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Preliminary Injunctions in German Pharmaceutical Patent Litigation

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Introduction

In German pharmaceutical patent litigation, preliminary injunction proceedings are no longer a peripheral or merely defensive procedural device. They have instead become one of the most effective instruments available to originators seeking to prevent generic or biosimilar entry. This is not because German law formally abandons the traditional caution associated with interim relief. Rather it reflects the reality that, in the pharmaceutical sector, delayed relief is often commercially worthless. Once a generic or biosimilar enters the market, the originator may face immediate price erosion, loss of market share, and longer-term distortive effects that are difficult, and sometimes impossible, to reverse later by damages alone. For that reason, preliminary injunction proceedings have become one of the decisive battlegrounds of German pharmaceutical patent enforcement.

This point warrants explicit emphasis. Germany remains, in practical terms, an injunction jurisdiction. The statutory proportionality language introduced into the Patent Act has not altered the basic position that injunctive relief remains the standard remedy once infringement is established, and commentary continues to describe the German system as an "automatic injunction" jurisdiction in substance, even if that label is, strictly speaking, polemical.[32] In pharmaceutical disputes this matters acutely because patentees do not merely seek eventual success on the merits. They seek to stop launch. German practice provides them with a genuine opportunity to achieve this, and to do so within a very short timeframe.
The attraction of Germany as a forum for pharmaceutical disputes is not merely doctrinal. It is procedural. Current practitioner guidance confirms that preliminary injunctions may, in appropriate cases, be obtained within a very short period, either *ex parte* or following a brief inter partes hearing. Once issued and served, the order is directly enforceable, even if the defendant later challenges it by objection or appeal.[33] In launch-sensitive pharmaceutical cases, that combination of speed and enforceability gives preliminary relief a significance that goes well beyond its formally provisional character.

Scope and Speed of Relief

The practical leverage generated by German preliminary injunction practice can be highly significant in pharmaceutical cases. A German preliminary injunction is not merely an abstract judicial warning; it constitutes a coercive order backed by immediate enforceability. In the usual originator-versus-generic scenario, this may mean a market stop at the most commercially sensitive moment, often shortly before or immediately after launch. In appropriate cases, the relief may go beyond a simple cease-and-desist command and include obligations aimed at unwinding the market effects of entry, in particular recall obligations. That makes interim relief in Germany materially different from systems in which provisional measures are slow, hard to obtain, or narrow in scope.

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[32] On Germany's continuing reputation as an injunction jurisdiction and the narrow practical reach of the proportionality defense, see Stief, PharmR 2/2023, 61 (61f.); Stief, PharmR, 3/2023, 152 (158); see also Müller, ZdiW 2021, 407 (407ff.).
[33] Benkard PatG/Grabinski/Zülch/Tochtermann, 12. Aufl. 2023, § 139, Rn. 153.

The recent aflibercept litigation in Munich provides a particularly striking example of how German preliminary injunction practice may be used as a powerful enforcement tool for originators. In January 2026, the Munich Regional Court granted preliminary injunctions in favor of Regeneron and Bayer against several biosimilar entrants. Reporting on the case indicates that the injunctions not only blocked marketing activities but also included recall obligations. One order was even reported as extending beyond Germany.[34] Whatever the precise territorial reach of individual orders, the broader point is unmistakable: in present-day pharmaceutical litigation, German courts are capable of granting interim relief with immediate and serious market consequences.

The Munich courts, in particular, warrant separate consideration. Current commentary frequently characterizes Munich as a patentee-friendly venue that is prepared to proceed expeditiously, to adopt a comparatively assertive approach to interim protection, and to accord considerable weight to existing validity decisions when assessing the availability of broader relief.[35] From the perspective of an originator confronted with an imminent generic or biosimilar launch, that combination is highly attractive. Without resorting to rhetorical exaggeration, it can be stated that Munich is a forum in which patentees may reasonably expect rapid handling of cases and, in suitable constellations, interim measures of considerable remedial force.

This is one reason why Germany has retained, and in some respects strengthened, its strategic importance for pharmaceutical patentees after the advent of the UPC. Even where wider European litigation is conceivable, the prospect of obtaining a rapid German injunction remains an important source of leverage. That is especially true where the threat concerns the German market itself, where pricing and reimbursement dynamics create acute launch pressure, or where a German order can be used to influence settlement dynamics on a broader front.

Urgency and the Threat of First Infringement

A particular feature of pharmaceutical disputes is that the patentee often begins from an unusually advantageous informational position. The pharmaceutical regulatory setting allows the originator to assess the threatened launch comparatively early through product information, SmPCs, listing data, pricing activity, and other market signals. That transparency facilitates rapid enforcement. At the same time, it also supports the courts' expectation that the patentee will proceed quickly and in a focused manner. Therefore, German case law on urgency, though not lax, is commercially realistic. The question is not whether the patentee moved with theoretical maximum speed. The question is whether a patentee acted with sufficient determination to show that it genuinely wanted immediate enforcement and did not delay unnecessarily.

The Duesseldorf Cinacalcet decisions remain especially important here, but they should not be read as signs of special restraint. Their real message is practical: a patentee does not lose urgency merely because it waits for reliable evidence, commissions laboratory work,

[34] *See also* JUVE Patent, Regional Court Munich grants PI to Regeneron against generics in Eylea case (2026)< https://www.juve-patent.com/cases/regional-court-munich-grants-pi-to-regeneron-against-generics-in-eylea-case/> accessed 12 March 2026.

[35] *See* Chambers and Partners, Life Sciences & Pharma IP Litigation 2026 - Germany, Trends and Developments, describing Munich's role in life sciences patent litigation and the current forum landscape.

coordinates across several jurisdictions, or investigates several threatened infringements in parallel.[36] That line of authority benefits serious claimants. It means that a well-organized originator can build a robust evidentiary record without being told later that it waited too long. In pharma launch disputes, that is a major advantage. The system rewards thorough preparation while at the same time enabling rapid enforcement.

At the same time, German courts insist that urgency does not arise in a vacuum. The applicant must still establish a sufficiently concrete threat of infringement. In pharmaceutical cases, that often raises the question whether a marketing authorization, a listing, a price notification, or other preparatory act already makes launch sufficiently imminent. The courts have traditionally resisted the idea that mere market anxiety is enough. The fact that the pharmaceutical market is comparatively transparent cuts both ways: it enables early enforcement, but it also underpins the expectation that the claimant will identify and articulate concrete launch facts rather than rely on broad assumptions.[37]

The possibility of *ex parte* relief further intensifies the analysis of urgency. German practice recognizes protective briefs precisely because defendants know that, in truly urgent matters, courts may still proceed without first hearing them. Current German practice materials confirm that protective briefs remain a central defensive instrument in industries, such as pharma, where the claimant may attempt to block a launch at very short notice. The existence of that mechanism itself is telling: *ex parte* injunctions are not a historical curiosity, but continue to form a significant element of strategic planning.

Secured Validity and the Generics/Biosimilars Problem

If urgency is one foundation of interim relief, secured validity is the other. Traditionally, German patent injunction case law, especially in Duesseldorf, insisted that a patent should normally have survived first-instance adversarial validity proceedings before interim relief would issue. That basic position was rooted in a structural concern rather than in doctrinal formalism. Summary proceedings are ill-suited to resolve technically difficult validity disputes with the degree of certainty that a market-excluding order may require. The classic authorities therefore demanded a legal situation to be clear enough that a materially erroneous decision was not seriously to be expected.[38]

In pharmaceutical disputes, however, the secured validity requirement has long been softened where imminent generic entry threatens to destroy the remaining practical value of the right. The *Flupirtine*, *Maleate*, and *Desogestre*l litigations are the classic examples of this.[39] Their central insight was straightforward: where generic entry is imminent and the likely harm to the originator is severe, insisting on the ordinary validity timetable may deprive the patent of any meaningful commercial residue. In those circumstances, the balance may justify interim enforcement even before validity has been secured in the usual sequence.

[36] OLG Duesseldorf, judgment of 15 Feb. 2021, 2 W 3/21 - Cinacalcet I; OLG Duesseldorf, judgment of 9 July 2021, 2 U 4/21 - Cinacalcet III.
[37] OLG Duesseldorf, judgment of 20 Sept. 2012, I-2 U 44/12 - HIV-Drug; on market transparency and Lauer-Taxe, see also the discussion in the injunction chapter of the handbook.
[38] OLG Duesseldorf, judgment of 29 Apr. 2010, I-2 U 126/09 - Urinary Catheter Set; OLG Duesseldorf, judgment of 9 July 2021, 2 U 4/21 - Cinacalcet III.
[39] OLG Duesseldorf, judgment of 17 Jan. 2013, I-2 U 87/12 - Flupirtine Maleate; OLG Duesseldorf, judgment of 7 Nov. 2013, I-2 U 94/12 - Desogestrel.

This generics-specific logic has, if anything, become more significant in current practice. The commercial asymmetry is obvious. If a generic or biosimilar launch goes ahead and the patent is later upheld, the originator may suffer immediate and lasting harm. If, by contrast, the defendant is wrongly restrained for a limited period, the system proceeds on the basis that the resulting loss is, at least in principle, compensable. German courts have been prepared to work with that asymmetry, and it is one of the central reasons why preliminary injunctions have become so powerful in originator-versus-generic and biosimilar disputes. This is not a sector in which interim relief merely preserves the status quo; in many cases it effectively determines which party will control the market during the decisive launch window.

That said, one should not overstate the point. The case law has never meant that every pharmaceutical dispute automatically warrants an injunction. Nor has the mere fact that the defendant is a generic company been treated as sufficient in itself to grant the injunction. The *Rivastigmine* litigation remains a useful reminder that the nature of the right the patentee asserts still matters. An unexamined utility model is not automatically treated like a fully examined patent merely because the defendant is a generic manufacturer.[40] More broadly, the pharmaceutical context influences the balancing exercise; it does not abolish the need for a persuasive infringement case and a serious showing on legal status.

The issue becomes even more acute in biosimilar litigation. Biosimilars are expensive to launch, commercially significant from the first day, and often embedded in wider European rollout strategies. In that setting, the availability of a fast German preliminary injunction can exert pressure far beyond the immediate German market. Recent Munich practice confirms that, where the patentee presents a strong rights position and a clear launch threat, German courts are prepared to grant relief with immediate strategic consequences for biosimilar entrants.[41]

Phoenix Contact, Forum Practice and Present-Day Reality

The Court of Justice of the European Union ("CJEU")'s decision in *Phoenix Contact* reinforced the broader movement toward preliminary injunctions in pharmaceutical patent cases. It rejected a rigid national practice under which preliminary patent injunctions would, in principle, be unavailable until validity had been confirmed in first-instance opposition or invalidity proceedings.[42] The decision did not abolish the requirement of secured validity, but it did remove the conceptual foundation for any categorical refusal to protect newly granted patents on an interim basis. For pharmaceutical patentees, that matters because it strengthens the argument that the court must look at the actual circumstances of the case, including the apparent strength of the patent, the quality of the attacks raised, and the market consequences of withholding relief.

Even after *Phoenix Contact*, the practical difference between the main German fora remains highly important. Duesseldorf continues to be associated with a more structured and, at least rhetorically, more cautious approach to secured validity. Munich, by contrast, has acquired a reputation for speed and practical willingness to protect patentees in strong cases. Current commentary describing Munich as prepared to move quickly and to grant powerful interim

[40] LG Duesseldorf, judgment of 12 Sep. 2013, 4b O 43/13 U – Rivastigmine.
[41] LG Munich, judgment of 25. Sep. 2025, 7 O 16055/24 – Formycon.
[42] CJEU, judgment of 28 Apr. 2022, C-44/21, ECLI:EU:C:2022:309 - Phoenix Contact.

relief in high-stakes life sciences cases is therefore not merely journalistic color. It reflects a real and perceived feature of forum practice.[4]

This, in turn, explains why German preliminary injunction practice in pharmaceutical litigation often appears more far-reaching than the formal doctrinal vocabulary might suggest. The law still speaks in the language of exception, urgency, and careful balancing. In practice however, especially in originator-versus-generic or biosimilar cases, the approach is frequently markedly robust. Orders can issue quickly, they are directly enforceable, and the commercial effect of even a short-lived injunction may be decisive. German preliminary injunction practice therefore operates as a system of highly effective interim enforcement rather than as a merely symbolic preservation mechanism.

A 2022 PharmR article already captured an essential part of this development: pharmaceutical patent disputes have to be understood in the tension field between formal procedural caution and the commercial necessity of immediate enforcement.[43] What has become even clearer since then is the extent to which German practice - above all in Munich - has moved toward a distinctively patentee-effective model. That is not the same as saying that patentees always win. It is, however, a fair description of a system in which a well-prepared rights holder has a serious opportunity to stop launch quickly and decisively.

Conclusion

The broader lesson is clear: in German pharmaceutical patent litigation, preliminary injunctions are not merely available in theory. They are fast, directly enforceable, and capable of producing consequences that go well beyond a simple cease-and-desist order. In suitable cases they may stop launch, force recall, and reshape competitive conditions before the merits have been finally decided. Germany therefore remains one of the most attractive European jurisdictions for originators seeking rapid patent enforcement, and Munich in particular stands out as a venue in which patentees can expect both speed and serious remedial force.

That is why it remains fair, at least as a practical characterization, to describe Germany as an injunction jurisdiction and, in some commentary, even as an automatic injunction jurisdiction.[44]The legal framework still speaks in the language of proportionality, urgency, and secured validity. But in present-day pharmaceutical practice, especially in disputes involving generics and biosimilars, the system is markedly more assertive than that restrained language might imply. The result is a model of interim enforcement that is commercially highly effective and strategically central to modern pharmaceutical patent litigation.

A fuller treatment of these questions is contained in Pharmaceutical, Biological and Chemical Patents by Marco Stief, Maximilian Haedicke, and Annelie Wünsche. The handbook places preliminary injunctions in the wider context of German pharmaceutical patent litigation and complements that discussion with detailed analysis of validity, infringement, enforcement and compulsory licensing in chemical, biological, pharmaceutical and life sciences patent law. Beyond this specific topic, the handbook offers a highly comprehensive overview of German patent law as it applies to pharmaceutical, chemical, biological, and life sciences inventions. It covers the full range of substantive and procedural issues that arise in practice, from

[43] Stief/Meyer, Originator vs. Generika - Pharmapatente im Spannungsfeld des einstweiligen Verfugungsverfahrens, PharmR 2022, 425 ff.; id., PharmR 2022, 509 ff.
[44] See also Samer, The new PatR/Samer, § 1 Rn. 3; Stierle, GRUR 2019, 873 (873); Hofmann, NJW 2018, 1290 (1292).

patentability and validity to infringement, enforcement and compulsory licensing, and does so in a structure that is particularly useful for the reader. The relevant statutory provisions and guiding principles are presented first, followed by concise case summaries and English translations of the principal decisions. The result is a reference work that provides a clear map of the leading German case law in this field and a highly practical guide to one of the most dynamic areas of European patent litigation.

This article is but an excerpt from the book entitled "Handbook Pharmaceutical, Biological and Chemical Patents." *See https://www.maiwald.eu/de/publikationen/handbook-patents/*. Please contact Dr. Marco Stief at stief@maiwald.eu for more information.