Patent had not demonstrated any concrete risk that they would misuse the HCI. Moreover, if the appeal ultimately succeeds, the employees' access would be terminated and they would be barred from using the information, while the alternative relief sought by Sun Patent (restricting their participation in licensing negotiations) would remain fully addressable in the appeal. Since the appeal therefore retains its purpose even without suspensive effect, and Sun Patent failed to establish any overriding interest justifying an exception to the default rule of non-suspensive effect, the application was dismissed.

The Court of Appeal[99] recalled in another case that an appeal has no suspensive effect unless the appellant demonstrates exceptional circumstances justifying a departure from this rule. Suspensive effect may only be granted where maintaining the status quo is warranted because the appealed order is manifestly wrong or because the appeal would otherwise be rendered pointless. The Court reiterates that an information order serves to equip the patent proprietor with the data needed to quantify damages and to prevent further infringements, including by identifying distribution channels and third parties involved. Because such orders are protective in nature, their enforcement may only be suspended in truly exceptional circumstances, which were not shown here. The Court emphasizes that confidentiality concerns must be raised before the Court of First Instance so that appropriate protective measures can be taken at the time of the merits decision. A later reservation that a confidentiality request may be submitted is insufficient, and confidentiality issues generally do not interrupt compliance deadlines set in penalty-reinforced orders. The Court further notes that objections to the substantive correctness of the information order must be assessed in the appeal on the merits, and that the applicant must demonstrate a manifest error on the basis of a summary assessment to obtain suspensive effect. In the present case, the risks asserted by the appellant did not meet this threshold and did not show that the appeal would be deprived of purpose absent suspension.

95 UPC-CoA, 19 September 2025, UPC_CoA_699/2025.
96 UPC-CoA, 14 August 2025, UPC_CoA_317/2025 and UPC_CoA_376/2025.
97 UPC-CoA, 15 August 2025, UPC_CoA_740/2025 and UPC_CoA_741/2025.
98 UPC-CoA, 25 August 2025, UPC_CoA_759/2025.
99 UPC-CoA, 6 November 2025, UPC_CoA_897/2025.

Res Judicata of National Nullity Decisions and Prior Use Rights at the UPC

Tomasz Klama*

Case note to UPC-LD Munich (DE), 10 October 2025, UPC_CFI_114/2024, UPC_CFI_448/2024

The Munich Local Division of the UPC has issued a decision addressing the binding effect of final national nullity decisions and the assertion of prior use rights. The Court held that a final judgment of the German Federal Patent Court on grounds of invalidity constitutes an absolute bar to proceedings under R. 362 RoP for corresponding objections in UPC proceedings. At the same time, the Court confirmed the existence of a prior use right for Germany and dismissed the infringement action in its entirety.

I. Summary of facts and decision

The Claimant, Heraeus Electronics GmbH & Co. KG, is the proprietor of European Patent EP 3 215 288 B1, which relates to metal sintering preparations used for firmly bonding components. The patent is in force in several European states, including Germany, France, Italy and Romania. The patent concerns preparations comprising silver particles with specific characteristics defined by a mathematical product of tap density and specific surface area.

The Defendant, Vibrantz GmbH, markets connection pastes under various designations which, in the Claimant's view, infringe the patent in suit. The Claimant brought infringement proceedings before the UPC and sought preliminary injunctions, disclosure of information, rendering of accounts, damages and other relief across multiple UPC member states.

The Defendant filed a counterclaim for revocation, asserting lack of novelty and inventive step among other grounds. A crucial aspect of the case was that the German part of the patent in suit had already been subject to nullity proceedings before the German Federal Patent Court, which by final judgment of 7 November 2023 had maintained the patent in amended form. The Defendant was the legal successor of the plaintiff in those national proceedings. For the other countries in issue (France, Italy, Romania), the Claimant defended the patent only to the extent of Auxiliary Request 3, corresponding to the version confirmed by the German Federal Patent Court.

With regard to infringement, the Defendant relied on a right of prior use under Art. 28 UPCA in conjunction with Sec. 12 German Patent Act for Germany. The Defendant submitted that it had already manufactured and marketed sintering pastes with features according to the patent before the priority date. The Defendant provided extensive evidence including data sheets, batch run cards and witness statements demonstrating that it had used silver flakes of types SF 30 and SF 70A which inevitably resulted in the claimed mathematical product of tap density and specific surface area.

The Court decided that the counterclaim for revocation was inadmissible with regard to the ground of lack of patentability for Germany due to the binding effect of the final national decision. For France, Italy and Romania, the patent was revoked to the extent it exceeded Auxiliary Request 3, as the Claimant had limited its defence to this scope. In all other respects, the counterclaim for revocation was dismissed. The infringement action was dismissed in its entirety because a right of prior use existed for Germany and no acts of infringement had been alleged for the other countries.

II. Discussion of the main findings

1. The principle of res judicata and binding effect of national decisions

The decision addresses comprehensively the question of the extent to which final national nullity decisions bind the UPC. This is of considerable practical importance during the transitional period under Art. 83 UPCA, which provides for concurrent jurisdiction of the UPC and national courts.

The Court clarified that the UPCA as a legal source does not contain specific provisions on res judicata. Therefore, according to Art. 24(1)(e) UPCA, recourse must be made to national law. Since the UPC, within the framework of concurrent jurisdiction, takes the place of the German Federal Patent Court, the situation does not differ from a renewed national nullity action by the same nullity claimant. Under German law, when a patent nullity action is dismissed, the res judicata effect extends only to the ground for revocation asserted. Each of the grounds for revocation listed in Art. 138 EPC constitutes a uniform ground for action. The binding effect of the final judgment of the German Federal Patent Court operates under Sec. 325(1) German Code of Civil Procedure also against the Defendant, which became the legal successor of the plaintiff in those proceedings while they were still pending.

The Court emphasized that the res judicata of the German Federal Patent Court's decision of 7 November 2023 constitutes an absolute bar to proceedings under R. 362 RoP insofar as the German Federal Patent Court decided on the ground of lack of patentability under Art. 138(1)(a), Art. 52–57 EPC. In all other respects, there is no absolute bar to proceedings. This interpretation is consistent and creates legal certainty. The Court thereby prevents the same parties from repeatedly litigating over identical grounds for revocation. The solution is also convincing because it gives due consideration to the principle of res judicata without unduly restricting the jurisdiction of the UPC.

The Court's reasoning is particularly noteworthy in its reliance on the principle that decisions must be given the effects which they have in the state in which they were rendered, as established by the CJEU (CJEU, 8 June 2023, C-567/21 para 47). The Court correctly identified that in the absence of special provisions in the UPCA, it must apply national law to determine the binding effect of national judgments. This approach respects the dual nature of the UPC as both a supra-

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national court and, in the exercise of concurrent jurisdiction, a court that stands in the place of national courts.

In this case, the German Federal Patent Court had not addressed the ground of insufficient disclosure, which remained available for examination by the UPC. This differentiation is important for practice, as it shows that parties must carefully analyse which grounds were actually part of the national proceedings and which remain open for assertion before the UPC.

2. Right of prior use under Art. 28 UPCA

The second focal point of the decision concerns the requirements for a right of prior use. The Court followed the Defendant's submission that such a right existed for Germany. Art. 28 UPCA provides that anyone who in a contracting member state would have had a right of prior use or a personal right of possession in respect of an invention if a national patent had been granted for it, shall have the same rights in that contracting member state also in respect of a patent covering that invention. The UPC must therefore apply national law, in this case Section 12 German Patent Act.

The Defendant submitted that before the priority date it had manufactured sintering pastes with silver flakes of types SF 30 and SF 70A which fulfilled all the features according to the patent. It submitted data sheets, batch run cards and witness statements evidencing this. The Court found that by using these types of silver flakes, the Defendant inevitably achieved the product according to the patent comprising tap density and specific surface area. It was immaterial that the employees had not recognized that these two values could be expressed as a mathematical product. However, they had recognized that the use of these silver flakes led to the production of sintering pastes which enabled a firm connection of components.

Consistent with earlier decisions of the Local Division Düsseldorf (3 July 2024, UPC_CFI_7/2023), the Local Division Munich points out that the question of a right of prior use, in the absence of regulation in the UCPA, is governed by national law. The Court applied established principles from German case law, according to which possession of the invention exists if the person concerned knows, on the basis of their own knowledge, which measures must be taken in order to achieve the success according to the invention. This knowledge exists if the technical teaching resulting from the problem and solution is objectively complete and has been subjectively recognized in such a way that actual implementation is possible. The Court correctly noted that it is not necessary for the beneficiary to have considered what they used to be a patentable invention or to have considered the invention complete. The action of the person relying on Section 12 German Patent Act must, however, be supported by knowledge which makes it possible at any time to carry out the technical teaching in a repeatable manner.

The decision clarifies that no intellectual possession of the invention is required. The Defendant did not need to recognize that a specific mathematical product leads to particularly good adhesive strength. It suffices that it knew which measures led to the success according to the invention, i.e. that it had recognized the external causal connection. The Court emphasized that it was always possible for the Defendant to carry out the technical teaching in a repeatable manner, since it used commercially available silver flakes. It had thus left behind the stage of mere experimentation.

The evidential burden was particularly important in this case. The Defendant submitted extensive documentation including product data sheets dated from October 2014, batch run cards showing specific recipes and quantities used, and witness statements from employees involved in production. The Court found that based on this evidence, it was established with the degree of certainty required in practical life that the Defendant regularly manufactured and marketed sintering pastes for firmly bonding components before the priority date, using silver flakes of types SF 65, SF 70A and SF 30, and that these sintering pastes exhibited all the features of claim 1 in the version according to Auxiliary Request 3.

3. Absence of infringement in other territories

For France, Italy and Romania, the Court dismissed the infringement action because the Claimant had not alleged any specific acts of infringement. The Claimant attempted to derive a risk of infringement for other territories from acts committed in Germany. However, the Court clarified that the acts committed in Germany were covered by a prior use right and were therefore lawful. They therefore do not constitute acts of infringement and consequently do not give rise to a risk of infringement for other territories.

The application of Art. 34 UPCA, according to which in principle it suffices to allege acts of infringement in at least one contracting member state, did not assist the Claimant. In the present case there was a lack of acts of infringement in at least one contracting member state. The Court's reasoning on this point is concise but significant. It makes clear that Art. 34 UPCA, which provides that decisions of the Court shall have effect in the territories of the contracting member states for which the European patent has effect, cannot be used to circumvent the requirement to establish actual infringement. Where alleged acts of infringement are lawful because they are covered by a prior use right, they cannot serve as a basis for asserting infringement in other territories.

4. Substantive assessment of validity

Although the Court's decision on validity was limited due to the res judicata effect, the Court did examine the ground of insufficient disclosure under Art. 83 EPC, which had not been addressed in the national proceedings. The Court found that this ground did not succeed. The Defendant had argued that the feature "for firmly bonding" was not defined by the patent and that the claimed range of values was not sufficiently supported by the examples in the specification. The Court rejected these arguments, finding that the skilled person could readily understand from the patent specification what was meant by a firm connection and that the technical teaching was sufficiently disclosed to enable the skilled person to carry it out.

The Court's analysis on this point is instructive. It emphasized that for the question of sufficiency of disclosure, one must look not only at the claim wording but at the overall content of the disclosure from the perspective of the skilled person based on common general knowledge at the priority or filing date. The specification disclosed that the metal sintering preparation could contain various additional components beyond the minimum amounts of metal particles and organic solvent specified in the claim, thereby providing a complete recipe to the skilled person. The Court also found that the claim ranges were sufficiently disclosed even though not all conceivable combinations were

exemplified, noting that this was a question of support by the description under Art. 84 EPC, which is generally not subject to revocation proceedings unless the claims have been amended.

III. Closing remarks

The Munich Local Division's decision has significant practical implications for UPC litigation. Final national nullity decisions create a binding shield against relitigating the same grounds before the UPC, at least between the same parties and their successors. Patent proprietors should recognize that positive national decisions offer protection during the transitional period, though limited to the specific grounds actually decided. Careful analysis of the scope of national judgments is essential.

The decision confirms that prior use rights remain an effective defence even where the theoretical basis was not fully understood. Actual use and reproducibility are decisive. Companies should preserve development and production documentation meticulously, as contemporaneous business records such as data sheets, batch cards, certificates and witness statements can be highly persuasive. Since Art. 28 UPCA refers to national law, prior user rights must be established separately for each contracting member state.

Specific acts of infringement must be alleged for each territory. Art. 34 UPCA provides no shortcut where alleged acts in one territory are lawful or where no acts are substantiated elsewhere. Multi-jurisdictional claimants must investigate and document distribution channels, sales activities and commercial acts in each specific country where relief is sought.

The decision underscores the need for thorough preparation. Patent proprietors must assess how existing national decisions affect UPC proceedings. Defendants should identify potential prior use rights early. The Court's willingness to apply national law where the UPCA leaves gaps demonstrates the continuing importance of understanding national legal systems even in supranational litigation. The coexistence of national and UPC proceedings during the transitional period creates both opportunities and risks of inconsistent outcomes. As the UPC's jurisprudence develops, careful monitoring of how different divisions approach the relationship between the unitary system and established national frameworks will be essential.

Munich Muscle: Cross-Border Injunction for Infringement by Equivalence

Jeroen Boelens*

Case note to Munich Regional Court I, 25 September 2025, 7 O 9383/25

In its decision of 25 September 2025, the Munich Regional Court I granted a cross-border preliminary injunction based on patent infringement under the doctrine of equivalents. This case note discusses the court's reasoning for both the finding of equivalence and the territorial scope of the injunction, including the burden of proof for the defendant to rebut the injunction's cross-border effect.

I. Summary of facts and decision

The dispute concerns a preliminary injunction application regarding a formulation of the inhibitor of vascular endothelial growth factor ("VEGF") aflibercept. Aflibercept is used in the treatment of a certain form of decreased vision in the patient (macular degeneration) and is commercialized by the claimants. The application is directed against the defendants' aflibercept biosimilar. The patent in question relates to formulations comprising a VEGF antagonist and specified excipients, and was upheld in limited form by the German Federal Patent Court in June 2025. The claimants are also licensees of an SPC for aflibercept in Germany expiring on 23 November 2025, after which the defendants signalled intent to launch their biosimilar "in major parts of Europe, including Germany." The claimants allege that the biosimilar practices the claimed teaching at least by equivalence, specifically that substitution of the claim's phosphate buffer with histidine achieves the same effect and would be discoverable to the skilled person. Parallel and related proceedings were pending abroad, including in the United Kingdom and The Netherlands.

The Munich Regional Court I (7th Civil Division) granted a preliminary injunction restraining the defendants from manufacturing, offering, importing, or possessing ophthalmic formulations within the claim scope across 22 countries, with penalties up to EUR 250,000 per infringement or substitute imprisonment. The court affirmed its international and local jurisdiction and relied on the CJEU's *BSH/Electrolux*[1] ruling to proceed notwithstanding validity objections elsewhere. On standing, the court held that the claimants were entitled to sue, rejecting objections based on registration formalities or sublicensing, which the court characterized as procedural issues governed by *lex fori*. Substantively, the court found equivalent infringement under German law and applied a strong indicative effect that the same result should obtain in the other EPC states absent concrete, expert-supported proof of divergent national law or materially different technical facts from the defendants. The court concluded that injunctive relief was necessary to prevent fragmentation and to avoid strategic, staggered launches that would overburden the patentee's enforcement resources across multiple jurisdictions.

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1 CJEU, 25 February 2025, C-339/22, EPLP 2025, 135–142 – BSH/Electrolux. See also Speyart, The Practical Consequences of BSH v Electrolux and Fujifilm v Kodak, EPLP 2025, 107–110; Luginbuehl and Pickard, BSH Hausgeräte GmbH v Electrolux AB (C-339/22) – Another Boost for the Unified Patent Court and an (Un-)Intended Provocation for Courts Outside of the EU?, EPLP 2025, 122–128.

II. Grounds for the decision

The patent specifies a formulation for intravitreal use that includes, among other components, a buffer expressly defined as a sodium phosphate. The defendants' biosimilar product employs histidine as the buffer rather than sodium phosphate, giving rise to the central question of whether histidine is an equivalent substitute for the claimed phosphate buffer within the meaning of the German and foreign equivalence doctrines.

The Chamber characterised the dispute as a "simple equivalence" constellation because the only modification in the accused formulation is the substitution of histidine for phosphate to achieve the specified pH, without altering the invention's technical core as reflected in the claim structure and description. On that basis, it applied the standard three-step test of the German Federal Court of Justice for equivalence and emphasised that, under Art. 69(1) EPC and its Protocol, prosecution statements cannot narrow the patent's objective scope of protection, save for a limited role under the doctrine of contradictory conduct; the court considered the patentee's references to histidine during prosecution as, at most, "additional" arguments rather than any waiver. Applying the three-step test, the court first held that the biosimilar's histidine-buffered formulation achieves the same effect as the claimed phosphate-buffered formulation because the buffer's function is to set the pH and does not define the invention's technical core. Second, the court found that the skilled person could have identified histidine as a replacement using common general knowledge and routine stability testing. Third, it accepted equality of value because neither the claim nor the description assigns any function to sodium phosphate beyond pH adjustment, and nothing in the file history evidences a deliberate limitation to phosphate that would normatively exclude histidine.

The *Formstein* defence failed because the prior art document invoked by the defendants disclosed aflibercept with histidine but did not disclose an ophthalmic formulation "for use in intravitreal administration"; accordingly, the accused embodiment was not fully anticipated, and extending protection by equivalence does not capture subject matter lacking patentable merit. In the court's analysis, the decisive factual point was that the buffer feature serves purely to achieve the claimed pH in a stable intravitreal formulation, and substituting histidine for phosphate achieves the same effect without changing the technical core; the buffer therefore functions as a non-core, functional means of implementation, with histidine an equally effective and findable alternative within the skilled person's routine toolkit.

On the cross-border transposition question, the Chamber articulated a strong indicative effect: a German infringement finding – based on the Protocol on the Interpretation of Article 69 EPC, Art. 2 – serves as a persuasive baseline for other EPC states in the absence of demonstrated foreign-law divergence. The court therefore declined to solicit country-by-country expert evidence absent a concrete showing from the defendants that established foreign substantive law or case law would compel a different result; differences in procedure, timelines, or evidentiary practices were deemed immaterial for this purpose, and the burden rested on the defendants to produce pertinent foreign materials and a qualified expert opinion so the court extended its equivalence assessment across the 22 asserted jurisdictions.

III. Discussion

This decision is noteworthy as it is reportedly the first time a court has granted a cross-border injunction for equivalent infringement since the CJEU's decision in *BSH/Electrolux*.[2] The *BSH/Electrolux* decision provides a powerful instrument for cross-border relief. Seeking cross-border relief requires the application of foreign law. Such foreign applications are inherently complex.

This in particular applies to the doctrine of equivalents. Although there is growing international harmonisation around Article 69 EPC and the Protocol, national courts still apply the doctrine of equivalents differently. As reported before in this journal,[3] German law uses a two-step structure organised by the three *Schneidmesser*[4] questions and has refined limits in cases like *Okklusionsvorrichtung*[5] and *Pemetrexed*.[6] The UK shifted in *Actavis v. Eli Lilly* from decades of purposive construction to a clear twostep equivalents inquiry, asking whether the variant achieves essentially the same result in substantially the same way, assessed at the priority date.[7] France applies a distinctive model: "literal" infringement focuses on essential means only, and equivalence follows the so-called *Mathély* test.[8] The Netherlands, historically oscillating between onestep and twostep approaches, now typically uses a two-step test: after literal scope, courts assess technical equivalence plus an explicit balance of fair protection and legal certainty, with a validity back-stop to avoid covering prior art.[9]

A court deciding cross-border equivalent infringement faces a formidable task, particularly when, as here, the patentee alleges infringement in 22 other countries. Applying that many foreign legal systems is a challenge, especially in preliminary proceedings. In its decision, the Munich Regional Court I appears to have assessed the various legal systems and found equivalent infringement under all of them. This "22-0 score" may reflect the court's view – perhaps more aspirational than practical – that equivalence analyses will yield the same result across EPC member states, despite their distinct legal tests. The 22-0 score is also noteworthy because the UK High Court found no equivalent infringement in parallel proceedings on the merits.[10] Although each case is argued differently,

2 CJEU, 25 February 2025, C-339/22, EPLP 2025, 135–142 – BSH/Electrolux. See also Speyart, The Practical Consequences of BSH v Electrolux and Fujifilm v Kodak, EPLP 2025, 107–110; Luginbuehl and Pickard, BSH Hausgeräte GmbH v Electrolux AB (C-339/22) – Another Boost for the Unified Patent Court and an (Un-)Intended Provocation for Courts Outside of the EU?, EPLP 2025, 122–128.

3 Wuttke, The Doctrine of Equivalents in the UPC, EPLP 2024, 61–66; Holtz et al., The Doctrine of Equivalents and its First Appearance Before the UPC, EPLP 2025, 61–71.

4 DE-BGH, 12 March 2002, X ZR 168/00 – Schneidmesser I.

5 DE-BGH, 10 May 2011, X ZR 16/09 – Okklusionsvorrichtung.

6 DE-BGH, 14 June 2016, X ZR 29/15 – Pemetrexed.

7 UK-SC, 12 July 2017, [2017] RPC 21 – Actavis v. Eli Lilly.

8 P. Mathély, Le nouveau droit des brevets d'invention (1991).

9 NL-SC, 1 March 2024, ECLI:NL:HR:2024:293 – Koopman/Tinnus; NL-Court of Appeal, 27 October 2020, ECLI:NL:GHDHA:2020:2052 – Eli Lilly/Fresenius.

10 UK-HC, 8 October 2025, [2025] EWHC 2527 (Pat) – Formycon et al. v. Regeneron et al.

the core technical question – whether histidine is equivalent to phosphate – was identical.[11] In jurisdictions like Ireland, which follow a UK-style doctrine of equivalents, one may think that a UK High Court decision might be more persuasive than a German one. That a foreign court, in preliminary proceedings, can issue an injunction with effect in Ireland when the UK High Court has rejected infringement might lead to some discomfort here and there.[12]

Needless to say, the appeal in this matter is highly anticipated.

11 The invoked claim in the UK was a different claim, but this does not seem materially relevant for the holding regarding equivalence.

12 Although this PI was confined to EU Member States, *BSH/Electrolux* suggests that it may have a broader reach and reports suggest the Munich Regional Court I will soon be asked to decide on infringement of US patents.

The Role of the Description and Unclaimed Embodiments – Düsseldorf Higher Regional Court on Equivalent Infringement

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Case note to Düsseldorf Higher Regional Court, 12 September 2025, 2 U 60/25

The decision by the Düsseldorf Higher Regional Court provides a textbook assessment of equivalent infringement and touches on principles of construction as well as the potential relevance of the original publication in the context of a selection invention.

I. Facts of the case

The claimant, as exclusive licensee of a European patent and supplementary protection certificate ("SPC") for a pharmaceutical composition for coordinated delivery of nonsteroidal anti-inflammatory drugs ("NSAIDs"), brought proceedings for interim injunctive relief against the defendant, a German company as subsidiary of a Turkish company.

The claimant's product contains the active ingredient combination naproxen and esomeprazole for treating osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in patients at risk of developing gastrointestinal ulcers when taking NSAIDs. The defendant obtained German marketing authorization on 27 November 2024 for its generic product "Naproxen/Esomeprazole 500 mg/20 mg modified-release tablets". Upon learning of the defendant's intention to launch its product in Germany, the claimant sought a preliminary injunction, alleging that the defendant's product infringed the SPC either literally or under the doctrine of equivalents.

At first instance, the application for a preliminary injunction was dismissed by the Düsseldorf Regional Court which found neither a literal infringement nor an infringement based on the doctrine of equivalence. The claimant appealed this decision, and the Higher Regional Court overturned the first instance decision.

The dispute has an international dimension: In corresponding disputes in Norway, Portugal and Switzerland, the courts at first instance rejected an equivalent infringement. However, the Norwegian appeal court overturned the first instance decision and assumed an equivalent infringement under consideration of the findings by the Düsseldorf Higher Regional Court – therewith showcasing the influence of this court in the European patent practice.

II. The appeal court's decision

On appeal, the Düsseldorf Higher Regional Court granted the preliminary injunction (and lifted the first instance decision). As there is only one substantive appeal instance in preliminary proceedings, the decision is final. There are, however, two parallel main proceedings pending before the Düsseldorf Regional Court in this matter (file numbers 4a O 79/25 and 4a O 80/25).

The Higher Regional Court carefully summarizes the teaching of the patent. In this regard, the court sees the technical effect of the patent in a sequential release whereby a proton pump inhibitor ("PPI") is released before the NSAID. This is in a certain tension to the understanding of the Opposition Division at the European Patent Office, which saw the technical effect primarily in the fast release of the PPI, i.e. putting emphasis on the short duration of the release. The court justifies the difference by stating that the Opposition Division did not refer to description passages describing sequential release as decisive but instead focused on the meaning of the word "outer" such that the PPI in the outer layer causes it to be released at the earliest possible time. In turn, the court comes to a broader claim scope based on its understanding that the general description section does not define a specifically quick release.

Further, the Düsseldorf Higher Regional Court clarifies its take on claim construction in general and with a view to invalidity arguments in specific: Here, a comparison with the publication of the patent application may be considered if this can help to clarify the scope of a limitation of the protected subject matter made when the patent was granted or in opposition proceedings in the event of contradictions between the description and the patent claim, or if it remains unclear whether the patent claim and description can be meaningfully related to each other. As neither was the case here, the publication of the patent application was not considered suitable material for interpretation of the claim.

On the basis of its construction, the Düsseldorf Higher Regional Court confirms that there was no literal infringement, as the attacked embodiment was missing both a "barrier layer" and an "inner core" as defined in the patent, but instead comprised a matrix structure with a gastro-resistant polymer

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where no coherent, delimitable spatial structure within the tablet body could be considered a "barrier layer" or an "inner core" within the meaning of the basic patent.

However, unlike the Regional Court, the Higher Regional Court assumes an equivalent infringement. In this regard, the court first recalls the principles established by the German judiciary regarding the framework of equivalent infringement:

First, the embodiment must solve the problem underlying the invention by means which objectively have the same effect. *Second*, the knowledge available at the priority date must have enabled the skilled person to find the modified embodiment to have said same effect. *Third*, the considerations made by the skilled person must ultimately be based/oriented on the meaning of the teaching protected in the patent claim. The court finds these three conditions to be fulfilled.

First, the court holds that the defendant's matrix structure has the same effect as the literally claimed design with an inner core of NSAID and a surrounding barrier layer. Even though some NSAID particles in the matrix structure were not fully surrounded by the polymer, the court finds that the claimant had sufficiently demonstrated that this involved such a small amount of NSAID that it had no technically or therapeutically relevant effect and thus dismissed this argument by the defendant. The court refers to its "WC-Sitzgelenk" decision, establishing that effects which may be objectively associated with the use of the means described in the literal wording of the patent claim, but which are not considered by the patent because they are irrelevant in the context of the invention, must be disregarded when assessing equivalent effect.[1]

Second, the court finds that the skilled person could identify the matrix structure as equivalent without inventive effort. As polymer-based matrix embedding was generally known as a method for producing tablet formulations at the priority date, the skilled person would have found this solution without inventive effort.

Third, and this is the most relevant item, the court finds that the skilled person would consider the matrix structure as equivalent and oriented on the patent claims. Notably, the description of the patent mentioned the possibility of NSAID being contained in a matrix, leading the defendant to argue that a "selection decision" had been made to explicitly exclude this variation. The court recalls the established principle that equivalent infringement is generally denied if the description discloses several possibilities for achieving a particular technical effect, but only one of these possibilities is included in the patent claim.

The court then refers to the "Pemetrexed" decision by the Federal Court of Justice, where it was held that it is not sufficient to apply this principle that an embodiment claimed by the patent is presented as a specific application of a more general solution on the basis of information in the description or for other reasons, and that the skilled person was able to find further embodiments corresponding to this solution principle on the basis of this knowledge.[2] Instead it is necessary for the patent description to disclose at least two concrete embodiments capable of achieving the technical effect according to the invention and only one of these to be represented in the patent claims.

Applying these principles, the court concludes that no selection decision had been made to exclude a matrix structure such as the one found in the attacked embodiment. The court justifies this by highlighting that the described embodiment comprising a matrix structure still also comprised a barrier layer. Neither the patent description nor any other circumstances affecting interpretation of the patent provided any indication that the choice of a layer structure excluded a matrix structure as found in the attacked embodiments. In particular, no embodiment wherein the matrix structure comprised a gastro-resistant polymer which would not resolve unless the pH-level amounted to at least 3.5 and where the matrix was not surrounded by a barrier layer – as was the case in the challenged embodiments – was disclosed in the patent.

Likewise, a comparison between the patent as granted and the original application did not show any selection decision. Such a decision could be assumed if the comparison reveals a concretization that was made to distinguish the subject matter of the patent from prior art to address doubts regarding patentability. If this were evident, then it would generally not need to be assessed whether this concretization was in fact necessary. On the other hand, where the concretization is made for the purpose of clarifying the claim or to avoid any added matter issues, this would not allow drawing any conclusions as to equivalent infringement.

Based on this, the court concludes that the defendant had failed to show that the choice of the layer structure was included in claim 1 of the patent to distinguish the protected teaching of the patent from prior art. While a different structure besides the layer structure was described in relation to a different single dose form (capsule instead of tablet), the court considers it possible that the patentee chose the form of a tablet to distinguish the patent from prior art. This would then not allow any conclusions as to the choice of a different structure.

Thus, the court granted the requested preliminary injunction.

III. Discussion

The decision by the Düsseldorf Higher Regional Court is consistent with established case law and still provides very helpful guidance, particularly for the assessment of equivalent infringement.

Regarding patent claim interpretation, the decision restates and applies the principle that there is no interpretive rule requiring patent claim language to be free of redundancies. Thus, the decision once again confirms that a patent claim may contain redundancies or state the obvious. Furthermore, it once again shows that courts are not bound by the interpretation of the EPO and may, where they see good arguments to do this, interpret a patent differently.

A specific value of the decision then lies in its detailed assessment of equivalent infringement. Here, it provides an important further piece in the case law, providing details to important criteria to be considered when assessing equivalent infringement, specifically in the life science sector and chemistry.

1 DE-OLG Düsseldorf, 7 November 2013, I-2 U 29/12, GRUR-RR 2014, 185.
2 DE-BGH, 14 June 2016, X ZR 29/15 – Pemetrexed, GRUR 2016, 921.

This is particularly evident regarding the third criterion for assessing equivalence, which is whether the skilled person's considerations are based on the meaning of the teaching protected in the patent claim. Here, the decision displays a practical implementation of the principle first established by the Federal Court of Justice in its decisions "Okklusionsvorrichtung", "Diglycidverbindung" and "Pemetrexed".[3]

In these decisions, the Federal Court of Justice established that patent protection does not extend to embodiments that the patent claim consciously excludes while identifying them as alternatives. This scenario needs to be carefully distinguished from a scenario where the patent claim provides a specific solution based on a general principle that is described in the patent.

The Düsseldorf Higher Regional Court soundly argues why the latter applied in the present case: The mere mention of a matrix structure containing NSAID in the patent description in the specific case is not sufficient to negate a finding of equivalent infringement as the described embodiment still included the key feature of a "barrier layer" (and thus a layered structure as such – i.e. even the embodiment with a NSAID matrix ultimately related to a layered tablet).

Likewise, it is reasonable to argue that it was not evident that different structures were only excluded as an annex to a decision towards a tablet. Thus, it can be argued that the patent did not provide the solution of a tablet with a matrix structure but without a barrier layer, but instead only a capsule with different structural properties.

On an abstract level, the underlying question for practitioners is whether a clear spatial and physical specification (here: requiring an inner core and separate layers) is eligible to equivalent infringement. E.g. in an older decision, the Düsseldorf Higher Regional Court considered such specifications as a boundary for the function-oriented interpretation of a claim feature.[4] There, the court rejected an equivalent infringement as one of the features providing a clear spatial and physical specification was missing in the attacked embodiments without equivalent replacement, meaning that the considerations of the skilled person to come to the solution of the attacked embodiment were not oriented on the patent claim.

In the present case, however, the court considered the attacked embodiments to realize the core of the inventive idea as it found the matrix structure of the embodiment to follow the idea of the technical teaching as in the claim.

Thus, it appears the court does not answer the above question in an abstract way, but on the basis of the specific case at hand (i.e. the claim, description and attacked embodiment).

All in all, the decision displays a detailed assessment of the facts of the specific case necessary to deal with equivalent infringement. Here, it is not sufficient for the general solution chosen for the challenged embodiment to be described in the patent, but it needs to be described in a way that comprises the crucial distinguishing feature. This also aligns with the principle established by the Federal Court of Justice in its cited earlier decisions.

Specifically, when a patent description reveals several possibilities for achieving a particular technical effect, but only one possibility is included in the patent claim, equivalent infringement can only be found if the modified solution corresponds in its specific effects to the protected solution and differs similarly from the solution variant shown only in the description but not claimed.[5] This condition is satisfied in the present case.

Regarding the two other questions to be answered in the test for equivalence, the decision also shows a detailed assessment and can serve as a valuable example of how to apply these criteria.

IV. Closing remarks

The decision by the Düsseldorf Higher Regional Court adds valuable guidance when it comes to the assessment of equivalent infringement. It is in line with the established principles regarding equivalent infringement. Regarding a possible selection decision as a factor negating equivalent infringement, the decision adds to these established principles and further develops and sharpens them.

From a practical standpoint, it is noteworthy that the original patent application did not provide information that could serve as a basis for finding a selection decision. Consequently, the question of the extent to which prosecution history documents may be considered in assessing equivalent infringement remains open. Nevertheless, the decision showcases how an assessment of the application would be conducted, thus allowing practitioners to consider this approach in the future.

3 DE-BGH, 10 May 2011, X ZR 16/09 – Okklusionsvorrichtung, GRUR 2011, 701; DE-BGH, 13 September 2011, X ZR 69/10 – Diglycidverbindung, GRUR 2012, 45; DE-BGH, 14 June 2016, X ZR 29/15 – Pemetrexed, GRUR 2016, 921.

4 DE-OLG Düsseldorf, 14 August 2014, 15 U 15/14.

5 DE-BGH, 13 September 2011, X ZR 69/10 – Diglycidverbindung.

Binding Effect of National Decisions on Patent Validity and Prior Use Right*

Country:	UPC Member States
Court:	Unified Patent Court, Court of First Instance, Munich Local Division
Decision name:	Heraeus Electronics v. Vibrantz
Decision date:	10 October 2025
File number:	UPC_CFI_114/2024, UPC_CFI_448/2024
Standards:	UPCA Articles 83, 24(1), 28; EPC Article 138; Brussels I Regulation (recast) Articles 71a, 71d; German Patent Act Section 12

In the absence of any specific provisions in the UPCA on this point, the question of whether a final judgment dismissing a national nullity action has binding effect must be determined with reference to national law, pursuant to Article 24(1)(e) UPCA.

Facts

[1] The plaintiff is a company incorporated under German law, engaged in the research, development, and distribution of material solutions for assembly and connection technology, in particular with respect to adhesives, metal-ceramic substrates, and sintering pastes.

[2] The plaintiff is the registered holder of European Patent 3 215 288 B1, filed on 8 May 2015 and claiming priority from 3 November 2014 (EP 14191408). The grant of the patent was published on 29 August 2018. Previously, the plaintiff's legal predecessor, Heraeus Precious Metals GmbH & Co. KG, was recorded as the patent holder.

[3] The patent is in force in several European countries, including Germany, France, Italy, and Romania.

[4] Claims 1–9 read as follows in the aforementioned territories, excluding Germany, […]:

1. A metal sintering preparation which comprises (A) 50 to 90 weight per cent of at least one metal selected from the group consisting of copper, silver, gold, nickel, palladium, platinum and aluminium, said metal being present in the form of particles having a coating which contains at least one organic compound selected from the group consisting of free fatty acids, fatty acid salts and fatty acid esters, and (B) 6 to 50 weight per cent of one or more organic solvents selected from the group consisting of terpineols, N-methyl-2-pyrrolidone, ethylene glycol, dimethylacetamide, 1-tridecanol, 2-tridecanol, 3-tridecanol, 4-tridecanol, 5-tridecanol, 6-tridecanol, isotridecanol, with the exception of a methyl substitution at the next-to-last C-atom non-substituted 1-hydroxy-C16-C20-alkane, dibasic esters, glycerin, diethylene glycol, triethylene glycol and aliphatic hydrocarbons with 5 to 32 C-atoms,
   characterized in that,
   the mathematical product of the packing density determined in accordance with DIN EN ISO 787-11:1995-10 and the specific surface of the metal particles of the component (A), determined in accordance with DIN ISO 9277:2014-01, is within the range from 40000 to 80000 cm^{-1}.
2. The metal sintering preparation in accordance with claim 1,
   wherein the mathematical product of the packing density determined in accordance with DIN EN ISO 787-11:1995-10 and the specific surface of the metal particles of the component (A), determined in accordance with DIN ISO 9277:2014-01, is within the range from 50000 to 70000 cm^{-1}.
   […]

[5] The German part of the patent in suit was upheld in amended form, with claims 1–8, by a now final and binding judgment of the German Federal Patent Court dated 7 November 2023. ([…]):

1. Use of a metal sintering preparation to permanently join components, wherein the metal sintering preparation comprises (A) 50 to 90 weight per cent of silver in the form of particles, which are flakes or have an irregular shape, having a coating which contains at least […],
   characterized in that,
   the mathematical product of the packing density determined in accordance with DIN EN ISO 787-11:1995-10 and the specific surface of the metal particles of the component (A), determined in accordance with DIN ISO 9277:2014-01, is within the range from 50000 to 80000 cm^{-1}. […]
2. Use of a metal sintering preparation in accordance with claim 1 to permanently join components, […]
   […]

[6] The defendant is a company incorporated under German law that manufactures various types of coating chemicals at multiple locations in Germany. It is in direct competition with the plaintiff. During the nullity proceedings before the German Federal Patent Court, the defendant became the legal successor to the plaintiff in those proceedings.

[7] It markets bonding pastes under the following names:
– customized Ag paste; especially designed for metallisation for chip bonding at low temperature, and
– Low Temperature Sintering Silver Paste.

Case history

[8] By order dated 2 December 2024 (App_55548/2024), and as corrected by order dated 26 February 2025 (ORD_9486/2025), the Court allowed the infringement action to be extended to include claims relating to the newly acceded Contracting Member State, Romania, as well as the corresponding extension of the nullity counterclaim. The subsequent extension of the action to include claims for infringement of the method claim was not contested. Furthermore, Heraeus Precious Metals GmbH & Co. KG was replaced by its legal successor, Heraeus Electronics GmbH & Co. KG.

* No official translation; translated by editorial team.

Arguments of the Parties

Interpretation

[9] The defendant contends that the feature "to permanently join" is not defined in the patent in suit. Therefore, anything that cannot be removed without force must be considered "permanent."

[10] […]

Infringement

[…]

Prior use right

[13] The defendant asserts a private prior use right. They state, for example, that the sintering paste 6380 0015 from October […] was documented. The same silver flakes of types SF 30 and SF 70A were used for these sintering pastes, and these flakes were subsequently employed in production and continue to be used today. Furthermore, the product "NTV-Paste Siebdruck" was delivered to a customer as early as 2009. In the same year, the product "6380 0015 Ag-Suspension" was also manufactured at the Hanau site for another customer. In 2013, a sample of sintering paste 6380 0025 was delivered to a customer in France.

Deceit and unlawful taking

[14] Furthermore, with reference to email correspondence from October and December 2009 between the defendant and […] – a company belonging to the corporate group of the patent holder – the defendant asserts, in addition to the private prior use right, the defences of deceit and unlawful taking. […]

Counterclaim for revocation – admissibility

[15] The plaintiff argues that the continuation of the proceedings concerning the counterclaim for revocation is barred by an absolute procedural impediment, given the final judgment of the German Federal Patent Court dated 7 November 2023. The fact that the Court and the national courts have parallel jurisdiction during the transitional period pursuant to Article 83(1) UPCA does not affect the principle of res judicata with respect to the same subject matter. Furthermore, it would be unacceptable for the special circumstances of the transitional period under Article 83 UPCA, and the resulting parallel jurisdiction of the UPC and the "regular" national courts, to override the principle of res judicata.

[…]

Grounds

[37] The counterclaim for revocation, insofar as it is directed against the German part of the patent in suit, is admissible only with respect to the ground of lack of enabling disclosure. However, this ground is not successful. With regard to the remaining national parts of the patent in suit, the counterclaim for revocation is admissible. To the extent that the plaintiff defends these parts only within the scope of the version upheld by the German Federal Patent Court, the counterclaim for revocation succeeds. In all other respects, the counterclaim for revocation is dismissed.

[38] The plaintiff has alleged acts of use only in Germany, not in France, Italy, or Romania. As these acts are covered by a national prior use right, no patent infringement can be established. Consequently, Article 34 UPCA cannot be applied to France, Italy, or Romania, and the infringement action is dismissed in its entirety.

A. The patent in suit

I. Subject matter

[…]

II. Interpretation

[…]

B. Revocation action

I. Admissibility of the counterclaim for revocation

[67] With regard to the ground of lack of patentability (Article 65(2) UPCA and Article 138(1)(a) EPC), a decision concerning the German part of the patent in suit is precluded by the res judicata objection within the meaning of Rule 362 RoP.

[68] Pursuant to Article 20 and Article 24(1)(a) UPCA, the Court shall base its decisions on disputes brought before it under this Agreement on Union law, the UPCA, the EPC, international agreements, and national law. The Court shall apply Union law in its entirety and respect its primacy.

[69] The Court of Justice of the European Union has emphasized the importance of the principle of res judicata within both the Union legal order and national legal systems. To ensure legal certainty, the stability of legal relationships, and an orderly administration of justice, judicial decisions that have become final after the exhaustion of legal remedies or the expiry of the relevant time limits for appeal must not be called into question (judgment dated 19 April 2012, C-221/10 P, para. 86; judgment dated 16 March 2006, Kapferer, C-234/04, [2006] ECR I-2585, para. 20; judgment dated 29 June 2010, Commission/Luxembourg, C-526/08, [2010] ECR I-6151, para. 26; judgment dated 29 March 2011, ThyssenKrupp Nirosta/Commission, C-352/09 P, [2011] ECR I-2359, para. 123).

[70] 1. The Court of Appeal has already ruled (order dated 16 January 2025, UPC_CoA_30/2024, Nos. 55–56) that, pursuant to Article 36(1) of the Brussels I Regulation (recast), judgments rendered in one Member State shall be recognized in the other Member States without any special procedure being required. However, for the UPC there is a specific provision in Article 71a of the Regulation, which defines the UPC as a court common to several Member States. Such a court is deemed to be a court of a Member State when, pursuant to the instrument establishing it, it exercises jurisdiction in matters falling within the scope of the Regulation. It follows from this that the UPC is considered to be a court of a Member State. Since national courts recognize their own judgments, it is not necessary for the Regulation to provide for the recognition of judgments of the courts of a Contracting Member State by the UPC. Where recognition and enforcement of a decision issued by the UPC is sought in a Member State that is a Contracting Party to the UPCA, the provisions of the UPCA on recognition and enforcement shall apply in place

of the provisions of the Brussels I Regulation (Article 71d, last paragraph of the Brussels I Regulation).

[71] 2. The UPC exercises its jurisdiction by ruling on a counterclaim for revocation of the German part of the patent in suit within the framework of concurrent jurisdiction. Therefore, with respect to the German part of the patent in suit, it is deemed to act as a German court.

[72] The fact that the UPC must also rule on counterclaims for the revocation of other national parts of the same European patent, as in the present case, is irrelevant because the nature of a bundle patent means that a European patent can have different fates in the contracting states. The entry into force of the UPCA has not changed this. Although the intention is to achieve a high degree of consistency in decisions, the legal nature of a European patent, as established under the EPC, still allows for, and in some cases requires, divergent national decisions.

[73] Therefore, the defendants' objection that it would be unacceptable for the UPC to possibly rule that a patent is infringed, despite considering the relevant national patent to be invalid in contradiction to a final and binding decision of a national court, is unfounded. This apparent contradiction is rooted in the principle of *materielle Rechtskraft*, or, in other jurisdictions, the principles of *l'autorité de la chose jugée* (in the French legal system) or res judicata (in common law).

[74] 3. When the UPC takes the place of the German Federal Patent Court within the framework of concurrent jurisdiction, the issue is the same as that which arises in the case of a new national nullity action brought by the same nullity plaintiff who was previously unsuccessful. In both cases, the question of binding effect must be answered consistently. In this respect, the German Federal Patent Court and the UPC exercise their jurisdiction as national German courts.

[75] In the absence of any specific provisions in the UPCA on this matter, the question of whether the judgment of the German Federal Patent Court dated 7 November 2023 has binding effect must be determined by reference to national law, pursuant to Article 24(1)(e) UPCA. This is because recognition is intended to "have the result of conferring on judgments the authority and effectiveness accorded to them in the State in which they were given" (CJEU, BNP Paribas SA/TR, para. 47, referring to the report on the Brussels Convention drawn up by P. Jenard (OJ 1979 C 59, p. 44); Court of Appeal, decision dated 3 October 2025, UPC_CoA_534/2024 and 19/2025 and 683/2024, para. 163).

[76] Under German law, when a patent nullity action is dismissed, the res judicata effect extends only to the grounds for revocation that were (unsuccessfully) asserted by the plaintiff. Each ground for revocation listed in Article 138 EPC constitutes a uniform "cause of action" in this respect. According to these special principles, recognized for nullity actions as an actio popularis, the dispute is limited to the grounds for revocation asserted. Consequently, a plaintiff whose action has been dismissed cannot rely on the grounds for revocation raised in previous proceedings when challenging the validity of a patent again. In this context, the ground under Sections 22(1) and 21(1) No. 1 of the German Patent Act, Article 138(1) EPC, and Article II Section 6(1) of the German Law on International Patent Treaties constitutes a uniform ground for revocation (Ann, Patentrecht, 8th edition, § 26, para. 244; see also the case law of the Reichsgericht and the German Federal Court of Justice under previous provisions: German Federal Court of Justice, judgment dated 19 February 1963, Ia ZR 64/63, GRUR 1964, 18, "Konditioniereinrichtung"; Reichsgericht, decision dated 23 November 1932, RGZ 139, 3, 5; German Federal Court of Justice, judgment dated 11 May 2010, X ZR 51/06, GRUR 2010, 901, "Polymerisierbare Zementmischung", regarding the plaintiff's extension of the claim).

[77] 4. According to these standards, the UPC's decision is precluded by the res judicata effect of the German Federal Patent Court's judgment dated 7 November 2023 with regard to the ground for revocation of lack of patentability pursuant to Article 138(1) EPC and Article II Section 6(1) of the German Law on International Patent Treaties. In that case, the plaintiff (who is the defendant in the present proceedings) relied on lack of novelty and lack of inventive step. However, the judgment of the German Federal Patent Court does not indicate that they also argued that the invention could not be carried out. An objective extension of res judicata is therefore excluded in this respect.

[78] 5. Pursuant to Section 325(1) of the German Code of Civil Procedure, a final judgment is effective for and against the parties, as well as for those persons who became their legal successors after the action was brought (lis pendens) (German Federal Court of Justice, judgment dated 29 November 2011, X ZR 23/11, GRUR 2012, 540, "Rohrreinigungsdüse"; NZG 2012, 149, para. 11, beck-online). It therefore also binds the defendant in the present proceedings, who became the legal successor of the plaintiff in the previous proceedings before the German Federal Patent Court. No objection under Section 325(2) of the German Code of Civil Procedure has been raised.

[79] Therefore, the continuation of the proceedings with respect to the counterclaim for revocation is subject to an absolute bar only insofar as the German Federal Patent Court has rendered a final decision on the ground of lack of patentability pursuant to Article 138(1)(a) and Articles 52–57 EPC with regard to the German part of the patent in suit. In all other respects, no absolute bar exists.

II. Merits of the counterclaim for revocation

[80] Insofar as the plaintiff is now defending the French, Italian, and Romanian parts of the patent in suit only to the extent of auxiliary request 3, these national parts must be declared invalid to the extent that they go beyond this, without a substantive examination.

[81] Otherwise, the patent in suit is valid in the version of auxiliary request 3, and the counterclaim for revocation is to be dismissed.

1. Clarity (Article 84 EPC)

[82] The defendant's objection regarding lack of clarity is unsuccessful.

[83] a) A violation of Article 84 EPC does not constitute a ground for revocation under either Article 138 EPC or Article 65(2) UPCA.

[…]

1. Disclosure of the invention in a manner for it to be carried out (Article 83 EPC)

[87] The defendant's objection of insufficient disclosure is unsuccessful.

[…]

2. Novelty (Article 54 EPC)

[96] The technical teaching defended under auxiliary request 3 is novel.

[…]

3. Inventive step (Article 56 EPC)

[109] The technical teaching defended under auxiliary request 3 involves an inventive step.

[…]

C. Infringement action

[129] The contested embodiments indeed make literal use of the subject-matter of auxiliary request 3. To the extent that the plaintiff has presented acts of use for the Contracting Member State Germany, the defendant may rely on a national prior use right. For the Contracting Member States France, Italy, and Romania, the plaintiff has not presented any acts of use. Given this factual situation, the application of Article 34 UPCA does not come into consideration for Italy and Romania, and the infringement action must therefore be dismissed for all asserted Contracting Member States.

I. Patent use

[130] The contested embodiments make direct and literal use of the teaching of the patent in suit.

[…]

II. Acts of infringement in Germany

[133] 2. The defendant has a private prior use right for the territory of the Federal Republic of Germany.

[134] a) Pursuant to Article 28 UPCA, any person who, if a national patent had been granted in respect of an invention, would have had, in a Contracting Member State, a right based on prior use of that invention or a right of personal possession of that invention, shall enjoy, in that Contracting Member State, the same rights in respect of a patent for the same invention. Within the scope of Article 28 UPCA, the user of the patented technology may rely only on those rights that the respective national provisions of the respective Contracting Member States confer upon them. On that basis, the existence of a prior use right must be substantiated for each of the protected Contracting Member States (Local Division Düsseldorf, decision dated 3 July 2024, UPC_CFI_7/2023).

[135] According to the case law of the Court of Appeal, it is for the parties to present facts and evidence concerning the content of the national law and its application (order dated 13 August 2025, CoA_446/2025 – Boehringer v. Zentiva). In the present case, the defendant bears the burden of pleading and proof, as it relies on a private prior use right.

a) Submissions of the parties

[136] The defendant contends that a prior use right for the Federal Republic of Germany arises from Section 12 of the German Patent Act, which provides as follows:

"(1) The effects of the patent shall not extend to any person who, at the time of filing of the application, had already begun to use the invention within the territory of Germany or had made the necessary preparations for such use. Such person shall be entitled to exploit the invention for the purposes of their own business in their own or in third-party workshops. This right may be inherited or assigned only together with the business. Where the applicant or their legal predecessor disclosed the invention to others prior to the filing of the application while reserving their rights in the event that a patent is granted, a person who became aware of the invention as a result of such disclosure may not rely on measures within the meaning of the first sentence that were taken within six months after the disclosure.

(2) Where the patent proprietor is entitled to claim priority, the earlier application shall replace the application referred to in subsection (1). However, this shall not apply to nationals of a foreign state which does not guarantee reciprocity in this respect, insofar as they claim the priority of a foreign application."

[137] The defendant further argued that German case law interprets this provision to mean that, for reasons of fairness, the legislator limits the exclusive right in order to protect an existing commercial position of the prior user, or one that has already been established through preparatory acts. The purpose of this limitation is to prevent the inequitable destruction of values that have been created in a legally unobjectionable manner. Based on an exclusive right that arose only at a later point in time or was legally established only thereafter, the patent proprietor should not be able to exclude from using the invention a person who had previously made use of the protected technical teaching or had taken concrete steps toward such use (German Federal Court of Justice, GRUR 2002, 231 [233 f.], "Biegevorrichtung"; BGHZ 182, 231 = GRUR 2010, 47, "Füllstoff", para. 16; see also, with regard to the prior use right in design law: German Federal Court of Justice, GRUR 2018, 72, "Bettgestell", para. 61).

[138] Accordingly, three requirements must be met to acquire a prior use right under Section 12 of the German Patent Act:

- possession of the invention
- exercise of that possession
- acquisition of possession of the invention prior to the priority date of the patent (see German Federal Court of Justice, GRUR 2012, 895).

[139] A person is considered to be in possession of the invention if, based on their own knowledge, they know which steps are necessary to achieve the result described in the invention. Such knowledge exists when the technical teaching, consisting of the problem and its solution, is objectively complete and the person subjectively recognizes that and how an actual embodiment can be realized. It is not required that the

person perceives what they are using as a patentable invention or considers the invention to be fully developed. However, the conduct of a person invoking Section 12 of the German Patent Act must be guided by an understanding that allows the technical teaching to be implemented reproducibly at any time. This requirement is met when the conduct is systematically directed toward carrying out a technical teaching that includes all features of the subject matter of the invention (cf. German Federal Court of Justice, GRUR 2012, 895, "Desmopressin", para. 18; Scharen in Benkard, PatG, 12th ed. 2023, Section 12, para. 5). Whether the person was aware of effects associated with the implementation of the invention's subject matter, as described in the specification, is irrelevant (cf. German Federal Court of Justice, GRUR 2012, 895, "Desmopressin", para. 18). The protection granted to the prior user cannot be undermined by a subsequent limitation of the scope of protection of the intellectual property right (cf. German Federal Court of Justice, GRUR 2023, 1184, "Faserstoffbahn", para. 86).

[140] bb) In factual terms, the defendant submitted that, prior to the priority date, it had decided on a formulation for its sintering pastes that included silver flakes with all features claimed in the patent. For example, it used silver flakes of the types SF 30 and SF 70A in its sintering pastes and actively promoted these pastes to third parties using data sheets. The defendant had thus committed itself to a specific formulation before the priority date and continues to manufacture its sintering pastes today according to the same recipe. The use, then as now, of the commercially available silver flakes SF 30 and SF 70A enabled the defendant to reproduce the technical teaching at any time.

[141] Specifically, prior to the priority date, silver flake SF 30 was used with a "mathematical product," as measured according to the patent claim, of 60,390 cm^{-1} (example 1.1), or alternatively, the silver flake SF 70A was used with a specifically measured "mathematical product" of 71,838 cm^{-1} (example 1.2). Both values lie squarely within the claimed range of 50,000–80,000 cm^{-1}. The defendant thus made a concrete choice for its commercial products to manufacture and deliver sintering pastes with all features claimed in the patent. Accordingly, possession of the invention existed prior to the priority date of the patent in suit, and this was confirmed to third parties by promoting and manufacturing the corresponding sintering pastes.

(1) The sintering paste according to example 1

[142] The defendant stated that, as of October 2014, it had manufactured and promoted the sintering paste 6380 0015. For these sintering pastes, silver flakes of the types SF 30 and SF 70A were used (JD39). The batches offered each contained a proportion of silver flakes of x % (as indicated in line 1 of the table in the middle of the data sheet) and differed in the mixture of solvents and thus also in their viscosity values. This enabled customers to select the paste suitable for their technical requirements with respect to viscosity properties and processability (the viscosity is shown in line 2 of the table in the middle of the data sheet). The silver paste was designated as "Low Temp Bonding Paste" (at the top right below the paste number), i.e., "paste for joining at low temperatures." This was explained in more detail in the product description at the top left of the data sheet, which reads:

"Product Description: 6380 0015 (SAP: 135 8940) is an Ag paste especially designed for metallization for Chip bonding at low temperatures."

[143] […]

[144] The data sheets originated from the defendant, which at that time was still operating under the name […] (visible at the bottom left of the data sheet). The data sheets are dated 27 October 2014 (each at the bottom right of the data sheets).

[145] The specific formulation of the pastes advertised is evident from the corresponding so-called "batch cards" (JD 40). At the top left of the batch card, the product number is shown, in this case the number 6380 0015. Next to it, the corresponding SAP number is noted. At the top right of the batch card, the respective batch number is indicated, for example "E 2670/2014." This corresponds to the data sheets as follows: the batch card for paste 6380 0015, batch E-2670/2014, belongs to the data sheet 6380 0015 # E-2670/14, and so on.

[146] The composition of the respective batch is shown in the middle table, which is labelled "Recipe." There, the individual components of the paste, together with their respective batch numbers and the quantities used ("weigh-in"), are recorded. For batch E-2670/2014, for example, x g of "Ag Flake SF 70A" (i.e., silver flake SF 70A) from batch 639449 was used, suspended in a solvent mixture of x and y. This batch of silver paste was manufactured and released on 23 October 2014, as indicated by the date at the end of the batch card. Other batches of the sintering paste with this silver flake offered different mixing ratios of the solvents: x, y, and z were used. X and y are common solvents to manufacture sintering pastes, each explicitly mentioned in claim 1 of the patent in suit ("…6 to 50 weight per cent of one or more organic solvents selected from the group consisting of X, … y, …"). For the various batches of sintering paste 6380 0015, two different silver flakes were used, SF 70A and SF 30, each constituting its own case of prior use.

[147] […]

(2) The sintering paste according to example 2

[148] In September 2009, a silver sintering paste in accordance with the patent for low-temperature bonding technology was manufactured for customer x in x. The batch card for the sintering paste produced is submitted as JD 49. Under product number 6380 0020 (SAP number 1331212), batch E-2351/2009 of the sintering paste was prepared. The batch card specifies the product type as "NTV-Paste Siebdruck," meaning a paste for use in screen printing in low-temperature bonding technology (Niedertemperatur-Verbindungstechnik – NTV). The delivery was intended for customer x in x ("customer: x (x)"). The paste was manufactured on 15 December 2009, as shown by the date at the top of the batch card and in the last line of the document. x g of silver flake SF 31 were used (line 1 of the table labelled "Recipe": component "Ag Flake SF 31" with the SAP number 1333884 in parentheses). x was used as the solvent. The recipe specifies a minimum amount of solvent of x g x, in addition to a variable amount of x g solvent designated as "Space (x or y)." This serves the purpose of allowing some variability in a batch so that the viscosity of the paste can be adjusted appropriately. Initially, an original mixture of x g silver flake and x g x was prepared, corresponding to a total

batch size of x g. As shown in the second table on the batch card (titled "Adjustment"), x g of this initial mixture was then used and mixed with an additional x g of x for adjustment. In the sintering paste thus produced, which was finely adjusted for viscosity, there were ultimately x g of silver flake in x g of x (derived from the x g of the original mixture totaling x g), plus the additional x g of x from the adjustment. This corresponds mathematically to a resulting proportion of silver flake of x %.

[149] The silver flake used was type SF 31, specifically batch 223628. The certificate of analysis for this batch is submitted as […].

[150] This certificate of analysis was reissued on 1 November 2023, as the original paper copy could no longer be located due to its age. As indicated in the boxed rectangle ("Certificate of Analysis"), however, the certificate was reproduced faithfully from the archived data, exactly as recorded and stated in the original certificate from 2006. The certificate of analysis relates to material number 1333884 "SF 31 Ag Flake." This is a silver flake of type SF 31 with the SAP material number, as also noted on the batch card. A few lines below, above the table on the certificate of analysis, the batch number is indicated ("lot: 223628"). In the first and second rows of the table, the tap density and the specific surface area are listed. For silver flakes of type SF 31, the general range of tap density is between 3.4 and 4.8 g/ml ("lower limit: 3.4; upper limit: 4.8"). For the specifically delivered batch, a tap density of 4.0 g/ml was determined. The specific surface area for silver flakes of type SF 31 generally lies between 1.5 and 2.4 m^2/g ("lower limit: 1.50; upper limit: 2.40"). For the batch actually delivered, a specific surface area of 2.00 m^2/g was determined. It follows from the data in the certificate of analysis that for the product to realize feature 1.3 of the patent in suit, this type of silver flake has a range of 51,000–115,200 cm^{-1}. For the batch actually delivered, the product is calculated as 4.0 g/ml × 2.00 m^2/g = 80,000 cm^{-1}. The sintering paste 6380 0020 was already advertised in 2009 in this form, as it continued to be in subsequent years. The data sheet dated 24 November 2008 is submitted as […]. The silver paste is described there as "Low Temp Bonding Paste" (at the top right, below the paste number), i.e., "paste for bonding at low temperatures." This is explained in more detail in the product description at the top left of the data sheet, which reads (at that time, still with a typo in "description"):

"Product discription: 6380 0015 (SAP: 135 8940) is an Ag paste especially designed for metallization for Chip bonding at low temperatures."

[151] The sintering pastes using silver flakes of type SF 31 therefore also correspond to the patent claim, as summarized below:

	Patent	SF312009
1.1 Metallpartikel, Gew.-%	**50-90 %**	**X %**
1.2 Lösungsmittel, Gew.-%	**6-50 %**	X %
1.3 Produkt, cm^{-1}	**50.000 -**	Charge gemäß
	80.000	Datenblatt: 80.000 Spanne gemäß Datenblatt: **51.000 — 115.200**

[152] The sintering paste was shipped to the customer, x, with address in x, on 27 January 2010 (SAP document JD 52).

[153] According to the values stated in the data sheet, the batch actually delivered, with 80,000 cm^{-1}, was at the upper end of feature 1.3. No quantities of the then-existing batch of silver flakes SF 31 remain today, so that a measurement according to the methods of the patent claim is no longer possible. However, this is immaterial, because either the value of the specific batch is taken as the basis for the prior use and thus falls within the scope of the patent, or the lower specification limit is applied. This lower limit is 51,000 cm^{-1}, which lies squarely within the originally granted and also within the restricted claim scope. Even if one were to hypothetically apply the same correction factor as in the other prior use examples mentioned above, according to which the value actually measured by the methods of the patent claim was approximately 1.3 times higher than the data sheet value, the lower limit of the specification range would be approximately 66,300 cm^{-1} and thus still well within the claimed range. Even within this tolerance range, silver flakes of the type SF 31, which have been recognized as suitable, are therefore used in accordance with their intended purpose.

[154] […]

[155] cc) The plaintiff agrees with the defendant's legal arguments. However, it says that the German Federal Court of Justice, in the cited decision "Faserstoffbahn" (GRUR 2023, 1184), merely stated that even if a prior use does not realize subsequently added features, a right of prior use may still exist. This does not, however, alter (cf. e.g., DE-OLG Düsseldorf GRUR-RR 2024, 61, "Rollwagen"; Bacher, GRUR 2024, 1387) the established principles regarding the limits of the right of prior use, particularly with respect to the realization of advantageous embodiments (cf. especially German Federal Court of Justice GRUR 2019, 1171, "Schutzverkleidung"). The raising of the lower limit to 50,000 cm^{-1} was not, contrary to the Statement of defence, "arbitrary"; rather, this was highlighted as particularly advantageous in section [0017] of the patent in suit and was already the subject matter of the granted dependent claim 2. Furthermore, the comparative tests described in sections [0084] and [0086] clearly demonstrate that with a product ≥ 50,000 cm^{-1}, a generally higher adhesion strength can be achieved than with a product ≥ 40,000 but < 50,000 cm^{-1}.

[156] Moreover, the plaintiff argues, the Federal Court of Justice, in its decision "Desmopressin" (GRUR 2012, 897, para. 18), emphasizes:

"Such insight is lacking where the technical activity has not yet progressed beyond the stage of experiments (Reichsgericht, Mitt. 1931, 72 [74]) or where an object has been used which only 'by chance' exhibited the features of the invention in individual specimens (Reichsgericht, MuW 1936, 406 [407 right col.]). In both cases, the activity is not supported by an insight that makes it possible at any time to reproduce the technical teaching in a repeatable manner, so that it is also not justified to attach to it a legal position conferring

possessory rights. Such cases of unconscious or at least insufficiently established use of the technical teaching are to be distinguished from conduct that is systematically directed toward its realization. The latter is to be regarded as establishing possession of the invention, because it is based on the secure insight that the invention can be carried out. Only to that extent can knowledge of the causal relationship between cause and effect be relevant (cf. Reichsgericht, MuW 1931, 449 [450]; GRUR 1939, 300 [302]; GRUR 1940, 434 [436]; Eichmann, GRUR 1993, 73 [80]; Benkard/Rogge, § 12 margin no. 5; Busse/Keukenschrijver, § 12 margin no. 16; Klauer/Möhring, Patent Law Commentary, Vol. 1, 3rd ed. [1971], § 7 PatG margin no. 7). By contrast, it is not necessary that the person acting has knowledge, beyond the insight into the assured practicability of the invention, of advantageous effects of the invention. For possession of the invention cannot be made dependent on prerequisites that have not become part of the technical teaching as defined in the patent claim. Knowledge of effects which, according to the description, are said to be associated with the use of the inventive subject matter, but which have not been incorporated into the patent claim, therefore cannot be decisive for the question whether possession of the invention has been established."

[157] The plaintiff says that the defendant did not submit any manufacturing specification or similar document from which it could be inferred that a specific product category was consistently manufactured according to the same rules in a repeatable manner. Consequently, the defendant's actions were not based on "secured knowledge" enabling the subject matter of the claim to be realized repeatedly. The defendant was neither in a position to describe the inventive achievement in a comprehensible way nor was it able to systematically reproduce the teaching of the patent in suit. Possession of the invention is already lacking insofar as the Statement of defence expressly did not assert that the defendant had followed any selection criteria regarding the parameters of tamped density and specific surface area that are crucial for the teaching of the patent in suit. On the contrary, the batch process cards underlying the production of the individual batches show that these parameters were of no concern to the defendant at any time. Although, according to German case law, "intellectual possession of the invention" in the sense that the defendant must have subjectively recognized that a product conforming to the claim or numerically defined by tamped density and specific surface area would result in particularly good adhesion strength of a sintered bonding, it is necessary that the defendant "knew which measures had to be taken to achieve the inventive success, i.e., had recognized the external causal relationship corresponding to the invention." At the very least, this would require a subjective, systematic selection of the functionally interacting parameters of tamped density and specific surface area.

[158] dd) The plaintiff contests the following factual assertions for lack of knowledge [Bestreiten mit Nichtwissen]:
- that these are remaining stocks of the same powder batches that were used at the time as starting material;
- that the analyses carried out in 2024 on these samples yield results that can be transferred to the actual characteristics of the silver powders, as measured in accordance with the claim, at the time the respective prior-use products were manufactured;
- that exhibits JD 31 and JD 32 under example 3 relate to a single technical subject matter;
- that the product designated as 6380 0020 under example 2 (exhibits JD 49, JD 60) was always manufactured according to this or the same formulation and, in particular, always using the same silver powders;
- that products of type 6380 0025 under example 4 were manufactured according to a generally binding formulation and, in particular, always using a silver powder of type SF 70A;
- that any one of the 15 processes actually fell within the scope of feature group 1.3.

[159] Moreover, the plaintiff explains in detail that, and why, it harbors doubts as to the defendant's presentation. For none of the processes asserted by the defendant can realization of feature group 1.3 be established. Rather, there are ambiguities in each case that preclude proof of the use of the invention, a burden which lies with the defendant. The plaintiff does not believe that the defendant would still have retained reference samples after ten years.

[160] ee) From a legal perspective, the Panel concurs with the defendant's submissions regarding the legal situation in Germany. The plaintiff has not disputed these submissions. However, in applying the principles established by the German Federal Court of Justice, the plaintiff arrives at a different conclusion.

[161] ff) The Panel is of the view that, for establishing the right of prior use, it is sufficient that the defendant, prior to the priority date, decided to manufacture sintering pastes for NTV applications using silver flakes of types SF65, SF70A, and SF30. As a result of their production, these flakes are shaped such that sintering pastes manufactured from them inevitably exhibit the relevant values of specific surface area and tamped density within the range of the "mathematical product" according to the patent in suit.

[162] This, as well as the realization of the remaining claim features, was substantiated by the submitted data sheets ([…]) and batch process cards ([…]), as well as the written witness statements of employees x ([…]) and y ([…]).

[163] Accordingly, the members of the Panel are convinced, with a degree of certainty sufficient for practical life and which silences doubts, that the defendant, prior to the priority date, regularly manufactured and marketed sintering pastes for the permanent joining of components and, in doing so, used silver flakes of types SF65, SF70A, and SF30. These sintering pastes realized all features of claim 1 in the version according to auxiliary request 3 and were used to create a permanent bond of components.

[164] As a result, the objections of the plaintiff outlined above, which are to be classified as denials based on lack of knowledge, are overcome. It can therefore remain undecided whether a denial based on lack of knowledge is even permissi-

ble under Rule 171.2 RoP (cf. Local Division Düsseldorf, decision dated 13 May 2025, UPC_CFI_505/2024, para. 74).

[165] By using these types of silver flakes, achieving the product of tamped density and specific surface area claimed by the patent in suit was predetermined. The defendant's employees may not have recognized that these two values can be expressed as a mathematical product, as the patent claim does. However, they did recognize that the use of these silver flakes leads to the production of sintering pastes that enable a permanent joining of components. It is irrelevant that the defendant's employees probably did not recognize that this achieves the particularly strong type of joint defined in the description by shear tests. According to the case law of the German Federal Court of Justice cited above, this is not a prerequisite for the establishment of a right of prior use in relation to a patent claim into which these details have not been included. By virtue of this knowledge, the defendant was at all times able to carry out the technical teaching in a repeatable manner. The defendant had therefore moved beyond the experimental stage.

[166] The defendant therefore has a private prior use right for the territory of the Federal Republic of Germany. This right at least covers the value ranges of the contested embodiments ([…]). Therefore, it is not necessary in the present case to clarify which deviating formulations may also fall within the scope of the prior use right.

III. Infringing acts outside Germany

[167] The plaintiff has not presented any specific acts of infringement by the defendant outside Germany. Rather, it derives a risk of infringement in France, Italy, and Romania from the acts of use committed in Germany. However, the acts of use committed in Germany were covered by a private right of prior use and are therefore lawful. Consequently, they do not constitute acts of infringement and do not give rise to a risk of infringement in the other territories.

[168] The application of Article 34 UPCA does not lead to a different result. According to this provision, the decisions of the Court in the case of a European patent apply to the territory of those Member States for which the European patent has effect. Accordingly, it is sufficient to allege and, if contested, prove acts of infringement in one of these territories (Local Division Munich, decision dated 15 November 2024, UPC CFI 15/2023, GRUR-RS 2024, 31582, para. 256 – Edwards Lifesciences v. Meril). In the present case, however, as explained above, there are no acts of infringement in at least one Contracting Member State.

[169] 1. The parties have presented the following arguments regarding acts of infringement outside Germany:

[…]

[181] 2. Accordingly, the plaintiff has not presented any specific acts of infringement by the defendant outside Germany.

[182] a. For Romania, the plaintiff expressly admitted this in its written submission of 22 April 2025.

[183] b. Contrary to the plaintiff's view, no more favorable outcome for France and Italy can be derived from the fact that the defendant did not contest the following statement: "Moreover, the defendant is part of a globally operating group, which also displays locations in France and Italy on its website; the relevant industry here operates across borders."

[184] While, pursuant to Rule 181.2 RoP, factual allegations that are not specifically disputed by either party are deemed undisputed between the parties, it is also the case that a party making a factual allegation must substantiate it in the required manner if it is disputed or likely to be disputed by the other party. This duty to facilitate the proceedings follows from paragraph 7 of the Preamble to the Rules of Procedure, which provides that the proceedings should be conducted so that the final oral hearing on infringement and validity in the first instance can normally take place within one year. Accordingly, Rule 171.1 RoP provides that a party making a factual allegation that is disputed or likely to be disputed by another party must specify the evidence supporting that allegation. The same applies to the substantiation of the factual submissions (Court of Appeal, decision dated 3 October 2025, UPC_CoA_534/2024 and 19/2025 and 683/2024, para. 212).

[185] This has not occurred in the present case. Even assuming this assertion to be true, the Panel is unable to determine whether – and if so, which specific act of use concerning which specific product – the defendant, and not another company belonging to the same group, has carried out in France and/or Italy.

[186] Finally, the plaintiff cannot derive a risk of infringement from the defendant's submissions regarding prior use. On the one hand, the plaintiff has contested these submissions and therefore has not adopted them. On the other hand, acts carried out before the grant of the patent are lawful and cannot give rise to a risk of infringement for the period after the patent is granted.

[187] 3. It can therefore remain open whether the defendant also has a private right of prior use for France, Italy, and Romania.

[188] It can likewise remain open whether the defences of deceit and unlawful taking succeed.

D. Ancillary orders

[…]

Cross-Border Preliminary Injunction*

Country:	Germany
Court:	Munich Regional Court I (*Landgericht München I*)
Decision name:	Aflibercept
Decision date:	25 September 2025
File number:	7 O 9383/25**
Standards:	German Code of Civil Procedure Sections 17, 32 and 940, 936, 920 et seq.; Brussels I Regulation (recast) Article 4(1), Article 63(1); German Patent Act Section 143(2); Doctrine of equivalents

1. In the opinion of the Chamber, the court that has been seized has local jurisdiction in cross-border patent infringement proceedings for Defendants whose general place of jurisdiction is located anywhere in the Federal Republic of Germany, and not only for those located within its own jurisdiction. This is because patent infringement proceedings are characterized by "flying" tort jurisdiction [*fliegender Gerichtsstand*]. […] (mn. 34)

2. In German preliminary injunction proceedings, whether the patent-in-suit is valid is a procedural question to be determined when deciding whether there are grounds for a preliminary injunction. The same applies in cross-border cases, as procedural questions are governed by the law of the state in which the court hearing the case is located. (mn. 43)

3. Procedural legal questions are governed by the law of the place of jurisdiction ("lex fori"). Questions of substantive law are governed by the law of the state in which the claims are asserted ("lex loci protectionis"). Based on this principle, it is necessary to determine exactly when a provision qualifies as substantive. Only such provisions are not subject to German law. Considering the fundamental principles of the European Patent Convention and Enforcement Directive 2004/48/EC, the starting point is the understanding that national procedural rules should not pave the way for patent infringements or make it more difficult for patent holders to conduct proceedings in cross-border cases. (mn. 49 et seq.)

4. Rules that govern technical or formal procedures in another country do not serve to enable patent infringements. These rules always fall under procedural law and are therefore governed by German law in this case. […] (mn. 51)

5. Indeed, this could mean that patent infringements in certain countries can only be pursued if the infringer is based in Germany. However, infringers based in Germany should not be entitled to the same low level of protection as infringers in other countries. There is no such thing as a right to equality in wrongdoing. (mn. 52)

6. In any case, a decision by the German Federal Patent Court on the validity of the German part of a European patent in nullity proceedings would also create urgency with regard to the other national parts of the European patent. […] (mn. 66)

7. The German legal assessment strongly suggests that the same outcome would be reached in the other EPC member states. Given this strong indicative effect, it is unnecessary for the Chamber to seek expert opinions on the relevant foreign law from independent experts. Otherwise, the effective enforcement of intellectual property rights, as required by the Enforcement Directive, would become unreasonably difficult for intellectual property rightsholders. Instead, it is up to the Defendant to present concrete indications that a different decision would be made based on national law. They must substantiate why other countries would reach a different legal outcome. (mn. 153 et seq.)

8. Whether proceedings are conducted differently in other countries (e.g. through expert evidence), whether [proceedings for] preliminary injunctions take significantly longer, or whether there is fundamental scepticism towards the legal concept of equivalent patent infringement is irrelevant. (mn. 156)

9. The only decisive factor is whether national law (in the form of statutes or established case law) modifies the requirements of the EPC in such a way as to lead to a different outcome. This means that the Defendant must present any provisions or decisions that they consider relevant. In addition, they must submit a qualified opinion from an expert who is bound, at least by professional ethics, to tell the truth. These principles on the indicative effect of infringement under German law apply not only to literal patent infringements but also to equivalent patent infringements, particularly in cases involving a simple equivalence constellation. In the Chamber's view, extending the scope of protection to equivalent forms of infringement serves to include clear circumvention solutions within a patent's scope of protection. A clear circumvention solution does exist when a feature that does not form the core of the invention is modified. (mn. 157 et seq.)

10. Statements made during the granting procedure may, at most, influence the protection granted by the patent in terms of contradictory behaviour. The scope of a patent's protection must always be determined objectively. If a patent has been granted wrongfully because inaccurate information was provided in the application, this can only be used to oppose enforcement based on contradictory behaviour. (mn. 168)

11. The requirements for the Plaintiff's submissions regarding the risk of first infringement must not be exaggerated. In particular, the Plaintiff may present facts that demonstrate imminent direct patent infringement is suffi-

* No official translation; translated by editorial team.

** Some of the editors were involved in the proceedings on behalf of the Defendants. Appeals have been filed against this decision and the parallel decision (7 O 9382/25), which only concerns the German part of the patent. The parallel decision in the main proceedings (7 O 16055/24) has also been appealed.

ciently likely in all the countries in question. For example, this could be demonstrated by the possible imminent offering of a product. It is sufficient to state that approval has been applied for and that a distribution structure is in place that would enable the product to be distributed. In the pharmaceutical sector in particular, significant investments in new products can only be recouped if the product is widely available. This applies particularly to biosimilars, which are costly to develop. If the Plaintiff has made such a submission, it is then up to the Defendant to show, and potentially prove, that despite the possibility, no distribution is planned or that the legal prerequisites in a given country do not justify a claim for injunctive relief. (mn. 275)

12. For the member states of the European Union at least, effective enforcement of patent rights requires that injunctions can be obtained as a precautionary measure in the event of a sufficiently concrete threat, in accordance with Enforcement Directive 2004/48/EC. This is particularly pertinent when considering procedural concentration. Potential patent infringers should not be able to gain an advantage by acting gradually. Otherwise, they could place undue strain on the financial and human resources of patent holders, who cannot choose whether their rights are infringed by third parties in different countries. (mn. 278)

Facts

[1] The Plaintiffs are suing the Defendants for alleged infringement of European patent 2 364 691 B1 in 22 countries, using equivalent means. The patent-in-suit concerns formulations containing VEGF antagonists for intravitreal administration.

[2] European patent 2 364 691 B1 ([…] hereinafter: the patent-in-suit) was filed on 14 June 2007, claiming priority from US patent application No. 2006 0814484 P of 16 June 2006, for US. company R. The application was published on 14 September 2011, and the grant notice was published on 24 April 2013.

[3] The patent-in-suit is in force in its granted version in the following countries: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Greece, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, the Czech Republic, Turkey, Hungary, and Cyprus.

[4] In nullity proceedings brought by a third party before the German Federal Patent Court against the patent-in-suit (case number 3 Ni 15/23 (EP)), […] the patent was upheld in a limited version by judgment dated 26 June 2025. At the time of the oral hearing, the written grounds for the judgment were unavailable.

[5] Claim 1 of the patent-in-suit, which is relevant here, reads as follows in its limited version:

An ophthalmic formulation of a vascular endothelial growth factor (VEGF) antagonist for use in intravitreal administration, wherein said ophthalmic formulation comprises:

(a) 1–100 mg/ml of a VEGF antagonist consisting of amino acids 27–457 of SEQ ID No:4, which is glycosylated at Asn residues 62, 94, 149, 222 and 308;
(b) 0.01–5 % of one or more organic co-solvent(s) which is one or more of polysorbate, polyethylene glycol (PEG), and propylene glycol;
(c) 30–150 mM of a tonicity agent selected from sodium chloride or potassium chloride;
(d) 5–40 mM of sodium phosphate buffer; and
(e) 1.0–7.5 % of a stabilizing agent selected from the group consisting of sucrose, sorbitol, glycerol, trehalose, and mannitol, pH between about 5.8–7.0.

[6] The difference compared to the granted version of the patent-in-suit is that the formulation only had to be suitable for intravitreal administration in the granted version.

[7] The patent holder also holds supplementary protection certificate DE 12 2013 000 041.4 (hereinafter: SPC), which protects the use of the active ingredient aflibercept for ophthalmic applications. This SPC expires on 23 November 2025 following renewal. The product is marketed by the B Group under the trade name E®.

[8] The Plaintiffs belong to the B Group and are involved in developing and marketing medicines, including those for eye diseases. On 18 October 2006 ([…]), a license agreement regarding the patent-in-suit was concluded between R and Plaintiff 1). Plaintiff 2) derives their rights in the patent-in-suit from the license agreement concluded between them and Plaintiff 1) in December 2012/January 2013 ([…]).

[9] Defendant 1) is involved in the manufacture of biosimilar medicines, inter alia in the field of ophthalmology. They developed the biosimilar F, applied for and obtained regulatory approval for it. Defendant 2) is involved in the manufacture and distribution of medicines and is the licensee and holder of the worldwide marketing rights for F.

[10] The composition of biosimilar F is as follows: ([…]):

[…]

[11] In a letter dated 18 June 2025 […], the Defendants informed Plaintiff 1) that they intended to market the biosimilar F "in major parts of Europe, including Germany" after the SPC expired. The Defendants also requested that Plaintiff 1) declare that the biosimilar did not infringe the patent-in-suit.

[12] The patent-in-suit and the issue of its infringement by biosimilar F are subject to further proceedings before the Chamber, with some different parties involved. In injunction proceedings 7 O 9382/25, Plaintiff 2) is seeking an injunction against the Defendants and R GmbH (which is to distribute the biosimilar in Germany) for Germany. In the main proceedings (7 O 16055/24), the patent holder is seeking an injunction against the Defendants and others in Germany and other EU countries by way of a counterclaim, as well as asserting consequential claims. The main proceedings began as a negative declaratory action. The four parties against whom the counterclaim was brought are seeking a declaration that the patent-in-suit is not being infringed.

[13] In addition to the above proceedings, further legal disputes are pending or have already been decided in other countries. For this reason, proceedings 7 O 9382/25 and 7 O 16055/24 relate to different countries in part. Specifically, no injunction is being sought in the main proceedings relating to Italy, France and Belgium.

[14] Following the oral hearing, the UK High Court issued the decision [2025] EWHC 2527 (Pat), in which the Defendants brought an action against Plaintiff 1) and the patent holder, seeking a declaration that the biosimilar F does not infringe the patent-in-suit in a version limited to sub-claim 5. According to the UK High Court, the first question of the equivalence test used in the UK must be answered negatively.

[…]

Grounds

[23] The application for a preliminary injunction is both admissible and fully justified.

[24] The biosimilar F infringes claim 1 of the patent-in-suit by equivalence in all 22 countries […]. This is because equivalent patent infringement is enshrined in Article 2 of the Protocol on the Interpretation of Article 69 EPC, so the same standards for determining equivalent patent infringement are assumed to apply in all countries. Therefore, the assessment of patent infringement by equivalent means under German law serves as a guideline for the other EPC countries. The Defendants have not succeeded in demonstrating that a different standard applies in any of the aforementioned states.

[25] The UK High Court came to a different conclusion regarding the biosimilar F because, among other things, […] claim 1 was not the subject of the proceedings, but rather a version limited to independent auxiliary claim 5.

[26] Furthermore, […] there are considerable doubts as to whether the facts of the case brought before the Court in the present proceedings are the same as those decided upon by the UK High Court after hearing from several experts. […]

[27] […]

A.

[28] The application for a preliminary injunction is admissible. In particular, the Munich Regional Court I has both local and international jurisdiction, as both Defendants are domiciled within its area of jurisdiction (see I.). […] There are no concerns regarding the validity of the patent-in-suit in the relevant foreign countries. In this respect, the decision of the German Federal Patent Court is highly indicative of the position in other countries too – it has a lighthouse effect (see III.).

I. Jurisdiction of the Munich Regional Court I

[29] […]

[30] […]

[31] In the case of patent infringement, there has always been consensus that Defendants can be sued across borders in the court of their place of residence. However, the CJEU previously ruled that national courts have exclusive jurisdiction over validity proceedings, even if the issue of validity is raised only in defence (GRUR 2007, 49, GAT/LuK). Consequently, proceedings in international cases had to be suspended as soon as the defence of invalidity was raised. This has effectively meant that cross-border proceedings have not been conducted, at least in Germany.

[32] According to the new CJEU case law (GRUR 2025, 568, BSH Hausgeräte), the seized infringement court remains competent even if an invalidity defense is raised, regardless of its form. According to the Chamber's understanding, the infringement court has discretion over how to deal with the invalidity defense. The court can either stay the proceedings in view of nullity proceedings in another country or issue a decision on the merits, provided it deems the asserted patent to be valid.

[33] […]

II. Local jurisdiction for Defendants based outside the court's district

[…]

III. Validity of the patent-in-suit – assessment under national law

[43] […]

[44] […]

[45] Whether the infringement court suspends pending proceedings in relation to invalidity proceedings conducted in another member state, or in relation to an invalidity defense, depends on whether the infringement court deems the validity of the European patents in question to be sufficiently assured. In the opinion of the Chamber, this can be assumed about the 22 national European patents asserted in the present proceedings (i.e. […]) because the German Federal Patent Court upheld the patent in a limited version in a first-instance decision.

[46] The decision of the German Federal Patent Court has a strong indicative effect: it is reasonable to assume that the corresponding patents are valid in other countries in the same form. It is irrelevant whether the claims granted in other states are already limited to the version asserted in the infringement action, or if this has not yet been done. This is because the limited claims are included as a minus in the claims granted.

B.

[47] The Plaintiffs have demonstrated that their claim for injunctive relief is justified.

I. Applicable law

[48] When it comes to cross-border proceedings, it is important to distinguish between issues of procedural and substantive law with regard to the applicable law.

1. Differentiation between procedural and substantive legal issues

[49] […] Only substantive legal provisions are not subject to German law.

[50] […] National procedural rules should not pave the way for patent infringements or make it more difficult for patent holders to conduct proceedings in cross-border cases.

[51] Rules that govern technical or formal procedures in another country do not serve to enable patent infringements. In other words, the Defendant cannot successfully argue, for example, that a license agreement is not entered in a register or that the patent claim has not yet been limited in other countries, if there is no doubt that the Plaintiff has the underlying substantive right. […]

[…]

2. Relevance of this distinction to the present case

[…]

a. Registration of the licensee

[57] The parties agree that enforcing a patent by an (exclusive) licensee in certain countries (including Spain and France) requires the licensee to be entered in the relevant national patent register beforehand. However, this requirement is merely procedural and does not prevent the enforcement of claims. This is because it is purely an administrative requirement for the enforcement of rights based on civil law. Contrary to the Defendants' opinion, it does not constitute a substantive legal requirement relating to standing to sue, but rather a procedural rule.

[58] The registration requirement does not protect a potential patent infringer who has been sued. Instead, it is sufficient for the licensee to be substantively entitled to enforce the patent.

[59] […]

b. Assertion of a limited version of the patent claim

[60] The Defendants argue that in some countries, including Belgium, Spain and France, it is inadmissible to enforce the patent-in-suit in its version limited by the German Federal Patent Court, unless this limited version has first been entered in the relevant national patent register. However, this requirement is only a procedural rule. It can be assumed for these countries that the limited version is included as a 'minus' in the granted version. This applies to all the countries in question.

c. Grounds for a preliminary injunction (particularly urgency)

[61] Whether there are grounds for a preliminary injunction is a procedural question.

[62] [In addition to a substantive claim for injunctive relief,] the granting of a preliminary injunction requires two things: urgency in terms of time and a favourable weighing of interests for the Plaintiff. The question is whether a given substantive claim can be granted in a special way, i.e. in the form of interim relief. In other words, the key question is whether the Plaintiff should have to wait for the main proceedings, which can sometimes be very lengthy. As the way infringement proceedings are conducted does not affect the existence of the substantive claim, there is no reason not to consider the grounds for a preliminary injunction to be a purely procedural rule.

[63] Therefore, if urgency is established and the weighing of interests favours the Plaintiff by German standards in proceedings against a German-based party, this is sufficient to act against that party throughout Europe in similar cases.

[64] The Chamber recognizes that there is a debate about whether the grounds for the injunction are a substantive or procedural requirement. There is no consistent answer to this question within the field of intellectual property […]

[65] […]

[66] […]

II. Standing to sue

[67] The Plaintiffs have standing to sue.

[68] Both Plaintiff 1), as the exclusive licensee, and Plaintiff 2), as the exclusive sublicensee, are entitled to bring an action under the patent in their own names.

[…]

III. Claim for injunctive relief

[88] […] The Plaintiffs can claim injunctive relief against the Defendants in all 22 countries due to equivalent patent infringement. The patent-in-suit has been validated in all of these countries.

[89] This judgement is based on the Court's finding of equivalent patent infringement under German law (see also the parallel proceedings, case number 7 O 9382/25) (see point 1 below), and on the presumption that the legal situation regarding equivalence in the other EPC countries is similar to that in Germany (see point 2 below). The Defendants have not shaken this presumption.

[90] The UK High Court's ruling on 8 October 2025 in [2025] EWHC 2527 (Pat) that the challenged embodiment (the biosimilar) does not utilize the teaching of the patent-in-suit (in its version asserted in the UK proceedings) by equivalent means does not call for a different assessment.

[91] Ultimately, it can be assumed that all EPC member states will decide the question of when a patent infringement with equivalent means exists in the same way. This also applies even if different examination steps are used to determine equivalence in each case. This assumption is based on Article 2 of the Protocol to Article 69 EPC, which is applicable in all states. Against this background, it is irrelevant whether standardization applies to states that have ratified the UPCA, at least. This is because the EPO uses a uniform standard when examining a patent, regardless of whether a unitary patent or a conventional European bundle patent has been applied for.

1. Equivalent patent infringement under German law

[92] Under German law, the challenged embodiment (the biosimilar F) constitutes an equivalent infringement of claim 1 of the patent-in-suit.

[…]

[96] a) The patent-in-suit, in its maintained form, relates to an ophthalmic formulation of a VEGF antagonist intended for intravitreal administration.

[97] According to the patent specification, the invention relates to pharmaceutical formulations comprising agents capable of inhibiting vascular endothelial growth factor (VEGF), which are intended for intravitreal administration (para. [0001]). Intravitreal administration means administration into the vitreous body of the eye.

[98] VEGF is a group of proteins that stimulate the growth of the vascular endothelium, i.e. the innermost layer of blood vessels that comes into contact with blood. In cancer, VEGF enables the pathological formation of new blood vessels in tumor tissue, supplying it with blood and allowing it to grow. This process can be prevented by inhibiting vascular growth, for example using VEGF antagonists, which bind to VEGF. The active ingredient in the patent-in-suit, aflibercept, is a protein-based VEGF antagonist.

[99] In the prior art, it was already known that VEGF antagonists could offer effective treatment for eye diseases such as neovascular 'wet' age-related macular degeneration (hereinafter referred to as nAMD). This disease is characterized by the growth of fragile blood vessels under the retina which break through structures that are essential for vision. In this case, unlike in cancer therapy, the VEGF antagonist is administered by injection into the vitreous body of the eye (i.e. intravitreally).

[100] According to the patent-in-suit, the stability of proteins that can be used in pharmaceuticals poses a significant challenge (para. [0041]). The required stability conditions vary from protein to protein.

[101] b) Against this background, the patent-in-suit's objective – in line with the German Federal Patent Court's qualified opinion in the nullity proceedings ([…]) – is to provide VEGF antagonist formulations consisting of the amino acids mentioned in feature 1.1 that are suitable for intravitreal administration.

[102] c) The patent-in-suit presents claim 1 as a solution. It is asserted in the version of the German Federal Patent Court's judgment and can be broken down as follows:

1. An ophthalmic formulation of a vascular endothelial growth factor (VEGF) antagonist for use in intravitreal administration, wherein said ophthalmic formulation comprises:

1.1. (a) 1–100 mg/ml of a VEGF antagonist consisting of amino acids 27–457 of SEQ ID No:4, which is glycosylated at Asn residues 62, 94, 149, 222 and 308;

1.2. (b) 0.01–5 % of one or more organic co-solvent(s) which is one or more of polysorbate, polyethylene glycol (PEG), and propylene glycol;

1.3. (c) 30–150 mM of a tonicity agent selected from sodium chloride or potassium chloride;

1.4. (d) 5–40 mM of sodium phosphate buffer; and

1.5. (e) 1.0–7.5 % of a stabilizing agent selected from the group consisting of sucrose, sorbitol, glycerol, trehalose, and mannitol,

pH between about 5.8–7.0

[103] d) Claim 1 of the patent-in-suit protects an ophthalmic formulation containing aflibercept as the active ingredient, intended for intravitreal administration.

[104] (1) The Chamber considers a team consisting of an ophthalmologist and a university-educated pharmaceutical technologist with several years of practical experience in manufacturing pharmaceutical formulations to be the skilled person ([…]). The skilled person will read the patent-in-suit as follows:

[105] The formulation is injected into the vitreous body of the eye, so it must meet particularly high standards in terms of its properties and stability.

[106] The tonicity agent primarily determines the osmotic properties of the formulation. The stabilizer protects the folding of the active ingredient, enabling aflibercept to reach the areas of the vitreous body where it exerts the desired medical effect in the required form. The buffer keeps the formulation stable within a specified pH range.

[107] Comparing the ophthalmic formulations suitable for lyophilization mentioned in claim 6 (which are not the subject of these proceedings) with the formulations in question shows that both a tonicity agent and a stability agent can be dispensed with. However, a buffer cannot be dispensed with. It is not stated whether such a design would also be suitable for ophthalmic formulations that are not suitable for lyophilization.

[108] With regard to the buffer, the patent-in-suit only mentions sodium phosphate, or clarifies in paragraph [0047] that, even when only "phosphate" is mentioned, "sodium phosphate" is meant. At the end of paragraph [0047], it is also explicitly stated that the buffer is used to adjust the pH value of the solution. However, this is self-evident to the skilled person.

[109] The skilled person would also be aware that ranibizumab was the only protein active ingredient in late-stage clinical development for the intravitreal treatment of nAMD at the priority date of the patent-in-suit. This active ingredient differs from aflibercept in that it has a different, larger molecular structure, meaning it remains in the body for a longer period of time. Additionally, the ranibizumab formulation contained histidine and trehalose buffers instead of a sodium phosphate buffer, and did not contain sodium or potassium chloride.

[110] (2) There is no literal infringement of the patent-in-suit since the challenged embodiment uses a histidine buffer instead of a sodium phosphate buffer. However, using a histidine buffer does constitute the realization of feature 1.4 by equivalent means.

[111] (3) According to the established case law of the German Federal Court of Justice ([…]), equivalent patent infringement requires the following:

1. Equal effect of the means [technical-functional equivalence]: Does the challenged embodiment solve the underlying problem of the invention using modified means that have objectively the same effect?

2. Discoverability of the means: Does the expertise of the skilled person enable them to find the modified means as equally effective?

3. Equivalence [*Gleichwertigkeit*] of the modification: Could the skilled person arrive at the variant through considerations so oriented towards the meaning of the technical teaching protected by the patent claim that they would consider the variant with its modified means to be an equivalent solution to the teaching?

4. Furthermore, it must be examined whether the patent holder deliberately excluded certain embodiments from the scope of protection, and whether the so-called Formstein objection prevents the assumption of infringement by equivalent means.

[112] (aa) As part of the first step of the examination, namely equal effect, it must be determined whether the challenged embodiment essentially achieves the overall effect of the invention and precisely the effect intended by the feature that is not literally realized ([…]).

[113] Feature 1.4 relates to a buffer. A buffer's general function is to keep the pH value of the respective solution stable. The description of the patent-in-suit does not provide any further information on the function of the buffer in the claimed formulation, so nothing else can be inferred. The previously cited passage from paragraph [0047] shows that the buffer also serves to adjust the formulation's pH value. It can be assumed that histidine has the same properties as the sodium phosphate mentioned in the claim. However, this can ultimately be left open because the Defendants do not dispute the equal effect.

[114] (bb) The second question must also be answered in favor of the Plaintiff. At the time of priority, the skilled person could discover the buffer histidine, which can be used for protein formulations, as an agent with the same effect as sodium phosphate. This discovery does not require any inventive step on the part of the skilled person (see […]). The need for routine testing does not preclude the absence of an inventive step (German Federal Court of Justice, judgment of […]). In detail:

[115] (aaa) The skilled person is familiar with the use of buffer solutions in the manufacture of protein formulations. The role of the buffer is to ensure the pH stability of the formulation. Suitable buffers for protein formulations have specific pH ranges within which they can be used. In this respect, histidine and phosphate are known to have a very similar range of applications. Histidine can be used in the pH range of the claimed formulation (feature 1.6) of 5.8–7.0 because it can be used in the pH range of 6.2–7.8. Meanwhile, phosphate can be used in the range of 6.0–8.2, which largely overlaps with the aforementioned range.

[116] As shown in the following pre-published table from the textbook "Formulation Development of Protein Dosage Forms" ([…]), this area of application distinguishes phosphate and histidine from most other buffering agents commonly used in protein formulations:

Table V
Buffers Used in Protein Formulations

Buffer system	pK_a	pH range of use
Acetate	4.76	2.5–6.5
Citrate	3.14, 4.8, 5.2	2.5–6.0
Glutamate	9.67(pK_{a3})	8.2–10.2
Glycinate	2.4,9.8	6.5–7.5
Histidine	1.8, 6.0, 9.2	6.2–7.8
Lactate	3.8	3.0–6.0
Maleate	1.92, 6.23	2.5–5.0
Phosphate	7.2 (pK_{a2})	6.0–8.2
Succinate	4.2, 5.64	4.8–6.3
Tartrate	2.93, 4.23	3.0–5.0
Tris	6.2 (pK_b 7.8)	6.8–7.7

[117] These properties suggest to a skilled person that histidine could be used as an alternative to sodium phosphate. Skilled persons are aware that formulations consist of various usually interchangeable components. However, there is no guarantee that the overall formulation will retain the desired properties following an exchange. Further tests will therefore always be necessary in this respect, but these also fall within the usual practice of skilled persons.

[118] (bbb) In the present case, another indication points to the use of histidine. This is because the only comparable drug that was developed to a high degree by the priority date also uses histidine as a buffer. This drug is L, which is based on the active ingredient ranibizumab. This protein-based drug was also intended for intravitreal administration. It was in the final stage of clinical trials. The formulation contained histidine at a concentration of 10 mM as a buffer (cf. […]).

[119] The patent specification intended to protect the ranibizumab formulation (WO 2006/047325 A1; […]) shows the formulation intended for intravitreal administration (including 10 mM histidine) on page 31, line 27 onwards. This patent specification was published on 4 May 2006, prior to the priority date of the patent-in-suit.

[120] […]

[121] In this respect, the decisive factor for the Chamber is that, at the priority date, the known ranibizumab formulation was the only protein formulation suitable and tested for intravitreal administration (at least as far as VEGF antagonists are concerned). Given this, the skilled person would also consider the alternative buffer histidine, even taking into account the different structures of aflibercept and ranibizumab.

[122] (ddd) The fact that stability studies are also necessary within the same pH range to verify whether histidine would provide sufficient stability for the specific formulation does not affect discoverability. This is because these are routine tests that do not rule out the absence of an inventive step, and thus discoverability. In particular, the undisputed unpredictability of the effect of replacing excipients on the stability of the respective protein does not argue against discoverability. This is because it is not apparent, nor has it been argued by the Defendants, that more than routine tests would have been necessary.

[123] In particular, the Defendant's reference to the Plaintiff's statements in […] regarding the great challenge of developing a stable protein formulation based on aflibercept

is incorrect and misguided. In that passage, the Plaintiff describes the situation prior to filing the patent-in-suit, whereas the question of discoverability is assessed based on knowing the patent specification.

[124] (eee) The parties unanimously argued that histidine was suspected of causing a yellowish discoloration of the formulation over time, which was undesirable, particularly in the human eye. […]

[125] As the Plaintiff stated during the oral hearing in response to a question from the Chamber, this yellow discoloration only affects the formulation. Injecting a formulation with this discoloration does not cause the eyeball to turn yellow. However, patients have reservations about having a yellowish solution injected into their eyes. Nevertheless, this circumstance did not preclude commercial use.

[126] However, this means that the concerns expressed by the patent holder during the granting procedure were only about an aesthetic aspect, which can be interpreted differently. Therefore, this circumstance does not preclude use, especially since patients do not administer the drug themselves, and treating physicians are not likely to be deterred by the color of the injection fluid.

[127] (cc) The considerations that the skilled person had to make to identify histidine as a buffer are so closely oriented toward the meaning of the technical teaching protected by the patent claim that the skilled person would consider the alternative embodiment, with its modified means, to be an equivalent solution.

[128] (aaa) An orientation toward the patent claim means that the claim, with all its features, forms the starting point and decisive basis for the skilled person's considerations.

[129] This is the case here because claim 1 protects a formulation that uses a buffer to adjust its pH value. Neither the claim nor the description attributes any additional purpose or function to the sodium phosphate chosen specifically. Therefore, the skilled person recognizes that the function of the buffer does not extend beyond pH adjustment. Thus, the use of histidine instead of sodium phosphate is considered equivalent. This is because histidine is also suitable for determining the pH value of a protein formulation.

[130] (bbb) The patent holder has not deliberately limited the patent claim. This would occur if the patent were objectively limited to a narrower claim than required by the technical content of the invention and the prior art. In that case, experts could reasonably assume that the protection was limited accordingly. The patent holder would then be prevented from claiming protection for something they did not have protected. This applies even if the skilled person recognizes that the effect of the invention (in the narrower sense described above) could be achieved beyond the claimed scope of protection. Therefore, an embodiment is excluded from the patent's scope of protection if, although it is disclosed or at least discoverable by the skilled person, the reader of the patent specification must assume that it should not be protected for whatever reason ([…]). It is not necessary for the patent specification to direct the skilled person to a different design of the patented teaching ([…]).

[131] Regarding the selection decision, the case law of the German Federal Court of Justice on patent infringement by equivalent means is to be understood as meaning that the decision *Pemetrexed* is a response to the uncertainty created by the decision *Okklusionsvorrichtung*. The assessment contained in para. 68 is decisive: as a rule, one cannot assume that the patent holder made a selection decision. Rather, special reasons must be present to assume a selection decision. The Defendants have not presented any such reasons, nor are they otherwise apparent. This is a typical situation in which an equivalent patent infringement is assumed. In detail:

[132] (i) Although the patent specification does not explicitly refer to sodium phosphate, but rather to "phosphate" (e.g., paragraphs [0011] and [0059]), paragraph [0047] clarifies that the term "phosphate" always refers to sodium phosphate. No other substances or generic terms are mentioned.

[133] Furthermore, paragraph [0048], under the heading "Stable Liquid Ophthalmic Formulations," does not mention a specific substance for the buffer, whereas specific substances are listed for the other excipients according to claim 1 of the patent-in-suit.

[134] Paragraph [0049] reveals that the formulation's composition corresponding to claim 1 includes sodium phosphate as a buffer. However, the varying degrees of specificity regarding the different excipients in paragraph [0048] suggest to the skilled person that the buffer does not necessarily have to consist of sodium phosphate.

[135] (ii) This indication is further supported by the absence of any explanation of the specific advantages of sodium phosphate or reasons why the buffer must be derived from sodium phosphate or a specific superordinate group (e.g., salts or inorganic substances) in the patent specification.

[136] (iii) Therefore, the skilled person concludes from the patent specification that the function of the buffer is more important than the specific buffer material. As explained above, this plays an important role in the orientation toward the patent claim ([…]). Based on this consideration, the definition of a specific embodiment does not exclude other embodiments from the patent's scope of protection. Otherwise, patent protection would always be excluded if the patent holder recognized (or could have recognized) that substitutes were conceivable for a solution element named in the claim, yet failed to work toward a version of the patent that would cover the substitutes under the literal meaning of the patent claim. This result would not be appropriate ([…]).

[137] In this respect, the present case, in which the patent refers to the supergroup "buffers," is similar to the *Pemetrexed* case, which was decided by the German Federal Court of Justice. In that case, the German Federal Court of Justice stated that equivalence [*Gleichwertigkeit*] (and thus the assumption of an equivalent infringement) is not precluded if the patent specification discloses a group of suitable substances, yet only claims one specific substance from that group. This is because discoverability of an alternative substance does not equate to explicit disclosure in the patent specification ([…]). The same applies here.

[138] (ccc) The statements and actions of the patent applicant in the grant procedure referred to by the Defendants do not contradict this.

[139] (i) According to case law from the German Federal Court of Justice, the principle applies that a patent holder cannot subsequently claim protection for something that they did not have protected by the legal concept of equivalence ([…]). This would be the case if the wording of the claim were restricted between filing and granting of the patent to distinguish it from the prior art. However, in the present case, there is no difference between the filed, granted, and restricted versions of the patent claim regarding the use of sodium phosphate as a buffer.

[140] (ii) The Defendants argue that during the grant procedure, the patent holder distinguished the claimed invention as being inventive, among other things, from the prior art documents D1 (the patent specification WO 2006/047325 […], i.e., the patent specification underlying the drug L) and D2 (the patent specification WO 2005/000895 […]), by pointing out the use of sodium phosphate instead of histidine ([…]).

[141] According to general German patent case law, it is widely accepted that documents from the grant procedure cannot, as a rule, be used to determine the scope of a patent's protection. This is because Article 69 EPC specifically excludes statements made during the grant procedure from being used for this purpose. However, it is permissible to use statements made by the applicant and the examiner during the grant procedure as an indication of how a skilled person would understand the subject matter of the patent ([…]).

[142] According to the Chamber, a distinction must be made between statements made by the examiner and those made by the applicant. As a rule, statements made by examiners during the granting procedure have high indicative value. However, this cannot be assumed in the case of statements made by the patent applicant. Rather, limited indicative value must be assumed. This is because, in the battle of arguments for patent grants, many arguments are sometimes put forward, sometimes knowing they stretch the general technical understanding far beyond its limits. Using such statements later to argue against the patent holder would disregard patent grant procedure practices. When analyzing statements made by the patent holder, it is important to examine whether they are reflected in the examiner's reasoning. This is because the examiner, not the applicant, performs the sovereign act of granting the patent from which the legal effects of the patent follow […]. If so, these statements may be considered as the understanding of the skilled person at that time.

[143] Even if the statements made by the patent holder during the granting procedure, as referenced by the Defendants' representatives, were considered, the patent holder did not limit the patent to sodium phosphate instead of histidine or other buffers. There is no evidence suggesting that the patent holder intended to exclude histidine from the patent's scope of protection.

[144] The inventive step is justified in the letters dated 5 October 2009 on the grounds that the patent uses a VEGF antagonist different from those in D1, and the skilled person would have no reason to replace the D2 VEGF antagonist with the D1 VEGF antagonist. The reference to the use of a different buffer (histidine) was made in the sense of an "in addition" argument. Such an argument cannot be considered a waiver. Adding histidine to the patent claim would have constituted an inadmissible extension, which makes this clear.

[145] The same applies to the statement […] regarding the letters from the patent attorney representing the patent holder during the grant procedure concerning the prior art document D3 (patent specification WO 2006/104852 […]). The letters stated that D3 did not disclose any formulation with a phosphate buffer, except in combination with 20 % sucrose. Otherwise, only a buffer consisting of histidine or a combination of citrate and phosphate was present. Therefore, the patent-in-suit was novel. However, for the aforementioned reasons, this statement does not indicate a waiver of histidine.

[146] dd) The *Formstein* objection does not rule out a patent infringement.

[147] (aaa) If the Plaintiff asserts patent infringement by means that are modified but equally effective, the Defendant may defend itself by objecting that the challenged embodiment is not patentable because it was anticipated or suggested by prior art on the patent's priority date (FCJ, case number X ZR 28/85, GRUR 1986, page 803 – *Formstein*). This is the argument of the free state of the art, which can only be applied in the case of an extension of the scope of protection by equivalent means. Therefore, the challenged embodiment, including the equivalently infringed feature, must have existed in the prior art at the patent's priority date.

[148] This is not the case because D10 ([…] which contains aflibercept as the active ingredient and histidine as a buffer), as referenced by the Defendants, does not show an ophthalmic formulation of a VEGF antagonist intended for intravitreal administration. While D10 is suitable for intravitreal administration, it is not intended for this purpose. Therefore, the challenged biosimilar is not part of the prior art.

[149] (bbb) During the oral proceedings, the Defendants argued that the *Formstein* objection ought to apply for reasons of legal certainty. They justified this by stating that the granted version of patent claim 1 corresponded to the teaching of D10 and the formulation of the challenged embodiment. If this version were still valid, they could invoke the *Formstein* objection.

[150] In this respect, it is true that the limited version of patent claim 1 distinguishes it from D10. However, the Defendants could not reasonably "trust" the granted version. It is well-known that patent claims can be limited during nullity proceedings. Third parties are free to form their own opinion of the patent's true scope of protection by reading the claims, description, and figures.

[151] […]

2. Equivalent patent infringement in Austria, Belgium, Bulgaria, Denmark, Finland, France, Greece, Ireland, Italy, Lithuania, Luxembourg, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Czech Republic, Hungary und Cyprus

[152] Regarding the alleged patent infringement in the 22 EPC member states, all of which are also EU member states, infringement by equivalent means must be assumed. This is because the scope of protection of the patent-in-suit, which was divided into national patents after being granted by the EPO, must be assessed uniformly.

a. Indicative effect of the assessment in Germany

[153] The assessment of the legal situation in Germany strongly suggests that the same result will be found in the other EPC member states.

[154] Because of this strong indicative effect, it is unnecessary for the Chamber to obtain expert opinions from independent experts on the relevant foreign laws. Otherwise, effectively enforcing industrial property rights, as required by the Enforcement Directive, would be unreasonably difficult for the owners of those rights.

[155] Instead, the burden is on the Defendant to provide concrete indications that a different decision would be made under national law. They must demonstrate why other states would reach a different conclusion.

[156] The argument that proceedings in other countries are conducted differently cannot be taken into account. In other words, it is irrelevant if proceedings are conducted differently (e.g., through expert evidence), if preliminary injunctions take significantly longer, or if there is skepticism toward the legal concept of equivalent patent infringement (typically, judges who do not regularly deal with patent infringements are reluctant to apply this legal concept). These are factual circumstances that a party sued for patent infringement cannot invoke.

[157] The sole criterion is whether national law – either statutes or established case law – modifies the requirements of the EPC in a way that would lead to a different result. Thus, the Defendant must submit any relevant provisions or decisions. Additionally, the Defendant must submit a qualified opinion from an expert who is bound – at least by professional ethics – to tell the truth.

[158] These principles regarding the indicative effect of infringement under German law apply not only to literal patent infringements but also to equivalent infringements, particularly in cases involving simple constellations of equivalence. In the Chamber's view, extending the scope of protection to equivalent forms of infringement ensures that clear circumvention solutions are covered by a patent's protection. A clear circumvention solution exists at least when a feature that is not central to the invention is modified.

[159] This is the case here; only the formulation's buffer solution is changed. According to the patent-in-suit, the sole purpose of this buffer is to adjust the formulation's pH value. The Chamber recognizes that the Defendants, presumably influenced by the proceedings in the United Kingdom, submitted an expert opinion ([…]) and argued that the choice of buffer impacts the stability of a protein formulation. As previously mentioned, this does not significantly increase complexity. Simple routine tests can determine whether replacing the buffer affects the stability of the formulation's overall structure. A skilled person can perform such tests without difficulty.

[160] The Defendant's argument can be classified as an attempt to imbue the exchanged feature with meaning beyond its wording and description. This attempt is made in order to give the exchange the appearance of an inventive step, which would lead to the denial of equivalent infringement. For the aforementioned reasons, this argument is not convincing.

b. The decision of the UK High Court does not shake this indicative effect

[161] The case law of the German Federal Court of Justice and the UK High Court is characterized by the understanding that all EPC member states essentially apply the same assessment of the conditions for assuming patent infringement by equivalent means. In its decisions on patent infringement by equivalent means, the German Federal Court of Justice often cites the case law and specific rulings of the UK courts. Judges in the United Kingdom also assume that essentially the same results are achieved.

[162] In the parallel case before the UK High Court, with file number [2025] EWHC 2527 (Pat), the court emphasized that the applied standard does not deviate from the German understanding (see paragraph 423, number 62). In the Chamber's view, there are two main reasons why the decision in this case was different.

[163] First, in the UK proceedings, it is not limited claim 1 that is being asserted, but rather a version limited to independent secondary claim 5. This means that the formulation protected by the claim is described in much greater detail. The discussions on the individual countries, specifically Belgium, will explain that this leads to a different result. However, this cannot be generalized to mean that the UK High Court would deny equivalence in the present case.

[164] Secondly, the parties presented different arguments in the two proceedings. This meant that the UK High Court had to rule on different facts, which could naturally lead to a different outcome. For example, the UK High Court denied the existence of the first question, according to the German understanding the equivalent effect. However, in the present proceedings, it was stated ([…]): The first question of equivalence – whether the modified embodiment (using histidine as a buffer) objectively achieves the same effect as the claimed formulation with sodium phosphate – can be left open at this point. Accordingly, this question was not the focus of the discussion. However, the Chamber does not overlook the fact that the Defendants have argued elsewhere that the buffer influences the stability of the formulation.

[165] Therefore, the aforementioned indicative effect is not affected by the UK High Court's decision.

c. Consideration of statements made during the patent grant procedure

[166] No different results arise from any different treatment of statements during the granting procedure in any of the 22 relevant states.

[167] As a starting point, it should be noted that the scope of protection of a European patent cannot be determined in any EPC member state based on statements made during the grant procedure. Article 69(1) EPC is conclusive in this regard. The patent claims are decisive and should be interpreted using the description and drawings.

[168] Statements made during the patent granting process may, at most, influence the scope of protection granted by the patent with respect to contradictory behavior. The scope of a patent's protection must always be determined objectively. If a patent has been wrongfully granted due to inaccurate information

provided in the application, the patent's enforcement may be opposed from the perspective of contradictory behavior at most.

[169] Regarding the statements made during the grant procedure, the Defendants noted that the patent holder had impliedly waived protection in some countries. Therefore, the patent holder waived an extension of the patent's scope of protection to an embodiment with histidine as a buffer during the proceedings on the grounds of lack of novelty or lack of inventive step. However, as explained in the discussion of the German legal situation, these arguments are not convincing. The UK High Court correctly came to the same conclusion.

[170] d. Based on this, it can be assumed that equivalent infringement of patent claim 1, as asserted in the main claim, is indicated in all 22 states. The Defendant's submissions are insufficient to refute this indication.

e. Assessment of the legal situation in the 22 countries in question

[171] Based on these general principles applicable to all the countries in question, as well as the parties' specific submissions on the laws of each state, the following comments can be made regarding each country.

[172] First, an assessment of the case's overall facts should be provided. The Plaintiffs base their case on 22 national patents that were granted uniformly by the EPO. The Defendants, who are based in Germany, have obtained a uniform marketing authorization for the biosimilar. This entitles them to market the biosimilar in all 22 states after taking a few additional steps. The necessary preparatory steps have already been taken. The Defendants have put forward several minor arguments against the injunction, claiming that specific aspects relating to the respective countries have not been considered. However, the Defendants fail to recognize the uniformity under the EPC and the Enforcement Directive regarding the assessment of equivalent patent infringement. Their arguments are based on standards and legal institutions that do not aim to hinder the enforcement of patent rights.

(1) Austria

[…]

(2) Belgium

[…]

(3) Bulgaria

[…]

[…]

f. Conclusion of the analysis of the equivalence assessment in the 22 countries in question

[272] It can be assumed that the Defendant's objections would not be successful and that a national judge in each state would conclude that there would be patent infringement by equivalent means.

3. Risk of first infringement

[273] The Plaintiffs' request for an injunction is justified because there is a risk of a first-time infringement in all 22 relevant states.

a. The risk of a first infringement is a substantive legal requirement

[274] The examination of the risk of a first infringement, which is a substantive legal prerequisite for a claim of injunctive relief, is governed by the law of the country for which protection is claimed [*locus protectionis*; *lex loci protectionis*] (see […]).

[275] The requirements for the Plaintiff's submissions regarding the risk of first infringement must not be exaggerated. In particular, the Plaintiff may present facts that demonstrate imminent direct patent infringement is sufficiently likely in all the countries in question. For example, this could be demonstrated by the possible imminent offering of a product. It is sufficient to state that approval has been applied for and that a distribution structure is in place that would enable the product to be distributed. In the pharmaceutical sector in particular, significant investments in new products can only be recouped if the product is widely available. This applies particularly to biosimilars, which are costly to develop. If the Plaintiff has made such a submission, it is then up to the Defendant to show, and potentially prove, that despite the possibility, no distribution is planned or that the legal prerequisites in a given country do not justify a claim for injunctive relief.

[276] In the present case, it is of crucial importance that the biosimilar could potentially be approved in all countries in accordance with pharmaceutical law. According to the Defendants, they have developed a structure that can supply the European market with the biosimilar through a division of labour. Additionally, negative declaratory actions have been brought or are currently pending in Germany, France, Belgium, and Italy. Overall, this can only be interpreted as indicating a risk of market entry in all relevant countries.

b. Sufficiently concrete risk of infringement in all 22 countries

[277] Given this threatening situation, it is unreasonable to expect the Plaintiffs to wait for the Defendants to announce their market entry in each country where the patent-in-suit is validated or to wait for the Defendants to bring further negative declaratory actions in these member states.

[278] For the member states of the European Union at least, effective enforcement of patent rights requires that injunctions can be obtained as a precautionary measure in the event of a sufficiently concrete threat, in accordance with the Enforcement Directive. This is particularly pertinent when considering procedural concentration. Potential patent infringers should not be able to gain an advantage by acting gradually. Otherwise, they could place undue strain on the financial and human resources of patent holders, who cannot choose whether their rights are infringed by third parties in different countries.

c. No different assessment based on the decision of the Düsseldorf Regional Court (4b O 103/23).

[279] […]

d. Assessment based on an overall review of the patent infringer's statements and actions in relation to the individual countries

[280] When the patent holder asserts the cessation of patent infringement in several foreign countries simultaneously, the risk of first-time infringement must be evaluated based on an overall view of the infringer's statements and actions relating to these countries. According to this standard, the following aspects are relevant:

[281] (1) In the letter […] sent on their behalf to Plaintiff 1), the Defendants announced:

"We therefore officially inform you that our clients will, in collaboration with […] market […] in Germany under the brand names […], starting after the expiry of the SPC […] licensing agreement […] for the semi-exclusive commercialisation […] in major parts of Europe, including Germany."

[282] Therefore, there is a threat of marketing in "large parts of Europe" […] This announcement coincides with the content of the report for the annual general meeting of Defendant 1) […]

[283] The previous page presents distribution partners for the challenged embodiment […]

[284] This shows that the Defendants are planning a global marketing strategy, particularly focusing on a rapid introduction to the European market […]

[285] (2) The Defendants also followed through on these announcements. In their protective letter […] they stated that they had notified the Italian authorities of the imminent manufacture […] "purpose of the manufacturing was export and storage, and that Italy was the member state in which the manufacturing was to take place" […]

[286] Furthermore, the Defendants filed negative declaratory actions in France and Belgium […] corresponding application for interim relief in Italy. In the pending main proceedings, case number 7 O 16055/24, before the Chamber, the Defendants expanded their negative declaratory action to include the Netherlands, Austria, Portugal, Switzerland, and Spain.

[287] […] all Belgian product information […] published […] included in the French Agency for the Safety of Health Products' (ANSM) list of biosimilar medicinal products […]

[288] Significantly, the Defendants have a uniform European marketing authorization for the challenged embodiment, meaning there are no major regulatory hurdles to marketing it in any EU member state.

[289] (3) The Defendants submitted a European Commission study entitled "Generics in small markets or for low volume medicines" […], which they argue proves that the simultaneous introduction of generics and biosimilars across Europe is the "absolute exception" […] However, in this context, the Defendants themselves state that "staggered market entries are common, with pharmaceutical companies serving large and lucrative markets first and smaller countries later or not at all." Therefore, they acknowledge that it is generally possible for smaller countries to be supplied, albeit later than larger ones. […]

[290] (4) […] The imminent market entry in Germany, Belgium, France, and Italy must lead to the conclusion that there is a risk of infringement in other European countries as well. The Defendants have admitted that biosimilars are launched simultaneously or with a delay in other European countries.

C.

[291] There are grounds for a preliminary injunction with respect to all relevant countries.

I. Grounds for a preliminary injunction

[292] A preliminary injunction will only be issued if grounds for one are substantiated in addition to the claim for an injunction. As previously mentioned, the assessment of these grounds is governed by the *lex fori*, in this case, German law.

[293] […]

II. Urgency

[294] The Plaintiffs met the one-month deadline for patent matters in Munich courts.

[295] This period began on 26 June 2025, with the decision of the German Federal Patent Court. […]

[296] […]

[297] […] This therefore triggers a new urgency deadline.

[298] This standard also applies in the present cross-border context. Given the significant impact of a decision by the German Federal Patent Court even beyond Germany's borders, the Plaintiffs were entitled to wait for this decision to be issued. Had the Federal Patent Court declared the patent invalid […], this would have significantly reduced the Plaintiffs' chances of success in other jurisdictions as well.

III. Balancing of interests

[…]

D.

I.

[…]

II.

[…]

Doctrine of Equivalents*

Country:	Germany
Court:	Düsseldorf Higher Regional Court (*Oberlandesgericht Düsseldorf*)
Decision name:	Multilayer tablet/NSAID
Decision date:	12 September 2025
File number:	I-2 U 60/25**
Standards:	EPC Art. 64(1), 69(1), 84; German Patent Act Sec. 9, 2nd sentence, no. 1, Sec. 16a, 2nd sentence, Sec. 139(1); German Code of Civil Procedure Sec. 925, 936, 920(2)

1. […]

2. […]

3. As a rule, patent infringement by equivalent means is to be denied where the description discloses several ways in which a particular technical effect can be achieved, but only one of those ways has been incorporated into the patent claim (German Federal Court of Justice: BGHZ 189, 330 para. 35 = GRUR 2011, 701 para. 35 – *Okklusionsvorrichtung*; GRUR 2012, 45 para. 44 – *Diglycidverbindung*; GRUR 2016, 921 para. 50 – *Pemetrexed*; GRUR 2016, 1254 para. 27 – *V-förmige Führungsanordnung*). By contrast, the denial of infringement by equivalence cannot be based solely on the fact that an embodiment claimed in the patent constitutes, in light of the information contained in the description or for other reasons, a specific application of a more general solution principle, and that the skilled person was, on the basis of that insight, able to identify further embodiments corresponding to that solution principle.

4. Effects which, although they may be objectively associated with the use of the means falling within the literal wording of the patent claim, are not taken into account by the patent because they have no significance in the context of the teaching of the invention, must be disregarded when assessing equivalence of effect (following Düsseldorf Higher Regional Court, GRUR-RR 2014, 185, 192 – *WC-Sitzgelenk*).

Grounds

I.

[1] The Applicant seeks injunctive relief against the Respondent by way of preliminary injunction on the grounds of the (alleged) infringement of a supplementary protection certificate for medicinal products.

[2] The Applicant is the exclusive licensee of European Patent 1 411 900 B2, which was granted with effect for the Federal Republic of Germany and published in the English language of the proceedings (hereinafter the *basic patent*; […]).

[3] The basic patent relates to a "pharmaceutical composition for the coordinated delivery of NSAIDs." During opposition proceedings, the patentee amended granted claim 1 of the basic patent (as evident from the B1 publication) […]. In this version, as shown in the B2 publication, the basic patent was maintained by decision of the Opposition Division on 12 December 2012 ([…]). The term of protection of the basic patent expired on 31 May 2022.

[4] Based on the basic patent, a supplementary protection certificate (DE 12 2012 000 052.7; hereinafter the *SPC*) was applied for on 25 July 2012. […] The SPC expires on 5 November 2025. The Applicant is the exclusive licensee of the SPC.

[5] The Applicant belongs to the G group, a corporate group that offers medicinal products for the treatment of chronic and acute pain. The product portfolio includes, inter alia, the medicinal product V, which contains the active substance combination N and E, and is used to alleviate the symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in adult patients at risk of developing gastrointestinal ulcers when taking non-steroidal anti-inflammatory drugs (hereinafter *NSAIDs*).

[6] The Respondent is a generic pharmaceutical company based in Germany and a subsidiary of the company A, which is based in Turkey (Istanbul) (hereinafter the *parent company*). The Respondent holds the marketing authorizations for A products for the European market. The parent company's products also include the medicinal product marketed in tablet form as "N/E tablets with modified release" (hereinafter the *contested embodiment*). The contested embodiment, for which the Respondent has held a German marketing authorization since 27 November 2024, has been listed in the so-called *Lauer-Taxe* since 1 June 2025. Rebate agreements relating to the contested embodiment exist between the Respondent and health insurers. The marketing authorization of the contested embodiment is based on the medicinal product V of the Applicant.

[7] The Applicant considers the listing of the contested embodiment […] and the market entry […] to constitute a direct literal, or alternatively an equivalent, infringement of the SPC. […]

[8] By judgment of 4 July 2025, the Regional Court dismissed the Applicant's request for the granting of a preliminary injunction, rejecting both direct literal use and use by equivalent means.

[9] The Applicant challenges this decision by way of appeal.

[10] […]

II.

[11] The Applicant's appeal is admissible and successful on the merits.

* No official translation; translated by editorial team.

** Some of the co-editors took part in the proceedings as the Respondent's legal representatives.

[12] The Applicant has substantiated both a basis for injunctive relief and a claim to such relief (Sections 936, 920(2) of the German Code of Civil Procedure). A claim to injunctive relief exists […] since the contested embodiment does not make literal use of the technical teaching of the SPC, but does make use of it by equivalent means.

A.

[13] The basic patent relates to pharmaceutical compositions that provide for the coordinated release of an acid inhibitor and a non-steroidal anti-inflammatory drug (NSAID) (para. [0001] of the B2 publication, […]; paragraphs without specific designation hereinafter refer to those of the B2 publication in the German translation).

[14] The basic patent initially describes NSAIDs as known effective agents for pain relief, the administration of which, however, may lead to the development of gastroduodenal lesions (e.g., ulcers or erosions) in susceptible individuals (para. [0002]). The basic patent further states that the presence of acid in the stomach and upper small intestine of patients contributes to the formation of such lesions (para. [0002]). Moreover, NSAID-associated gastropathy is caused by the local toxic effect of NSAIDs and the inhibition of protective prostaglandins, which may also render some patients more susceptible to the ulcerogenic effects of other noxious stimuli (para. [0002]).

[15] To reduce gastroduodenal lesions, the basic patent mentions the administration of acid inhibitors, with stronger and longer-acting acid inhibitors, such as proton pump inhibitors, being preferred over shorter-acting agents, such as histamine H_2-receptor antagonists (H2 blockers), in the context of chronic NSAID use (para. [0003]). The most likely explanation for this effect is that the gastric pH fluctuates significantly throughout the dosing interval, with short-acting acid inhibitors leaving the mucosa vulnerable for longer periods (para. [0003]). It appears that when a short-acting acid inhibitor and an NSAID are administered concurrently, NSAID-induced mucosal damage occurs before the pH of the gastrointestinal tract can be elevated and after the acid-suppressing effect of the short-acting inhibitor has worn off (para. [0003]).

[16] By contrast, active substances with a longer duration of action, such as proton pump inhibitors (PPIs), generally maintain a consistently higher gastroduodenal pH throughout the day (para. [0004]). With regard to this, the basic patent, however, describes it as disadvantageous that their antisecretory effect may be delayed by several hours after multiple days of administration and may only be fully established after several days (para. [0004]). Furthermore, their effect may weaken towards the end of the usual dosing interval, and the gastric pH rises particularly slowly upon the first dose of a treatment, delaying absorption by several hours (para. [0004]). Even then, some patients do not respond consistently to this type of active substance and experience a "breakthrough" of acid, making them more susceptible to NSAID-associated gastrointestinal damage (para. [0004]).

[17] With regard to approaches known from the prior art for avoiding the problems described, the basic patent mentions strategies for combining the two active substances, PPI and NSAID, for therapeutic purposes as known, but criticizes them on the grounds that they do not provide for coordinated drug release or for reducing gastric acid levels to a non-toxic level before the release of the NSAID (para. [0005]). Furthermore, attempts have been made to develop NSAIDs that are inherently less toxic to the gastrointestinal tract, but these have only been partially successful (para. [0006]). It is also known to attempt to provide an NSAID therapy with lower gastrointestinal toxicity by concurrently administering cytoprotective agents (para. [0007]). In this regard, however, a range of other serious side effects have been observed (para. [0007]). Finally, the basic patent refers to a known approach in which NSAID products are enteric-coated, but notes that there is no consistent evidence of long-term benefit in chronic treatment (para. [0008]).

[18] The basic patent specification does not explicitly formulate a technical problem; however, it criticizes, with regard to the prior art, that the risk of developing gastric ulcers in connection with the administration of NSAIDs has not yet been satisfactorily addressed (para. [0009]). Furthermore, it summarizes the invention in such a way that it offers a new approach to reducing the risk of gastrointestinal side effects in individuals taking NSAIDs for pain relief or other conditions (para. [0013]). Based on this content of the basic patent specification, the objective of the patent can be defined as providing a formulation improved over the prior art for the prevention of gastroduodenal side effects associated with NSAID administration.

[19] To solve this problem, claim 1 of the basic patent, in the version asserted here, proposes a multilayer tablet having the following features:

1. A multilayer tablet suitable for oral administration to a patient, comprising:
   - 1.1.1. an outer layer of an acid inhibitor,
   - 1.1.2. an inner core of a non-steroidal anti-inflammatory drug (NSAID),
   - 1.1.3. a barrier layer.

2. The *outer layer* of an acid inhibitor
   - 2.1. is a proton pump inhibitor; and
   - 2.2. is present in an amount effective, upon administration of one or more of the tablets, to raise the patient's gastric pH to at least 3.5.

3. The *inner core* of a non-steroidal anti-inflammatory drug (NSAID) is present in an amount effective, upon administration of one or more of the tablets, to reduce or eliminate pain or inflammation in the patient.

4. The *barrier layer*[***]
   - 4.1. surrounds the inner core of NSAID; and
   - 4.2. does not dissolve unless the pH of the surrounding medium is 3.5 or higher.

5. The tablet provides for the coordinated release of the acid inhibitor, followed by the NSAID.

[…]

[***] The English version of the claim reads *barrier coating*. The German version reads *Barriere-Schicht*, which translates as *barrier layer*.

B.

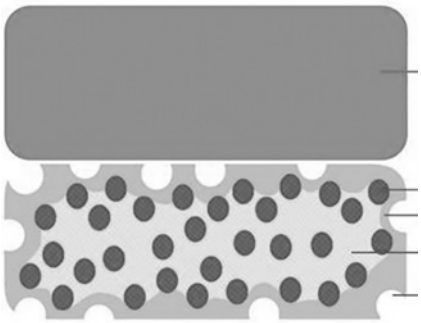
[72] The Regional Court correctly concluded that the contested embodiment does not literally realize the teaching of patent claim 1. However, the contested embodiment realizes the protected teaching by modified, equivalent means.

1.

[73] As the Regional Court correctly held, the contested embodiment does not make literal use of the technical teaching of the basic patent, since it has neither a barrier layer nor an inner core within the meaning of the basic patent.

a)

[74] In line with the findings of the Regional Court, the Senate proceeds on the assumption that the contested embodiment exhibits the tablet structure shown in the diagram reproduced below ([…]):



[75] According to this, with regard to the components relevant here, the contested embodiment is structured such that active ingredient E is located in one part of the tablet (the upper, blue-marked portion). This active ingredient is rapidly released after the patient ingests the tablet in order to increase the gastric pH value to ≥ 3.5. In the other half of the tablet (the lower portion), there is a matrix formed in a mesh-like manner, which contains the N components (marked in red) and an enteric material in the form of a copolymer (marked in orange and yellow), into which the N components are embedded. The copolymer is a methacrylic acid/ethyl acrylate copolymer, a substance marketed under the brand name E® ([…]). The enteric copolymer into which the N components are embedded is resistant to gastric juice; it releases the N components only once the gastric acid has been raised to a pH value of 5.5. N components may also be present at the edge of the matrix (the white recesses in the lower, orange-marked portion), which – since they are not embedded but are located at the periphery – may be released earlier, i.e. before the pH value is raised.

[76] For the question of the realization of the claim features, it is irrelevant whether […] the diagram otherwise accurately depicts the design of the contested embodiment (additional components, quantitative ratios, homogeneity of the matrix structure).

b)

[77] Based on the described structure of the contested embodiment, the Regional Court correctly assumed that the contested embodiment lacks a barrier layer (feature 1.3 / feature group 4).

aa)

[78] Due to the matrix structure provided in the contested embodiment, there is no (spatially and physically) continuous, (spatially and physically) delineable spatial entity within the tablet body (tablet sub-portion) that could be considered a barrier layer within the meaning of the basic patent.

[79] The matrix, consisting of the enteric copolymer and the N particles, is apparently *one* continuous, delineable tablet portion. This is because the individual N particles are distributed throughout the entire matrix together with the enteric copolymer.

[80] If the above schematic illustration, […], suggests that the inner part of the matrix structure – consisting of the (red-marked) N particles and the (yellow-marked) enteric copolymer – should be regarded as a continuous tablet portion, such an interpretation must be excluded. This is primarily because the matrix, composed of the N particles and the enteric copolymer, is materially uniform, i.e., the N particles and the enteric copolymer are distributed throughout the entire matrix. This materially uniform region cannot, purely from a functional perspective, be mentally divided into separate subportions, since this would not correspond to the spatially and physically delineable sub-portions of the patented tablet as required by the basic patent.

bb)

[81] […]

[82] […]

c)

[83] […] the contested embodiment also does not have an inner core within the meaning of the basic patent (feature 1.2 / feature 3). This is because there is no (spatially and physically) continuous tablet portion containing an amount of NSAID sufficient to reduce or eliminate pain or inflammation, which can be (spatially and physically) delineated from a tablet portion ("barrier layer") that contains the substance(s) that only dissolve at a pH of 3.5 or higher.

2.

[84] The contested embodiment, however, realizes the features not literally realized in a manner equivalent under patent law by comprising a matrix containing a non-steroidal anti-inflammatory drug (NSAID) in an amount effective, upon administration of one or more of the tablets, to reduce or eliminate pain or inflammation in the patient (feature 1.2 / feature 3), and by incorporating into this matrix an enteric polymer that does not dissolve unless the pH of the surrounding medium is 5.5, i.e., higher than 3.5 (feature 1.3 / feature group 4).

[85] For an embodiment that deviates from the literal wording of a patent claim to fall within its scope, three conditions must be met. First, the embodiment must solve the problem

underlying the invention by means that, while modified, are objectively equivalent in effect. Second, the knowledge available to the skilled person at the priority date must have enabled them to identify the modified embodiment with its differing means as producing the same effect. Third, the considerations that the skilled person must undertake in this regard must be guided by the technical teaching protected by the claim. If these requirements of equal effect, identifiability, and orientation toward the claim are fulfilled, the deviating embodiment with its modified means must, from the perspective of the skilled person, be regarded as an equivalent solution to the literal solution and thus taken into account when determining the scope of protection of the patent (established case law, e.g., German Federal Court of Justice: […] *Schneidmesser I* […] *Pumpeinrichtung* […] *Crimpwerkzeug IV* […] *Begrenzungsanschlag* […] *Kochgefäß* […] *Kranarm*).

[86] Contrary to the view of the Regional Court and the Respondent, these requirements are met in the present case.

a)

[87] The modified design of the contested embodiment, with a matrix structure of NSAID (N) and enteric polymer, is equivalent in effect to the embodiment proposed by the basic patent, which comprises an inner core of NSAID surrounded by a barrier layer.

aa)

[88] For the question of equivalence in effect, it is decisive which individual effects the claimed features – both individually and collectively – contribute to solving the problem underlying the patent claim, and whether these effects are achieved in the contested embodiment by other means. Accordingly, it is necessary to examine the patent claim to determine which of the effects achievable by its features must come together, according to the patent, to solve the underlying problem. This entirety represents the patented solution and therefore constitutes the effect relevant for the comparison to be made (German Federal Court of Justice: […] *Bratgeschirr* […] *Palettenbehälter III* […] *Kochgefäß* […] *Kranarm*). Only in this way is it ensured that, despite modification of one or more features, only those embodiments fall within the scope of the patent claim in which the purpose pursued by the protected invention is maintained. An embodiment can be regarded as equivalent in effect if it not only essentially achieves the overall effect of the invention but also specifically achieves the effect intended by the feature that is not literally realized (German Federal Court of Justice: […]; Düsseldorf Higher Regional Court: […]). It is sufficient that this effect is essentially achieved (cf. German Federal Court of Justice: […]).

[89] […] Equivalence may also be established if a function required by the patent claim is achieved by modified means only to a limited extent. From the perspective of providing a fair reward to the inventor, inclusion within the scope of a patent may be appropriate already if the effects intended by the invention are essentially achieved, i.e., to a practically significant extent. This assessment depends on the effect as defined by the patent and a weighting of the deficiencies observed in the contested embodiments in relation to that effect (German Federal Court of Justice: […]).

bb)

[90] According to these principles, the matrix structure of N (NSAID) and enteric polymer is objectively equivalent in effect to an inner core of NSAID (feature 1.2 / feature 3) surrounded by a separate barrier layer (feature 1.3 / group of features 4).

[91] The effect of the NSAID particles contained in the matrix structure corresponds to that of the NSAID-containing inner core (feature 1.2 / feature 3). In particular, the NSAID particles contained in the matrix structure are sufficient to reduce or eliminate pain or inflammation, as evidenced by the fact that the contested embodiment is approved for the symptomatic treatment of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in adults ([…]).

[92] Furthermore, the effect of the polymer, insofar as it surrounds the NSAID particles, corresponds to that of the claimed barrier layer (feature 1.3 / feature group 4), since as long as the polymer surrounds the NSAID particles, the release of the NSAID is prevented. The polymer is also enteric, as it only dissolves at an elevated gastric pH of 5.5.

[93] With regard to the equivalence of the polymer, it is irrelevant that in the matrix structure some N particles are located at the edge of the matrix and are not completely surrounded by the polymer, so that these peripheral NSAID particles are released prematurely upon administration to the patient (before the gastric pH is elevated to 5.5 by the PPI), and thus the enteric polymer does not fully achieve the effect intended for the claimed barrier layer in this respect. The Applicant has submitted that this involves such a small amount of NSAID that the release of these particles does not result in any technically or therapeutically relevant effect; in other words, the release does not occur to the extent that the NSAID would already exert anti-inflammatory effects and cause gastroduodenal side effects. […]

[94] Finally, equivalence in effect is not precluded by the fact that NSAID particles are arranged at the outer edge of the matrix structure at all (even if only in a technically insignificant amount). Even if the technical teaching of claim 1 was to be understood as excluding embodiments in which NSAID particles are contained in the barrier layer – so that, due to its spatial-physical arrangement between the inner core and the outer layer, the barrier layer separates the active ingredients of the other two patented layers (NSAID inner core / PPI outer layer) – this is an effect that is objectively associated with the use of the means as literally claimed, but to which the basic patent attaches no further significance. In particular, the basic patent […] is not concerned with protection against interactions, etc. Such effects, which may be objectively associated with the use of the means as literally claimed but are disregarded by the patent because they have no significance in the context of the teaching of the invention, are to be ignored (cf. Senate, GRUR-RR 2014, 185, 192 – *WC-Sitzgelenk*).

b)

[95] The skilled person could, based on their technical knowledge, also identify the modified means realized in the

contested embodiment as equivalent in effect without any inventive effort.

aa)

[96] It must be distinguished in this regard whether the substituting means was obvious to the skilled person or whether its identification itself constituted an inventive step. The same standards and rules apply as in the assessment of inventive step in the grant and validity proceedings. Unlike in the interpretation of the scope of protection, for the question of equivalent realization, not only the prior art acknowledged in the patent specification can be considered, but the entire body of knowledge available at the priority date (Kühnen, *Hdb. der Patentverletzung* [Handbook of Patent Infringement], 16th ed., Ch. A para. 195).

bb)

[97] Here, the NSAID–polymer matrix structure of the contested embodiment was identifiable by the skilled person as equivalent in effect without any inventive effort.

[98] At the priority date, the skilled person was aware of various methods for producing a tablet dosage form, which generally presented themselves as alternatives, in particular a method in which the active ingredient is enclosed by an enteric coating and one in which the active ingredient particles are embedded in a matrix. In the specification of the basic patent, such a matrix structure is also generally mentioned in connection with embedding an (active) substance together with excipients (paras. [0028], [0032], [0040], [0048]). It is furthermore undisputed between the Parties that the skilled person was generally familiar with polymer-based matrix embedding for achieving delayed release of an active ingredient.

[99] If the skilled person, in view of these methods, considers the purpose pursued according to the patent – namely to prevent the release of the NSAID by surrounding the active ingredient with an enteric layer whose dissolution depends on the action of a PPI – a matrix structure is readily conceivable from their perspective, also with regard to the tablet claimed in the basic patent. In particular, the technical teaching of the basic patent does not provide any technical-functional considerations that could prevent the skilled person from using the matrix structure, which is generally known to them as an alternative, also in relation to the claimed layer structure. According to the protected teaching, what is crucial for sequential release of the active ingredients (PPI before NSAID) is that the barrier layer surrounds the (NSAID-containing) inner core and that the PPI outer layer is positioned outside the barrier layer. The design of a layer structure in the (patent-compliant) sense – that is, with the active ingredients (PPI; NSAID) and the material performing the barrier-layer function arranged in separate, continuous sub-portions of the tablet body – is not strictly required. Rather, as the skilled person can easily recognize, a suitable matrix structure can also prevent the release of the NSAID before the action of the PPI, because the material embedded in the matrix that hinders NSAID release (polymer) only dissolves once the PPI provided in the outer layer has elevated the gastric pH. Instead of coating the NSAID core layer with a separate enteric layer, it is sufficient that the individual NSAID particles themselves are coated. This is achieved by embedding them in an enteric polymer.

[100] That the skilled person knows from their general technical knowledge that a matrix structure may result in a short-term release of a first portion of the active ingredient does not preclude the identification of the substituting means. In view of the fact that this involves only a small amount of active ingredient, which does not produce a technically relevant effect, the described effect does not deter the skilled person from using the matrix structure, which is generally known to them as an alternative.

[101] Insofar as the Respondent argued […] that it was not foreseeable in advance of the manufacturing process how the matrix structure would ultimately appear, this likewise does not preclude the identification of the substituting means. In particular, it is not apparent that the uncertainties regarding the final matrix structure would have shaken the skilled person's expectation that the matrix structure – which was generally known to them as an alternative for achieving delayed release of an active ingredient – could also achieve the desired effect (delayed active ingredient release) in the context of the protected teaching.

[102] […]

[103] […]

c)

[104] The foregoing considerations regarding the identification of the equivalent modification are also guided by the technical teaching of claim 1 of the basic patent.

aa)

[105] Orientation to the patent claim requires that the considerations the skilled person must make in order to arrive at the equivalent modification are guided by the teaching protected in the claim, such that the deviating embodiment with its modified means is regarded as an equivalent solution to the teaching according to patent. It is not sufficient that, based on their technical knowledge, the skilled person recognizes a teaching as technically sensible and equivalent in effect to the teaching formulated in the claims. Rather, the skilled person must be guided by the patent claim, which, with all its features, not only provides the starting point but forms the essential basis for their considerations (German Federal Court of Justice: […]; Düsseldorf Higher Regional Court: […]). The patentee is bound by the technical teaching that they have protected. They must accept it as meaningful and may not question it in its factual validity when searching for an equivalent substituting means (German Federal Court of Justice […]). The considerations must not diverge from the meaning of the patent claim but must remain so close to it that it is justified to conclude that the contested embodiment, despite the deviation, is based on the patent claim and, in a broader sense, still represents a solution in accordance with the patent (Senate, judgment dated 10 June 2021 – I-2 U 19/19, GRUR-RS 2021, 15125 para. 63 – *Rohrreinigungsgerät* with further references; […]).

bb)

[106] According to these principles, the skilled person will regard the matrix structure of the contested embodiment as *gleichwertig* (oriented to the claim).

[107] As explained, for the teaching of the basic patent, the technical interaction between the barrier layer and the inner core, which delays the release of the NSAID, on the one hand, and the interaction of the barrier layer and its dissolution after the PPI has taken effect, on the other hand, is decisive. In this context, the technical instruction that the barrier layer surrounds the inner core is central. The matrix structure of the contested embodiment adheres to this instruction by surrounding the individual NSAID particles with an enteric substance, which does not dissolve unless the pH of the surrounding medium is 3.5 or higher. Only isolated NSAID particles at the edge of the matrix are not completely surrounded by the enteric polymer, so that these NSAID particles may be released prematurely upon administration to the patient (before the PPI takes effect). However, as explained, the release of these particles has no technically relevant effect and can therefore be disregarded. That in the contested embodiment the NSAID active ingredient and the enteric polymer are not each located in a (spatially and physically) separable, contiguous tablet portion, but are both provided in a single portion, does not constitute a difference in assessment. What is decisive is that this is a tablet which, unlike the prior art, constitutes a single-dose product that additionally provides the advantage of coordinated release of the active ingredients (paras. [0013], lines 38–41).

cc)

[108] The basic patent also does not make any "selection decision" in favor of the layer structure described in the patent claim.

(1)

[109] It is correct that in cases where the patent claim is based on a selection among different options, the requirement of orientation to the claim demands that the skilled person's considerations regarding possible modifications must also be consistent with this selection (German Federal Court of Justice […]). Therefore, an infringement by equivalent means is generally excluded if the description discloses multiple ways of achieving a particular technical effect, but only one of these possibilities has been included in the patent claim (German Federal Court of Justice […]). These are cases in which the description of the patent shows (at least) two specific embodiments for achieving the effect according to the invention, but only one of these embodiments is reflected in the claim. For the applicability of this principle, however, it is not sufficient, for example, that an embodiment claimed in the patent represents a special application of a more general solution principle based on the description or other reasons, and that the skilled person, based on this knowledge, was able to identify further embodiments corresponding to this principle (German Federal Court of Justice, GRUR 2016, 921 para. 50 – *Pemetrexed*).

(2)

[110] Based on this, the patent claim in the present case does not express any selection decision.

[111] The description of the basic patent does disclose that the NSAID (e.g., N sodium) that may be contained in the first layer can be distributed in a matrix of pharmaceutically acceptable fillers, excipients, binders, disintegrants, and lubricants (para. [0028]; see also para. [0027]). However, the relevant embodiment does not dispense with a barrier layer within the meaning of feature group 4. An embodiment in which the NSAID is distributed in a matrix with an enteric polymer, etc., that does not dissolve unless the pH is 3.5 or higher, and in which the matrix is not surrounded by a barrier layer within the meaning of feature 4, is not disclosed in the patent description.

(3)

[112] Nor does it follow from the patent specification or from any other circumstances relevant for its interpretation that the layer structure of the claimed tablet is based on a selection that would exclude a matrix structure of NSAID (N) and enteric polymer from the scope of the patent.

[113] […]

(i)

[114] Based on the principle that a patentee may not, by way of equivalence, subsequently claim protection for something that was not actually protected, it can, according to the case law outlined above, indicate a selection decision if the patentee initially claims protection for a group of compounds (here: multiple spatially defined structures for a single-dose form), but later drafts the claims such that their literal wording covers only a single compound (here: a single spatially defined structure, namely a layer structure) ([…]).

[115] The assumption of a selection decision within the meaning of the aforementioned case law can be justified if a comparison of the different claim versions, taking into account the remaining content of the corresponding application, sufficiently clearly shows that the specification was made in order to distinguish the subject matter of the patent from the prior art and thus avoid doubts regarding patentability ([…]). […] However, if the specification was made for formal reasons (for example, to meet requirements of claim clarity or to avoid an impermissible extension) – regardless of whether these requirements objectively existed – or if it is not sufficiently clear for what reason the specification was made, a selection decision generally cannot be assumed ([…]). […]

(ii)

[116] In the case at hand, a comparison between the granted version of the basic patent and the (published) patent application ([…]) does not give rise to a selection decision […].

[117] […]

[118] […]

dd)

[119] The fact that the description of the basic patent does not contain any indications that would guide a skilled person to the modified design realized in the contested embodiment does not exclude equivalence either. Such indications can indeed support the inclusion of an embodiment deviating from the literal wording of the patent claim within the scope of the patent, but they are not a necessary requirement ([…]).

3.

[120] The contested embodiment […] has an outer layer in the sense of the basic patent (literal implementation of feature 1.2 / feature group 2).

[121] The E, which […] is a PPI within the meaning of the teaching of the basic patent, is located outside the matrix structure. In particular, it is not surrounded by the particles of the enteric polymer. E is thus – which is what matters to the basic patent – outside the tablet sub-portion that performs the function of the patent-specified barrier layer. That the tablet sub-portion containing E does not fully surround the matrix structure is irrelevant. E is also present in the tablet sub-portion in an amount sufficient to raise the pH to 5.5 (i.e., a pH of at least 3.5).

[122] Since the contested embodiment has an outer layer within the meaning of the basic patent, it is no longer relevant whether the arrangement of the PPI in a tablet portion, as shown in the contested embodiment, constitutes a modified but equivalent means (second auxiliary request).

[…]

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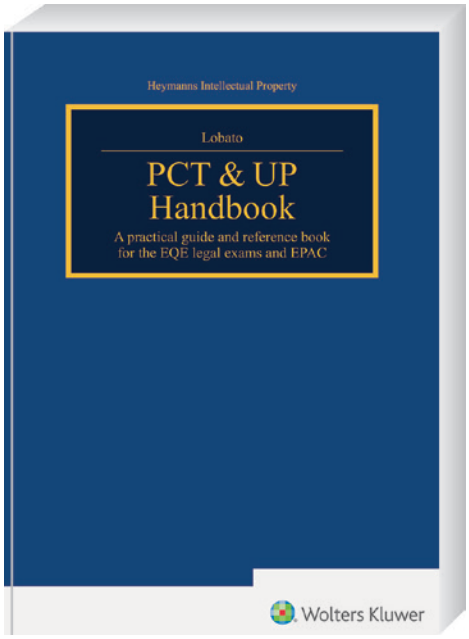

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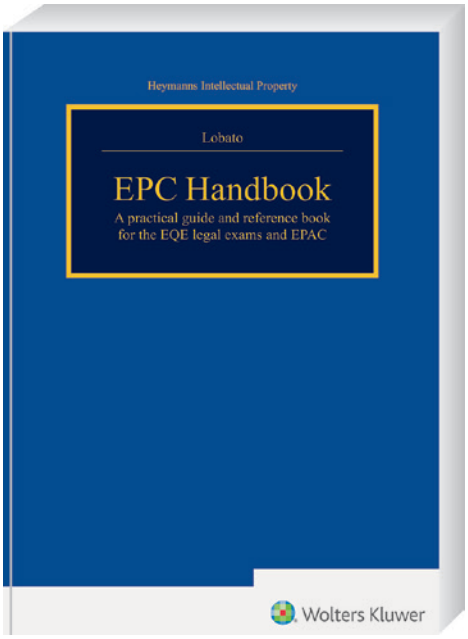

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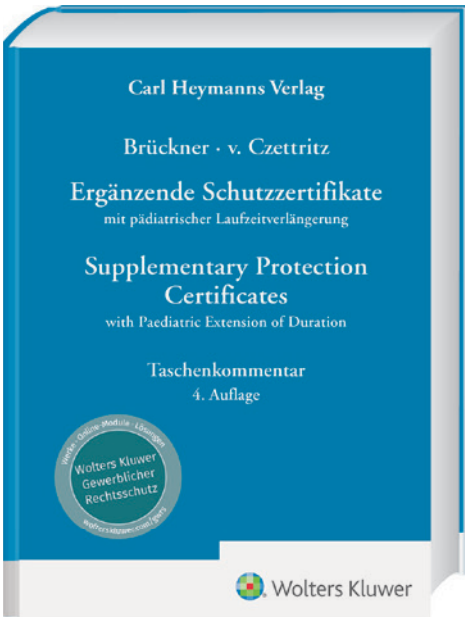

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