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Patentrecht in der Praxis

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- BEITRÄGE**
- 2** | WINFRIED TILMANN
Zum Start von EPG und GRUR Patent
 - 8** | RONNY HAUCK
Covenant not to sue und Erschöpfung im Patentrecht
 - 14** | TIM W. DORNIS
Künstliche Intelligenz und Patentrecht – Klarstellungen zur „Erfindung ohne Erfinder“
 - 20** | CHRISTIAN CZYCHOWSKI/SEBASTIAN DWORSCHAK
Durchsetzung von technischem Know-how – Parallelen zu patentrechtlichen Verfahren und Besonderheiten am Beispiel der Düsseldorfer Besichtigungspraxis
 - 25** | MARCUS GROSCHE
Provisional injunctions in the UPC and the sufficient degree of certainty regarding validity
 - 34** | TILMAN MÜLLER-STOY/JULIA BERNATSKA
File Wrapper Estoppel at the UPC?
- RECHTSPRECHUNG**
- 37** | EPA: Anspruchsauslegung beim EPA (Kemal Bengi-Akyürek)
 - 39** | BGH: Klagehindernis nach § 81 Abs. 2 S. 1 PatG (Julia Nobbe)
 - 41** | OLG Düsseldorf: Geheimnisschutzantrag im Vollstreckungsverfahren (Cordula Schumacher)
 - 43** | OLG München: Verjährung der Ansprüche auf Übertragung der Anmeldung und des Patents (Fabian Schubach/Kilian Seidel)

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1/2023

Inhalt

EDITORIAL	1	GUNNAR BAUMGÄRTEL/HERMANN DEICHFUß/TIM W. DORNIS Patentrecht in der Praxis
BEITRÄGE	2	WINFRIED TILMANN Zum Start von EPG und GRUR Patent
	8	RONNY HAUCK Covenant not to sue und Erschöpfung im Patentrecht
	14	TIM W. DORNIS Künstliche Intelligenz und Patentrecht – Klarstellungen zur „Erfindung ohne Erfinder“
	20	CHRISTIAN CZYCHOWSKI/SEBASTIAN DWORSCHAK Durchsetzung von technischem Know-how – Parallelen zu patentrechtlichen Verfahren und Besonderheiten am Beispiel der Düsseldorfer Besichtigungspraxis
	25	MARCUS GROSCH Provisional injunctions in the UPC and the sufficient degree of certainty regarding validity
	34	TILMAN MÜLLER-STOY/JULIA BERNATSKA File Wrapper Estoppel at the UPC?
RECHTSPRECHUNG	37	EPA 23.1.2023 – T 169/20 Anspruchsauslegung beim EPA (Kemal Bengi-Akyürek)
	39	BGH 6.12.2022 – X ZR 47/22 Klagehindernis nach § 81 Abs. 2 S. 1 PatG (Julia Nobbe)
	41	OLG Düsseldorf 4.1.2023 – 2 W 28/22 Geheimnisschutzantrag im Vollstreckungsverfahren (Cordula Schumacher)
	43	OLG München 15.12.2022 – 6 U 2665/19 Verjährung der Ansprüche auf Übertragung der Anmeldung und des Patents (Fabian Schubach/Kilian Seidel)

| MARCUS GROSCH*

Provisional injunctions in the UPC and the sufficient degree of certainty regarding validity

It is very likely that the first UPC decisions will concern provisional injunctions. Provisional relief in patent infringement matters is generally a challenge, particularly because of the complexity that the validity analysis presents. This article examines the requirements under the UPC with regard to determining validity in summary proceedings for provisional injunctive relief. Especially in the field of provisional injunctions, it becomes evident that the UPCA is rooted in different legal traditions which all have to comply with European law, particularly with the Enforcement Directive. This article analyzes the German practice regarding provisional injunctive relief in patent infringement matters against the background of the ECJ decision “Phoenix Contact” in order to develop standards for the application of the pertinent UPC provisions.

Es ist damit zu rechnen, dass die ersten Entscheidungen des UPC sich mit einstweiligen Unterlassungsverfügungen befassen werden. Einstweiliger Rechtsschutz in Patentverletzungssachen ist insbesondere wegen der Komplexität der Analyse des Rechtsbestandes eine Herausforderung. Der Beitrag untersucht, welche Anforderungen an die Feststellung des Rechtsbestandes in summarischen Verfahren für einstweilige Unterlassungsverfügungen nach dem UPC zu stellen sind. Gerade im Bereich der einstweiligen Unterlassungsverfügungen wird deutlich, dass sich das UPC aus unterschiedlichen Rechtstraditionen speist, die aber alle den Anforderungen des europäischen

Rechts, insbesondere der Enforcement-Richtlinie, gerecht werden müssen. Der Beitrag analysiert insofern die deutsche Praxis zur einstweiligen Verfügung in Patentstreitsachen vor dem Hintergrund der EuGH-Entscheidung „Phoenix Contact“, um daraus Maßstäbe für die Rechtsanwendung im UPC zu gewinnen.

Introduction

[1] Enjoining a defendant from using a technology is a drastic measure, but one that, in the European legal tradition, forms the practical and conceptual backbone of intellectual property rights.¹ Absent injunctive relief, using a protected technology without authorization, i. e., infringing, would not pose a significant risk to the alleged infringer.² As injunctive relief in-

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¹ In the United States, since *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), injunctive relief is not a primary factor in district court patent litigation anymore (exclusion orders are available in the ITC though). In its concurring opinion, Justice Kennedy, inter alia, referred to the “suspect validity” of some of the involved patents asserted by NPEs as a factor against injunctive relief.

² Punitive damages are not available and are even considered to be at odds with the *ordre public*, so foreign decisions awarding such damages would not be acknowledged under Art. 45(1) of the Regulation 215/2012/EU. There is a certain leeway for a deterrent effect in calculating damages under German law including the Enforcement Directive (2004/48/EC), particularly regarding the infringer’s profits as a form of damages. Cf. Leistner GRUR 2022, 1633 (1635) with further references in footnote 11.

herently only applies prospectively, time is of the essence because any period that elapses without relief presents a *fait accompli*. Furthermore, patent protection is limited by its term (20 years from filing the application) and the grant is inevitably delayed by the examination procedure which further reduces the effective period of protection. Adjudication in the field of patent law, however, involves the most complex factual and legal tasks and presents the utmost analytical challenges whose proper handling takes time, even for the most experienced judicial authorities and parties, including the latter's outside counsels who are mainly responsible for filtering out and feeding the required specific factual basis into the proceedings. That complexity is inherently linked to the required determination of validity. Validity is a moving target during the term of the patent and beyond.³ Despite high quality examination at the European Patent Office (EPO) and at other national patent offices throughout the world, the decisive pieces of prior art in significant patent litigation cases are often only identified during the course of the litigation, or the actual disclosure and bearing of identified prior art references are only fully appreciated and properly assessed post-grant as a function of the evolving discussions between the parties.⁴ The aspired quality of these decisions is not only linked to the technical expertise so that judicial bodies with legal members could just easily defer to a bench with technical members. Rather, correctly ascertaining the subtle association of law and facts, requires a high degree of patent law expertise and analytical capabilities on the side of both the decisionmakers and the parties, including their representatives. That is why precedents like the famous decision to grant a provisional injunction by the Duesseldorf appellate court ("Olanzapin"⁵) notwithstanding the invalidation of the patent in suit by the Federal Patent Court are legally not only possible, but also necessary⁶. For the same reason, the decision to grant following examination cannot be conclusive even if no further prior art has been identified. The latter is even more so as the defendant did not have its day in court yet. Notwithstanding these specific subject-matter challenges, patent litigation must provide legal certainty in a fair and timely manner. That also requires interim relief if the case stands out from the ordinary cases. Finding the right balance between reaching the right conclusions (relief or no relief) early enough and with sufficiently lasting effect, is therefore the primary legal task regarding provisional injunctions. The UPC's attempt to strike this balance is reflected in Art. 62(2) of the UPCA requirements to "weigh [...] the parties' interests," along with the sufficient degree of certainty as to infringement and validity provided by Art. 62(4) UPCA in combination with UPC Rule of Procedure 211(2). An understanding of European law and in particular German law (infra I.) and the recent ECJ Phoenix Contact judgment will help inform the interpretation of these UPC provisions (infra II.).

I. National laws and the European Directive on the Enforcement of Intellectual Property Rights

1. Balance of convenience and merit-driven approach

a) United Kingdom: The American Cyanamid standard

[2] In the trial-based UK system, the bench takes into account that the evidence and arguments before the court are incomplete and untested.⁷ Accordingly, interim proceedings focus on a "balance of convenience"-test. Under the guidelines set out by the House of Lords in the "American Cyanamid"⁸ test, there must be a "serious issue to be tried" which means that frivolous or vexatious claims are filtered out. For claims that meet the serious-issue threshold, the court must in turn determine the balance of convenience: i.e., it must determine what the refusal or the grant of an injunction⁹ would implicate for the claimant and the defendant, respectively.¹⁰ If the parties are similarly situated, the relative strength of each party's case can be considered in tipping the balance of convenience,¹¹ but "the court should not be sucked into a merits analysis unless the facts are so clear that 'there is no credible dispute'".¹² A more extended consideration of the merits is possible where the provisional injunction will give the claimant substantially all of the final relief sought, which applies to cases in which the patent expires before trial or soon after final judgment. Interim relief is also possible if a patent has been revoked by the EPO Opposition Division unless there is no credible dispute with regard to the invalidity of the patent in suit, i.e., the patent would be unambiguously invalid.¹³

b) German law: Merit-driven analysis supported by balancing the interests

[3] German law, on the contrary, follows a primarily merit-driven approach. The merits of the infringement claim present the first and most important prong in the analysis for provisional relief. In proceedings for provisional relief, the merits are assigned to the cate-

³ Different from any other administrative act ("Verwaltungsakt") known in the German system, the patent never becomes genuinely final, as it can, throughout its lifetime, be subjected to judicial review and be revoked/nullified with ex tunc effect.

⁴ Also, in a significant number of cases, the Opposition Divisions (typically sitting the examiner as rapporteur) correct themselves not only on the assessment of the prior art, but quite frequently also on added matter. As every practitioner knows, added matter is as much a hot topic for opposition proceedings as novelty and inventive step.

⁵ Higher Regional Court Duesseldorf GRUR-RR 2008, 329 (329 f.).

⁶ The Duesseldorf court's assessment regarding validity of the patent in suit was later confirmed by the Federal Court of Justice in the appeal against the Federal Patent Court's decision to nullify the patent (cf. Federal Court of Justice GRUR 2009, 382 – Olanzapin).

⁷ Roughton, Johnson and Cook on Patents, 5th ed. 2022, Pt. 1 Ch. 8.13 p. 473.

⁸ American Cyanamid Co v Ethicon Ltd [1975] AC 396, HL.

⁹ Combined with the claimants undertaking for damages to the defendant.

¹⁰ A key factor in this analysis is if damages are an adequate remedy for the claimant. Even if damages might be an adequate remedy the balance of injustice might still indicate that the grant of an injunction was appropriate.

¹¹ American Cyanamid Co v Ethicon Ltd [1975] AC 396, HL at 409.

¹² Neurim Pharmaceuticals (1991) Ltd v Generics UK Ltd (t/a Mylan) [2020] EWHC 1362 (Pat) at 17.

¹³ Neurim Pharmaceuticals (1991) Ltd v Generics UK Ltd (t/a Mylan) [2020] EWHC 1362 (Pat) at 29–37.

gory of the “Verfügungsanspruch”¹⁴. The elements of infringement must be sufficiently corroborated both as to all issues of law and of fact.¹⁵ For example, when the court is not convinced based on the claim construction and the claimant’s factual contentions that there must be an infringement, the application for provisional relief must be dismissed. This is true even if the claim construction could be objectively “tenable”. The merits of infringement only present the first prong in the analysis for provisional relief. There is a further requirement under Sec. 940 German Code of Civil Procedure (ZPO)¹⁶ according to which the injunction must be necessary in order to avoid significant disadvantage. Supported by this statutory basis, a comprehensive analysis has developed under the prong “Verfügungsgrund”.¹⁷ The „Verfügungsgrund“ hallmarks the claimant’s specific legal interest to obtain provisional relief in summary proceedings.¹⁸ This requires not only urgency as a limitation in time for an application to be brought.¹⁹ Rather, the claimant has to substantiate why there is a need for an interim relief²⁰ and why waiting for permanent relief is not acceptable for the claimant.²¹ This involves the balancing or weighing of the parties’ interests (“Interessenabwägung”) under the principle of proportionality.²² The negative effects for the claimant that would result from withholding injunctive relief must be balanced against the detrimental impact that the grant of the injunctive would have on the defendant.²³

[4] While German courts are generally rather generous to render (even ex-parte) provisional injunctive relief in other IP matters,²⁴ this is fundamentally different in patent matters, both because of their complexity (which is to be dealt with on short notice) and the typically rather severe impact on the defendant.²⁵ Different from the English approach, in Germany there is a clear emphasis on the merits. If the merits of both infringement and validity are unambiguously clear in favor of the claimant, the prong “Interessenabwägung” does not require any further weighing of the parties’ interests.²⁶ Also, a verdict like the decision in the Olanzapin case is only possible based on a very detailed analysis of the merits and a clear conviction that the validity decision was legally flawed.²⁷ In the “middle ground” cases, in which the assessment on the merits is not unambiguously clear in favor of the claimant, but where there are also no serious doubts as to the merits, the weighing of the interests plays a bigger role and a flexible standard applies: The less clear the merits and the more significant the effects of the injunction are for the defendant, the more exceptional and specific the claimant’s interests have to be.²⁸

2. Validity in German patent law

a) Interim relief in the bifurcated system

[5] Early in the development of German doctrine, the validity analysis was, like the infringement part, allocated to the merit prong “Verfügungsanspruch”.²⁹

That changed over time, and by now “validity” has become part of the comprehensive analysis under the “Verfügungsgrund” prong.³⁰ This structural change is inextricably linked to the German bifurcation system in which infringement courts have no jurisdiction to determine patent validity.³¹ Accordingly, the infringement court cannot dismiss an action for permanent relief for lack of validity of the patent suit. It can only stay an action according to Sec. 148 ZPO pending the nullity action or opposition proceeding. Yet, actions for interim relief can, as a matter of law, not be stayed pending the invalidity determination as that would inherently conflict with the nature of summary proceedings. Thus, the application for provisional relief would have to be dismissed if the court is not satisfied with the required certainty as to the validity.

b) Validity must be robust

[6] The German practice was originally very restrictive with the grant of interim relief in light of potential validity issues. According to older case law of the Dueseldorf appellate court, validity of the patent needed to be clear beyond any doubt (“über jeden Zweifel erhaben”).³² That strict standard was not maintained, how-

¹⁴ Literal translation “injunction claim”.

¹⁵ The standard of proof for contested issues of fact in summary proceedings is different from main proceedings as “Glaubhaftmachung” according to Sec. 294 ZPO applies. A preponderance of evidence is sufficient, i. e., it is sufficient that a fact is more likely than not (“überwiegend wahrscheinlich”) while in proceedings for permanent relief the “Vollbeweis” is applicable (Sec. 286 ZPO).

¹⁶ In part, Sec. 935 ZPO is also quoted as a statutory basis for preliminary injunctions.

¹⁷ Literal translation “injunction ground”, functionally preferable: “reason for provisional injunctive relief”.

¹⁸ Cf. Higher Regional Court Karlsruhe GRUR-RR 2015, 509 para. 35 – Ausrüstungssatz.

¹⁹ The case law in the appellate circuits differs. As a rule, in preparing and pursuing its claims, the claimant has to act quickly and consistently enough such that the seriousness of his endeavor is objectively ascertainable and justifiable (cf. Kühnen, Patentverletzung-HdB, 15th ed. 2023, Ch. G para. 162 et seq.). Once all the facts and evidence have been secured in such timely manner (cf. Higher Regional Court Munich GRUR-RR 2021, 297 para. 49 – Cinacalcet), the claimant typically has one month for filing (cf. for the Munich appellate circuit: Higher Regional Court Munich GRUR 2020, 385 para. 60 – Elektrische Anschlussklemme; Higher Regional Court Munich GRUR-RR 2021, 297 para. 49 – Cinacalcet).

²⁰ “Besonderes Rechtsschutzbedürfnis” (specific legal interest).

²¹ Regional Court Duesseldorf GRUR 2022, 1806 para. 48 – MS Therapie III.

²² Schulte/Voß, Patentgesetz, 11th ed. 2022, Sec. 139 para. 439.

²³ Regional Court Munich I GRUR-RS 2022, 44524 para. 70 – Haarschneidegerät.

²⁴ In unfair competition and trademark matters, there is a presumption in favor of the “Verfügungsgrund”, cf. Sec. 12(3) German Act against Unfair Competition (UWG) and Sec. 140(3) German Trademark Act (MarkenG). Schacht has been arguing for a similar presumption in patent matters, see GRUR-Prax 2020, 120 f. For design matters see, e.g., the famous ex-parte injunction in the “iPad” case of Apple v. Samsung (Regional Court Duesseldorf GRUR-RR 2011, 361).

²⁵ Higher Regional Court Duesseldorf GRUR-RR 2008, 329; Schulte/Voß, Patentgesetz, Sec. 139 para. 436; Kühnen, Patentverletzung-HdB, Ch. G para. 44.

²⁶ Kühnen, Patentverletzung-HdB, Ch. G para. 45; Higher Regional Court Duesseldorf BeckRS 2011, 129629 – Haltbarkeitsdatum.

²⁷ Higher Regional Court Duesseldorf GRUR-RR 2008, 329 (331 f.).

²⁸ Cf. Kühnen, Patentverletzung-HdB, Ch. G para. 45 at the end.

²⁹ Cf. Higher Regional Court Karlsruhe GRUR 1979, 700 (701) – Knickarm-Markise; Meier-Beck GRUR 1988, 861 (861) sub III.

³⁰ This is universally recognized cf. Schulte/Voß, Patentgesetz, Sec. 139 para. 440; Benkard, PatG/Grabinski/Zülch, 11th ed. 2015, PatG Sec. 139 para. 152, 153 b.

³¹ Cf. Haedicke/Timmann, PatR-HdB/Zigann, 2nd ed. 2020, Sec. 15 para. 358.

³² Higher Regional Court Duesseldorf GRUR 1959, 619, cf. also Meier-Beck GRUR 1988, 861 (863) with further references and Meier-Beck GRUR 2023, 603 (605).

ever, and replaced by the requirement that the validity analysis (as well as on infringement) needs to point so clearly in favor of the claimant that a later correction following a subsequent proceeding for permanent relief (including validity challenges) could not be seriously expected.³³ To satisfy this standard, as a rule, validity had to be confirmed in inter-partes proceedings. In the case law of the Duesseldorf appellate court and its presiding Judge Kühnen, that principle has developed into a refined system that accounts for the necessary exceptions to the rule. The list of exceptions is not final. Amongst those exceptions are cases in which the patent has been widely licensed in the market (reflecting the recognition of its validity),³⁴ the typical generic market entry case in which market entry would cause significant irreparable damage based on a price decline,³⁵ and cases in which the validity challenge was considered on its face as without merit.³⁶ The last appellate court to adopt this line of reasoning was Munich (under former Presiding Judge Retzer),³⁷ primarily referring to the fact that the court did not find itself in the position to make a sufficiently solid prediction as to the odds of the pending validity challenges which a number of cases would have shown.³⁸ The Hamburg appellate court has not formally adopted this approach and instead requires a high degree of certainty, which has to be affirmed by detailed analysis of prior art, including the references already considered during prosecution.³⁹

c) Federal Court of Justice precedent “Kurz Nachrichten”

[7] The hesitation of infringement courts regarding provisional injunctive relief in light of validity issues was prima facie at odds with the strong tendency not to stay cases for permanent relief even with pending validity challenges. Hence, given the significantly greater speed of German infringement courts, a permanent injunction can be granted and enforced (also with a pending appeal against the infringement ruling) while the full-blown judicial review of validity is still under way for some time. The decision to stay the infringement proceedings under Sec. 148 ZPO involves an exercise of discretion which mainly depends on the infringement court’s assessment and prediction of the prospects of success for the nullity action or opposition proceeding. Thus, practically speaking, the situation does not appear to be much different from the one the court finds itself in when it comes to preliminary relief, just later in time.⁴⁰ Yet, practice has been very much the other way around. A stay is the exception. It is typically only granted if there is a new piece of prior art that comes closer to the patented subject matter than the art considered during prosecution.⁴¹ The resulting injunction gap has been subject to intense debates. In its 2014 lead decision “Kurz Nachrichten”⁴² the Federal Court of Justice put the analysis under Sec. 148 ZPO into a constitutional perspective and thereby helped transform the debate and the judicial practice. The Court held that, as a matter of constitutional law, the defendant has to be provided with effective means to attack the validity of the patent in suit in

reaction to the assertion of an infringement. The defendant’s fundamental right to adjudication (“Justizgewährungsanspruch”), which is based on the rule of law (“Rechtsstaatsprinzip”) in connection with the fundamental rights (“Grundrechte”), requires not only a judicial avenue to attack the validity of the patent in suit, but also an adequate consideration that this attack might be the only defense against the infringement claim.⁴³ Thus, a stay is generally required if there is a sufficient likelihood that the patent in suit will not withstand the judicial invalidity review in the nullity action or opposition. The other element that in practice significantly mitigated any potential structural shortcomings of the bifurcated systems has been the defendant’s option to file a motion to stay the enforcement of the injunction pending appeal, Sec. 719(1) ZPO.⁴⁴

3. ECJ Phoenix Contact Part I

a) No general requirement of “inter-partes decision”

[8] The Regional Court Munich I⁴⁵ considered the newly adopted case law of its Appellate Court⁴⁶ at

³³ Higher Regional Court Duesseldorf GRUR-RS 2010, 15862 – Harnkatherterset; Higher Regional Court Karlsruhe GRUR-RR 2009, 443 – Vorläufiger Rechtsschutz.

³⁴ Kühnen, Patentverletzung-HdB, Ch. G para. 64.

³⁵ Also, in those cases, the court needs to reach a certain level of conviction as to the merits of validity or it has to at least ascertain that no conclusion one way or the other can be made. See Kühnen, Patentverletzung-HdB, Ch. G para. 70.

³⁶ Kühnen, Patentverletzung-HdB, Ch. G para. 65.

³⁷ Higher Regional Court Munich GRUR 2020, 385 – Anschlussklemme.

³⁸ See Higher Regional Court Munich GRUR 2020, 385 para. 68, 69 – Anschlussklemme. Before that turning point, the position was that a preliminary injunction could be granted if the claimant/proprietor was able to show that an opposition or nullity action would very likely not be successful. Higher Regional Court Munich BeckRS 2012, 16104, cited by Higher Regional Court Munich GRUR 2020, 385 para. 63 – Anschlussklemme.

³⁹ Higher Regional Court Hamburg GRUR-RR 2002, 244 (245 f.) – Spannbäckchen.

⁴⁰ Based on this recognition, Deichfuß (GRUR 2022, 33 (37)) concluded that a permanent injunction under the German bifurcation system would indeed be a sort of provisional relief for the purpose of Art. 9 of the Enforcement Directive.

⁴¹ Indeed, this is a standard that the Frankfurt Appellate Court wanted to apply also for provisional injunctive relief. See Higher Regional Court Frankfurt a. M. GRUR-RR 2003, 263 (274) – mini flexiprobe; Haedicke/Timmann, PatR-HdB/Zigann, Sec. 15 para. 359 argued for the same standard of review as long as the interim proceedings are conducted like a main proceeding and there would be no additional burden for the defendant due to short terms. See also Musmann GRUR 2023 152 (156) discussions of Regional Court Munich GRUR 2023, 152 – Bortezomib; Musmann rejects the notion of applying the Sec. 148 ZPO standards for the stay of the main proceedings to the analysis in cases for interim relief even if based on an amended more generous schedule to the benefit of the defendant (as suggested by Heinze GRUR 2022 1796 (1798 f.)) as this would be at odds with the accelerated nature of the proceedings for interim relief.

⁴² Federal Court of Justice GRUR 2014, 1237 – Kurz Nachrichten.

⁴³ Federal Court of Justice GRUR 2014, 1237 para. 4 – Kurz Nachrichten.

⁴⁴ Under Sec. 719(1) ZPO, the appellate court can stay the injunction – based on review in written proceedings – if there is a sufficient likelihood of success on the merits for the appeal and the weighing of the parties’ interests tips in the defendant’s favor. The typical adverse injunction effects on the defendant’s interests are not sufficient, but the system is flexible: The greater the likelihood of success for the appeal, the lower the required threshold for the affected interests. This has been a practically highly effective instrument as the appellate courts typically expect the claimant to abstain from enforcing the judgment pending their review of the stay motion. The motion has been used in many of the big patent litigation cases in Germany, cf. inter alia, Higher Regional Court Karlsruhe GRUR-RS 2021, 9325 – Wurzelsequenzordnung.

⁴⁵ Regional Court Munich I GRUR 2021, 466 – Rechtsbestand im Verfügungsverfahren.

⁴⁶ Higher Regional Court Munich GRUR 2020, 385 para. 69 – Anschlussklemme.

odds with Art. 9(1) of the Enforcement Directive (2004/48/EC)⁴⁷, because in the absence of an inter-partes decision on validity, the Appellate Court's approach would prevent the district court from granting injunctive relief even in cases where it has found the patent valid or does not see the validity "at threat". In response to the referral, the ECJ held that Art. 9(1) of the Directive precludes national case law under which applications for interim relief for patent infringement must "in principle" be dismissed where the validity of the patent in question has not been confirmed by an inter-partes decision.⁴⁸ The key point is, of course, what "in principle" means. The opinion is clear on that because it goes directly back to the referring court's own premises: "*In the present case, the referring court states that the patent at issue is valid and that it is the subject of an infringement, such that the application for interim relief brought by Phoenix Contact should be granted.*"⁴⁹ Such a system would be indeed overly rigid in its application of the inter-partes review requirement. The ECJ expressly held in paragraph 33 of the judgment that such a requirement deprives Art. 9(1)(a) of any practical effect "*in so far as it does not allow the national court to adopt [...] an interlocutory injunction [...] even though that patent, according to the national court, is valid and is being infringed.*"⁵⁰ Having further addressed the underlying rationale of the Directive, the opinion then turns again to this paragraph and states "*if the application of that procedure were subject to a requirement such as that laid down by the national case-law referred to in paragraph 33 of the present judgment*" it would disregard the objective of providing a high level of protection.⁵¹ Thus, the decision inherently confirms that the court, confronted with a request for interim relief, also seriously examines the issue of validity because the referring court's own conviction on this point – not anything derived from a presumption in favor of validity – was at the core of the Court's opinion. "In principle" therefore means "even if the court is convinced of the validity".⁵² That rationale delimits the bearing of the decision.

b) Presumption in favor of validity

[9] The ECJ in its opinion also mentions, more as an obiter dictum ("in that context"), that European patents enjoy a "*presumption of validity from the date of publication of their grant. Thus, as from that date, those patents enjoy the full scope of the protection guaranteed, inter alia, by Directive 2004/48*"⁵³ In recent case law of the Regional Court Munich I, it has been argued that this requires a structural change in the analysis, so even for newly issued patents, the validity would have to be presumed and the defendant would have to refute this presumption.⁵⁴ Notwithstanding that position, the Munich court carries out a detailed inventive step analysis considering intensive briefing of both sides⁵⁵ to support the conclusion that the bench is convinced of the patent's validity.⁵⁶ Indeed, if infringement courts are willing to

thoroughly analyze the issue of validity based on the parties' arguments rather than to cut short any discussion on validity, the structural change might prima facie not be outcome-determinative. The real issue is the necessary recognition of the factor of time. Patent cases allowing a quasi ad hoc validity assessment are rare. The perspective on the merits can change as the discussion evolves, so predictions as to the final holding on validity are more susceptible to error the earlier they are made in the process.⁵⁷ Initial assessments made early on can therefore typically only solidify into a higher degree of certainty over time. Accordingly, some leeway is required to factor this potential for a shifting perspective into the overall weighing analysis under the topic "Verfügungsgrund". Thus, in the early stages, particularly prior to the expiration of the opposition period,⁵⁸ any decisionmaker should maintain a healthy distance from its own ad hoc assessment of the merits of validity.⁵⁹ Reaching a sufficient degree of certainty regarding the patent's validity with regard to a complex technical teaching prior to the completion of the term for filing an opposition should therefore be the exception. Furthermore, the absence of a judgment confirming the patent's validity in inter partes proceedings can and should still be a strong factor in the analysis,⁶⁰ as long as it does not preclude the court from rendering preliminary injunctive relief if there is a solid degree of certainty regarding the patent's validity after a careful review.

⁴⁷ In the following "Directive".

⁴⁸ ECJ GRUR-RS 2022, 8632 – Phoenix Contact v Harting.

⁴⁹ ECJ GRUR-RS 2022, 8632 para. 33 – Phoenix Contact v Harting.

⁵⁰ ECJ GRUR-RS 2022, 8632 para. 34 – Phoenix Contact v Harting.

⁵¹ ECJ GRUR-RS 2022, 8632 para. 40 – Phoenix Contact v Harting.

⁵² There has been a debate on whether the Regional Court Munich I presented an accurate account of the German case law with regard to the exceptions to the rule (see Kühnen, Patentverletzung-HdB, Ch. G para. 81 seq., Meier-Beck GRUR 2023, 603; Deichfuß GRUR 2022, 800; Pichlmaier GRUR 2021, 557).

⁵³ ECJ GRUR-RS 2022, 8632 para. 41 – Phoenix Contact v Harting referring, by analogy, to the ECJ judgment of 30 January 2020, Generics (UK) and Others, C-307/18, paragraph 48.

⁵⁴ Regional Court Munich I GRUR 2022, 1808 at para. 68 – Fingolimid; Regional Court Munich I GRUR 2023, 152 para. 60 f. – Bortezomib; Regional Court Munich I GRUR-RS 2022, 44524 – Haarschneidegerät. Against such a presumption: Regional Court Duesseldorf GRUR 2022, 1806 – MS-Therapie III.

⁵⁵ Regional Court Munich I GRUR-RS 2022, 44524 para. 92-121.

⁵⁶ Cf. Regional Court Munich I GRUR-RS 2022, 44524 para. 91: "Taking into account the arguments of both parties, the chamber is convinced of the validity of the patent." See also para. 121. "Moreover, the chamber is also convinced of the existence of an inventive step with regard to the subject-matter of claim 1."

⁵⁷ Along those lines: Meier-Beck GRUR 2023, 603 (605); Deichfuß GRUR 2022, 800 (801).

⁵⁸ See also Regional Court Mannheim BeckRS 2009, 87748 sub 2. b) assuming that the substantive examination of the patent is not complete prior to the expiration of the term for filing of the opposition as a significant part of the prior art (including public prior use) would be hard to identify for the EPO during the pre-grant examination. In this direction also Deichfuß GRUR 2022, 33 (34).

⁵⁹ This also affects the process. In its decision, adopting the case law of the Duesseldorf and Karlsruhe circuits, the Munich appellate court had in an obiter dictum held that in a case of a patent in suit hot off the press, summoning a defendant to a hearing scheduled for a time 10 days after the filing of the motion for interim relief presents a violation of the constitutional right to be heard; see Higher Regional Court Munich GRUR 2020, 385 para. 65 – Anschlussklemme.

⁶⁰ See also Heinze GRUR 2022, 1796 (1799).

II. Provisional relief in the UPC

1. Provisional and permanent injunctions

a) Terminology

[10] The title of Art. 63 UPCA, “permanent injunction”, uses the typical language in the Anglo-American legal tradition. “Permanent” reflects the distinction to “provisional”⁶¹ which is used in Art. 62 UPCA. By contrast, the German translation “endgültige Verfügung” (Art. 63 UPCA) is not established in German legal practice under the ZPO in which the category of a “permanent injunction” is referred to by way of denoting the proceedings in which the relief is rendered (“Hauptsacheverfahren”). The term “Verfügung” is reserved for the “provisional injunction” only while the judgment ordering the permanent relief of an injunction is referred to as “Unterlassungsurteil”.⁶² The “provisional injunction” (Art. 62 UPCA) is typically referred to as “einstweilige Verfügung” (Sec. 935 ZPO).⁶³ The interim proceedings are referred to as “einstweiliger” or “vorläufiger Rechtsschutz” which is considered required as a matter of constitutional law and characterized as “summary proceedings”⁶⁴, a term which also the Rules use to refer to proceedings for provisional relief (UPC Rule of Procedure 205).

b) “May” and discretionary elements in the grant of permanent injunctions

[11] Similar to Art. 63 UPCA, Art. 62 UPCA provides that the court “may grant injunctions” and thereby refers to the language of the Directive in Art. 9(1) which is the same as Art. 11 of the Directive concerning permanent injunctions.⁶⁵ Under German law, permanent injunctive relief followed automatically based on the finding of an infringement with no discretion for the bench. Since judicial practice would not have developed beyond a very limited number of exceptions to this rule,⁶⁶ the legislature amended the German Patent Code (PatG) by adopting the language of the Federal Court of Justice’s holding in the “Wärmetauscher” decision.⁶⁷ Both English and German law can, therefore, involve a weighing of the parties’ interests in the grant of injunctive relief, yet with a rather different emphasis.⁶⁸ As the UK is not a member of the UPCA, the future focus with regard to rendering concrete the standards for “may” will certainly be less on the English common-law aspects of the historical roots of the Agreement and the Rules so the UPC practice can be expected to be closer to the German practice with regard to permanent injunctive relief. Furthermore, under the UPCA, different from German law, it is assumed that, as a rule, both the infringement action and the counterclaim for revocation will be tried and decided together (Art. 33(3)(a)).⁶⁹ Thus, the biggest concern in the debate on mandatory injunctions in Germany, namely the “injunction gap”, does not exist. The UPCA also provides for the functional equivalent to a stay motion under Sec 719(1) ZPO, namely an application for suspensive effect, un-

der Art. 74 UPCA and Rule of Procedure 223. If a flexible standard is used for these decisions ordering suspensive effect pending appeal, also considering a prima facie analysis of the merits, another significant concern against permanent injunctive relief, stemming from low quality or overly claimant-friendly practices, could be effectively addressed.

2. Requirements for provisional relief at the UPC

a) Art. 62(2) UPCA

[12] According to Art. 62(2) UPCA, the Court shall have the discretion to weigh up the interests of the parties and, in particular, the discretion to take into account the potential harm for either of the parties resulting from the granting or the refusal of an injunction. Art. 62(2) UPCA does not take up any express language from the Directive. Yet, this does not unduly limit any minimum standard that the Directive would request as the weighing of the parties’ interests renders concrete the discretion that forms the basis of Art. 9 (“may”). Furthermore, as discussed above, any relief under the Directive can (some would say must) in any event be limited by the proportionality analysis under Art. 3(2). The UPC Rules of Procedure take up this language in Rule 211(3), which puts it slightly differently by stating that “*in taking its decision the Court shall in the exercise of its discretion weigh up the interests of the parties*”. The latter language already reflects that the discretion to weigh up the interests is not just an “option” which a literal reading of the

⁶¹ Oftentimes also referred to as “preliminary”.

⁶² “Unterlassungsurteil im Hauptsacheverfahren” in the ZPO would be the technical equivalent to a “permanent injunction”.

⁶³ The proceedings for such a provisional injunction are referred to as “einstweiliger Rechtsschutz” while the UPC refers to it as “summary proceedings”. Despite the different meaning of the termini technici in their different legal frameworks, I have tried to stick to the terminology of the UPC and Directive as much as possible.

⁶⁴ “Summarisches Erkenntnisverfahren” see Zöller/Vollkommer, ZPO, 34th ed. 2022, before Sec. 916 para. 3.

⁶⁵ The term “may” (rather than “shall”) generally connotes the distinction between the continental European and the English practice. Any equitable relief in the English tradition necessarily involves – also for permanent relief – a certain degree of discretion (“Ermessen”). See Roughton, Johnson and Cook on Patents, 5th ed. 2022, Pt. 1 Ch. 8.4 p. 471.

⁶⁶ Those exceptions were set forth in the leading precedent case “Wärmetauscher” of the Federal Court of Justice (GRUR 2016, 1031). The Court held that such very limited “proportionality” exceptions to the rule of effective unconditional relief are possible under Art. 3(2) of the Directive. Contrary views in legal literature consider those exceptions required by the Directive cf. Ohly GRUR 2021, 304 f. (also “Festschrift” for Peter Meier-Beck); but cf. also Leistner GRUR 2022 1633 (1637).

⁶⁷ While weighing up the affected interests is at the core of the analysis, there is no disagreement that the defense and analysis under Sec. 139(1) s. 3 PatG is the exception rather than the rule in any determination of injunctive relief.

⁶⁸ While current English case law still requires a “prima facie position” to grant an injunction and the legal burden is on the defendant to show why it should not (cf. Supreme Court *Lawrence v Fen Tigers Ltd* [2014] UKSC 13, [2014] AC 822 at 120-121), according to the High Court in *Edward Life Science v Boston Scientific* [2018] EWHC 1256 (Pat) at 12-13, it appears to require more flexibility for exercising the discretion than the previous English case law which the German Federal Court of Justice quoted as roughly similar in terms of exceptions to the rule of effective unconditional relief under Art. 3(2) of the Directive (Federal Court of Justice GRUR 2016, 1031 para. 50 – Wärmetauscher). Leistner’s assumption of a required “gross disproportionality” as the requirement for damages in lieu of an injunction (GRUR 2022, 1633 (1634)) might not be consistent with these holdings.

⁶⁹ Bopp/Kircher/Bopp, *Handbuch Europäischer Patentprozess*, 2019, Sec. 13 para. 374; Meier-Beck GRUR 2023, 603 (607) sub V.

Art. 62(2) UPCA could suggest.⁷⁰ Rather, the mandatory weighing exercise is discretionary in nature, meaning that the discretion must always be exercised, but that the standards are flexible and depend on the circumstances of the case at bar. It is not just a backstop to avoid “unjust” results, but it is a requirement whose satisfaction needs an affirmative reasoning showing that, taking into account the defendant’s interests at issue, provisional relief is necessary to protect the claimant’s interests.⁷¹ Yet, while the exercise of the discretion implies that the entirety of the circumstances of the case at bar are taken into account, the decisive characteristics of the set of facts before the Court must be identified so that in any other case before any other Division of the Court, the discretionary decision would yield the same result.⁷² This ensures adjudication under the rule of law for which the equal administration of the laws (i.e., treating like cases alike) is of utmost importance. It is a conceptually distinct point if the UPC Court of Appeal is going to apply a limited scope of appellate review with regard to these discretionary decisions. Since the UPC is the first court of its kind, entertaining civil litigation at a supranational, European level involving local divisions with different traditions, it appears to be preferable to foster predictability and equality by emphasizing uniform standards for the UPC. Hence, the Court of Appeal should generally not limit its scope of appellate review regarding discretionary elements.

[13] Another part of this weighing exercise is urgency. In scope, provisional relief can only be reasonably distinguished from permanent relief if an element of time is required. If the applicant waits too long with asserting his or her claim, it cannot be maintained that immediate protection prior to permanent relief is required. The UPC Rules of Procedure mention urgency expressly, even though only in Rule 209(2)(b) as a factor in exercising the discretion to inform the defendant about the application and summon the defendant to a hearing.

b) Art. 62(4) UPCA

[14] Pursuant to Art. 62(4) UPCA, the Court may require the applicant to provide any reasonable evidence in order to satisfy itself with a sufficient degree of certainty that the applicant is the right-holder and that the applicant's right is being infringed, or that such infringement is imminent. This language is directly taken from Art. 9(3) of the Directive. The language of UPC Rule of Procedure 211(2) implementing Art. 62(2) UPCA is slightly different, because it also refers to the “validity of the patent”. Regarding validity, one could ask if there is really any genuine “evidence” that could prove the underlying factual assumptions upon which this legal conclusion is based. Limiting the language in Art. 9(3) of the Directive to “infringement” could have been based on the assumption that aspects of infringement like the configuration of the accused device typically involve contested issues

of fact and therefore require the taking of evidence. With regard to validity, for the German practice, it is generally not about evidence, at least not about evidence that the applicant could be expected to provide.⁷³ Determining the disclosure content of prior art references (for the purpose of novelty and inventive step)⁷⁴ as well as of the original application as filed (for purpose of added subject matter, Art. 123(2), 76(1), 100c EPC) and the determination of non-obviousness for inventive step are genuine issues of law. There might be factual elements to it pertaining to the common general knowledge as of the priority date, which is relevant for the skilled readers perspective,⁷⁵ but it is rare that specific factual aspects are in dispute between the parties such that the taking of evidence might be required.⁷⁶ When the UPC Rules of Procedure include validity in the language stemming from Art. 62(4) UPCA, this rather shows that there is a broader understanding not limited to genuine means of “evidence” within the meaning of Art. 53 UPCA. It just expresses the self-evident aspect that, in order to grant provisional relief, the court also must have a sufficient degree of certainty regarding the patent’s validity and that the burden to substantiate aspects pertaining to the validity can, depending on the circumstances, also be on the applicant.

c) Correlating the analysis under Art. 62(2) and Art. 62(4) UPCA

[15] This degree of certainty must be correlated with the weighing of interest prong under Art. 62(2) UPCA. The more significant the applicant’s interests at stake, the more the possible impact comes closer to irreparable harm, the lower the threshold for certainty regarding validity can be. Conversely, the higher the potential impact on the defendant, the closer it comes to irreparable harm, the higher the sufficient-certainty-threshold. The lesser time the defendant had to search for and analyze prior art, the more the court must consider that it makes a decision on an incomplete basis which needs further justification in the applicant’s interests. In any event, even in cases of

⁷⁰ The language of Art. 62(2) UPCA “shall have the discretion” could literally also be read this way. The German version “Das Gericht wägt nach Ermessen die Interessen der Parteien gegeneinander ab [...]” for a German reader suggests more clearly that the Court has to balance the parties’ interests.

⁷¹ Different Bopp/Kircher/Bopp, *Handbuch Europäischer Patentprozess*, Sec. 20 para. 93.

⁷² This is also not the making of law, but just articulating specific rules that could have been spelled out by other divisions confronted with the same facts.

⁷³ Evidence is typically only an issue for public prior use for which the defendant challenging the validity bears the burden of proof. Regarding “secondary indicators”, which require evidence of immediate commercial success (when coupled with evidence of a long-felt need if the success derives from the technical features of the invention and not from other aspects like advertising), see EPO-Guidelines for examination Part G Chapter VII, 10.3.), the patentee/claimant would have to provide the evidence.

⁷⁴ Benkard, *PatG/Schäfers*, PatG Sec. 87 para. 12 c.

⁷⁵ See Benkard, *PatG/Asendorf/Schmidt* § 4 para. 17, 18. Also, for issues of implicit disclosure (“Mitlesen”) as a form of “direct and unambiguous disclosure”, cf. Federal Court of Justice GRUR 2009, 382 para.26 – Olanzapin.

⁷⁶ That is why, e.g., the German Federal Court of Justice which is a court of record (“Tatsacheninstanz”) in nullity actions, almost never takes evidence, also not by way of seeking independent expert opinions.

clear merits, there must be aspects related to the parties' interest that set the case apart from a typical matter that has to wait for permanent relief. Conversely, even in cases where the applicant's interests significantly outweigh the defendant's interests, the degree of certainty regarding the merits might be lower, but cannot be entirely dispensed of.

3. Provisional Relief and Validity at the UPC – ECJ Phoenix Contact II

a) Presumption in favor of validity

[16] While Art. 33 (3)(b) UPCA regarding the main proceedings for permanent relief, enables a bifurcated process by giving the local division discretion to refer only the counterclaim for revocation to the central division while suspending or proceeding with the infringement action, it is assumed that proceeding with both the infringement action and the counterclaim for revocation under Art. 33(3)(a) UPCA will be the rule because the latter option comes with the allocation of a technically qualified judge so the local division would dispose over the same technical expertise as the central division.⁷⁷ Hence, different from the German system, the UPC, in the main proceedings, has to determine the merits independently rather than engaging in a prediction of the outcome of a nullity action pending before a different court. It would be at odds with the UPC's function of judicial review of the validity in the main proceedings to primarily refer to the EPO's decision to grant the patent in suit when it comes to the summary proceedings for provisional relief.⁷⁸ This is also consistent with the ECJ's obiter dictum concerning a "presumption in favor of validity" in Phoenix Contact. The "presumption" only relates to the self-evident principle that the patent's invalidity can only be confirmed (i. e., the patent revoked) if grounds for invalidation are established and confirmed.⁷⁹ The ECJ has not linked that statement with any substantive examination of the validity in the proceedings to grant the patent in suit. The Directive indeed does not only apply to patents that go through substantive examination, but also, e. g., to Community designs for which Art. 85(1) Community Design Regulation⁸⁰ even expressly stipulates a presumption in favor of validity or for utility models ("Gebrauchsmuster"). The latter are registered without examination as to validity and inventive step but they also enjoy a presumption in favor of validity meaning that the grounds for cancellation have to be positively established based on prior art to be presented by the applicant or the office. That also means that, in the rare cases of an actual non liquet regarding specific facts, the burden of proof is on the party invoking validity.⁸¹ The latter, however, can only pertain to specific factual aspects (like pre-publication) and it presupposes that the means for evidence have been exhausted. If that is not possible in a proceeding for provisional relief, the Court will have to take into account the likelihood of possible further evidence introduced in the main proceeding.

b) ECJ Generics C-307-18

[17] This is further supported by the only decision that the Court cites to support its obiter holding, i. e., the Generics judgment C-307/18⁸², where the Court stated that the presumption in favor of validity would not help in the instant matter as it was just the "automatic consequence of the registration of a patent and its subsequent issue to its holder."⁸³ The ECJ held that this factor did not help as the "outcome of any dispute in relation to the validity" is open and uncertain.⁸⁴ More specifically, the ECJ held: "the uncertainty as to the validity of patents covering medicines is a fundamental characteristic of the pharmaceutical sector; that the presumption of validity of a patent for an originator medicine does not amount to a presumption that a generic version of that medicine properly placed on the market is illegal; that a patent does not guarantee protection against actions seeking to contest its validity".⁸⁵ Indeed, all those statements are true not only for the pharmaceutical sector but for any patent and corresponding validity actions. No patent grants a protection against challenging its validity. That is why in any action pertaining to the assertion of infringement claims, the defendant must be enabled to effectively defend itself by contesting the validity. That is the constitutional principle that the Federal Court of Justice invoked in "Kurznachrichten".⁸⁶ This should even more directly apply to a non-bifurcated system, supported by Art. 47(1) Charter of Fundamental Rights of the EU.

c) Inter-partes validity decisions

[18] In part, the reasoning for the inter-partes requirement in the German practice has been based on the lack of technical expertise on the bench which makes it all the more difficult to assess the increasingly technically difficult cases on short notice.⁸⁷ This

⁷⁷ Bopp/Kircher/Bopp, Handbuch Europäischer Patentprozess, Sec. 13 para. 374; Meier-Beck GRUR 2023, 603 (607) sub V.

⁷⁸ Cf. Meier-Beck GRUR 2023, 603 (607) sub V. The UPCA does not provide for provisional relief when it comes to the revocation action. Hence, the necessary summary review regarding validity must be conducted in the proceedings for provisional injunctive relief.

⁷⁹ Cf. Meier-Beck GRUR 2023, 603 (606 f.).

⁸⁰ Council Regulation No 6/2002 on Community Designs.

⁸¹ Cf. Benkard, PatG/Goebel/Engel, GebrMG Sec. 15 para.25; cf. also Federal Court of Justice GRUR 1984, 339 (340) – Überlappungsnaht.

⁸² ECJ GRUR Int. 2020, 1071 – Generics (UK) Ltd. v Commission and Markets Authority. This competition case concerned with the settlement agreements between an originator and a generic pertaining to court disputes regarding the validity of the originator's patent.

⁸³ ECJ GRUR Int. 2020, 1071 para. 48 – Generics (UK) Ltd. v Commission and Markets Authority.

⁸⁴ ECJ GRUR Int. 2020, 1071 para. 48 – Generics (UK) Ltd. v Commission and Markets Authority.

⁸⁵ ECJ GRUR Int. 2020, 1071 para. 51 – Generics (UK) Ltd. v Commission and Markets Authority.

⁸⁶ Federal Court of Justice GRUR 2014, 1237 – Kurznachrichten.

⁸⁷ Cf. Kühnen GRUR 2021, 468 (469); against this position Pichlmaier GRUR 2021, 557 (559). Pichlmaier argues that in the summary proceedings under German law, the infringement court can only determine if the decision to grant involves evident and severe errors. In the absence of such errors, validity has to be accepted. Such a standard of review, according to Pichlmaier, would also be manageable for a bench without any technical members. It is doubtful, however, if that approach is consistent with the constitutional principles set out in "Kurznachrichten" (Federal Court of Justice GRUR 2014, 1237). Against this position also Deichfuß GRUR 2022, 33 (39) who requires a thorough examination of the defendant's objections against validity.

is different in the UPC as either of the parties and the panel on its own initiative could ask for a technical member (Art. 8(5) UPCA also applies in proceedings for interim relief⁸⁸). It heavily depends on how quickly that process works⁸⁹ and how the specific technical expertise of the technical member would fit for the case at issue. For many of the highly complex cases, a very specific technical expertise in the field at hand would be required to enable a sufficiently solid analysis of the merits in a short period of time. Also, the UPC could be more flexible than the German courts regarding evidence. Under UPC Rule of Procedure 210(3) the Court may order the parties to provide further information, documents or evidence to enable its decision and the Rules on Evidence of Part 2 only apply to the extent determined by the Court. While in most cases it would not be realistic to get an independent expert opinion in time, the court could instead ask for further corroboration in terms of party appointed experts – also in the form of affidavits – and request that such experts should be present during the oral hearing. Such a merit-oriented process, however, takes time and effort which can be at odds with the accelerated nature of the summary proceedings. Furthermore, the Court has to consider the basic rule of a fair process (cf. Art. 6(1) European Convention on Human Rights⁹⁰). Thus, if the claimant’s application has been thoroughly prepared and supported with detailed technical analysis by highly regarded experts, it ought to be considered that the defendant needs time to gather information and evidence at this level. Ultimately, fully exhausting the possible means for an in-depth analysis of the technical merits in highly complex matters still remains a function of time. In many cases a sufficient degree of certainty is difficult to secure on short notice so the cases should be limited to those that indeed urgently require provisional relief based on an expedited process. In the framework of this comprehensive merit and interest weighing analysis, inter-partes validity decisions play a significant role. This is supported by UPC Rule of Procedure 209(2)(a) which sets forth that it is a factor in exercising the discretion on the process, including ex-parte hearings, whether the patent has been upheld by the EPO or has been subject of other court proceedings.⁹¹ Due to the UPC’s competence to rule on validity, those decisions, however, cannot be dispositive of the validity issue in front of the Court. Pre-existing decisions on validity are not binding for the UPC, they can and will have to be considered but they may not necessarily persuade the panel, which has to carry out and substantiate its own analysis.

III. Summary

[19] In sum, it can be concluded:

1. The grant of a provisional injunction in the UPC requires a sufficient degree of certainty not only for infringement but also for validity of the patent in suit.

2. The sufficient degree of certainty regarding validity typically requires a thorough analysis of the defendant’s contentions against the validity. This cannot be disposed of by referring to a presumption in favor of validity. Even for prior art considered during examination of the patent in suit, the panel cannot limit itself to only determining evident or gross errors. As the UPC, by way of a judgment in the main proceedings on a counterclaim for revocation (or a revocation action), has jurisdiction to decide on validity, it is the very judicial instance that provides control of the EPO’s decision to grant the patent in suit. Both the claimant’s and the defendant’s rights to an effective legal remedy (Art. 47(1) Charter of Fundamental Rights of the EU) therefore ought to be considered in the summary proceedings for provisional relief.

3. This is consistent with the Directive and the ECJ’s decision in Phoenix Contact. The ECJ in Phoenix Contact only ruled out national case law under which the infringement court, while being convinced of the validity following its own analysis of the parties’ contentions, would still have to wait for an inter-partes decision in main proceedings confirming validity. The ECJ has not addressed which standard of review in summary proceedings the Directive might require. The “presumption in favor of validity” is just the “*automatic consequence of the registration of a patent and its subsequent issue to its holder*”⁹², which would be the same even for IP rights without prior examination (like utility models), but the “*outcome of any dispute in relation to the validity*” is still open and uncertain.⁹³

4. The required degree of certainty on the merits (of both infringement and validity) can only be determined in connection with the weighing of the parties’ interests. Hence, the acceptable remaining degree of “doubt” regarding validity can only be determined in the light of how the grant or refusal of the provisional injunction would affect the parties’ interests.

5. The more complex the technology at hand is and the earlier in the process the judicial review occurs (i.e., closer to the grant of the patent and before expiration of the opposition period), the more does the court have to consider that its assessment might change based on further input factors or analysis evolving as the case progresses. Thus, factors other than the merits, particularly the weighing of the parties’ interests, gain more importance in the overall assessment of the specific need for provisional relief.

⁸⁸ Bopp/Kircher/Bopp, *Europäischer Patentprozess*, Sec. 20 para. 61.

⁸⁹ The longer it takes, the more could it be at odds with the accelerated nature of proceedings for provisional relief, cf. Bopp/Kircher/Bopp, *Europäischer Patentprozess*, Sec. 20 para. 61.

⁹⁰ Art. 47(2) Charter of Fundamental Rights of the EU.

⁹¹ Same as for “urgency”, Rule 209(2)(b).

⁹² ECJ GRUR Int. 2020, 1071 para. 48 – Generics (UK) Ltd. v Commission and Markets Authority, referred to by ECJ GRUR-RS 2022, 8632 para. 41 – Phoenix Contact v Harting.

⁹³ ECJ GRUR Int. 2020, 1071 para. 48 – Generics (UK) Ltd. v Commission and Markets Authority.