

Pharmaceutical, Biological and Chemical Patents

Stief / Haedicke / Wünsche

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Preface

The advantages of patent litigation proceedings in Germany are often highlighted, even to the extent that the German system has been labelled a ‘rising threat’ vis-à-vis the US-system.¹ A considerable number of German cases also form the basis for judgments of the European Court of Justice. Consequently, German case law is also relevant in an international context and directly involved in the further development of (international) patent law.

Litigation in German courts therefore means German case law and the need to access, unlock and understand the ‘guiding principles’ embedded therein. The fields of (bio)chemical, pharmaceutical, and life science patents are no exception and represent a special field in European and German patent law. Here, the German Federal Court of Justice (*Bundesgerichtshof*) and the lower instance courts continue to develop the law, thereby giving rise to considerable dynamism and new findings in the legal assessment of (bio)chemical and pharmaceutical patents. In particular, the close relationship of patent law with the invention to be protected leads to great complexity in the assessment of patentability and enforceability in the case of (bio)chemical, pharmaceutical and life science patents. The handbook focuses on particularities that cannot be clearly assessed by applying general patent law doctrines.

However, the important role German case law plays in the global context cannot be truly realised in the German language. With this handbook we aim to provide legal practitioners worldwide with a well-founded overview in English of the current German case law of the highest courts in the special field of (bio)chemical, pharmaceutical and life science patents.

The handbook is divided into three parts: The first part presents the prerequisites for patentability of (bio)chemical, pharmaceutical and life science patents on the basis of the case law of the Federal Court of Justice in invalidity proceedings that has been in force since the year 2000. The second part illustrates the enforceability of patents by means of higher court patent infringement proceedings, especially in the last two decades. The German language version of this handbook, published in 2022, coincided with the COVID-19 pandemic, in which the discussion on the granting of compulsory licences for vaccine production gained new relevance. In this context, in the third part, the authors have shed light on the norm of § 24 Patent Act and examined the relevant judgments issued on compulsory licensing.

The chapters are structured according to the patenting requirements of the German Patent Act (*Patentgesetz* – PatG) and deal with the requirements of technicality, novelty, inventive step, and feasibility, and concludes with the prohibition of unauthorised extension. The content of these provisions often mirrors the corresponding provisions of Art. 52 et seq. EPC. Each chapter is prefaced by the relevant legislative provisions and the guiding principles that can be derived from the judgments discussed, followed by concise summaries of the relevant judgments. Each judgment is compactly presented in its own subchapter, which is divided into the legislative provisions and guiding

¹ Summersgill et al. The Rising Threat of German Patent Litigation: Are You Ready?, Intellectual Property & Technology Law Journal 2025, 1. See also Taylor Wessing, German Patent Cases: Statistics (2020), Kühnen/Claessen, Die Durchsetzung von Patenten in der EU – Standortbestimmung vor Einführung des europäischen Patentgerichts, GRUR 2013, 592.

Preface

principles of the judgment, a summary of the course and relevant points of the legal proceedings, a summary of the technical background and teaching of the patent in suit, and the presentation of the Court's reasons for the judgment. The full text of the summarised content can be found in the English translations of each judgment, which are also included in this handbook.

This handbook draws on key legislation and case law up to March 2025. To afford the reader clearer insights into the relevant German law, the English translations of the German legislation are included in the text.

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We are happy to receive corrections, comments and additions from readers. For this purpose, please contact us by email at HdBChemiePat@maiwald.eu and to ip@jura.uni-freiburg.de.

Munich and Freiburg
March 2025

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