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IP in review

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The German patent playbook: essential case law for chemistry and pharmaceutical innovation

Pharmaceutical Biological and Chemical Patents, a Handbook, Marco Stief, Maximilian Haedicke and Annelie Wünsche, C.H. Beck, Hart, Nomos, first edition, 2026. ISBN 978-3-406-64855-7. Hardcover, pp. 1268. Price: 500€.

The technical fields of chemistry, pharmaceuticals and the life sciences have always made intensive use of industrial property rights, particularly patents, to enable, protect and commercially exploit innovations. It is not surprising that Germany's first patent, 'Process for producing a red ultramarine colour,' granted on 2 July 1877, was a 'chemistry patent.' Chemistry and the life sciences remain key areas of patent prosecution and litigation practice in Germany nearly 150 years later.

Importantly, German case law on validity does not always necessarily follow the case law of the Boards of Appeal of the European Patent Office (EPO). Patent infringement and procedural questions are equally important and may differ from other European jurisdictions—particularly when it comes to preliminary injunction proceedings, which are so crucial for pharmaceutical originators seeking effective protection against generics. Another legal niche in the pharmaceutical sector is compulsory licences under § 24 of the German Patent Act (PatG), which gained significant media attention during the COVID-19 pandemic amid discussions about granting compulsory licences for vaccine production. Yet, even in pandemic-free times, compulsory licences can play an important role.

The multi-faceted legal issues and problems in these fields are now expertly illustrated in the present handbook, which was first published in German. The handbook is divided into three parts. The first part deals with the requirements for the patentability of chemistry, pharmaceutical and life science inventions, focusing on the most relevant Federal Court of Justice (BGH) case law in nullity proceedings since 2000. The second part relates to patent enforcement and relevant case law, including a particularly detailed chapter on preliminary injunction proceedings. The third part is about compulsory licences.

The first part is an exceptionally complete compilation of the relevant case law of the last two decades. The presentation and discussion of the featured decisions follow a clear structure: first, the headnotes of the decisions are reproduced; then, 'relevant points/procedural history' leading to the decision are outlined, followed by a brief presentation of the 'technical background/teaching of the patent in suit,' and finally, a more detailed discussion of the decision. This structure allows readers to familiarize themselves with the jurisprudence quickly and at their desired level of detail. Those interested in the details of the cases will be pleased to see that the handbook includes a collection of English translations of the decisions—a truly remarkable German case law collection for the non-native speaker!

Moreover, each subsection (such as 'Determination of the technical problem of the patent in suit' or 'reasonable expectation of success—motivation' in the discussion of the inventive step) begins with a brief summary as an introduction, making it easy for readers to place the subsequently presented case law in the relevant context. The coverage is impressively thorough, addressing everything from the patentability of dosage regimens and enantiomers to the complex ethical questions surrounding embryonic stem cell patents.

In the second part on patent infringement, the most relevant topics for practice and the decisions of recent years are discussed. This part emphasizes the scope of protection for second medical indications and preliminary injunction proceedings. When discussing the case law, the relevant framework is consistently established in brief introductions within the respective subsections, similar to the first part of the handbook. The case law is discussed in a clearly structured manner, though here, different from the first part, it is subdivided into 'Facts' and 'Decision' sections.

The third part introduces the topic of compulsory licences. It includes a detailed discussion of the latest 'Raltegravir' and 'Alirocumab' decisions and explains the examination requirements of § 24 PatG, including references to relevant but less recent cases (such as 'Polyferon' from 1995). Here, the handbook provides valuable insight into the circumstances when the public interest might justify the grant of a compulsory licence.

This handbook is highly recommended for every lawyer and patent attorney working in the relevant technical fields and contains an excellent overview of the most important national jurisprudence of the last two decades. By providing English-speaking practitioners worldwide with well-founded access to current German case law from the highest courts, this work fills a crucial gap in international legal literature. It is particularly helpful that the handbook contains full translations of all the cited decisions.

The authors have succeeded in creating a work that serves both as a comprehensive reference and a practical guide. The clear structure, methodical approach to case analysis and focus

on the most pressing practical issues make this handbook an invaluable resource. Whether you are dealing with the intricacies of the inventive step assessment in pharmaceutical patents, navigating the complexities of preliminary injunction proceedings, or grappling with the rare but important area of compulsory licensing, this handbook provides the guidance you need for a good understanding of German practice.

For anyone dealing with chemistry, pharmaceutical and biotechnology patents in Germany who wants to understand German case law and its differences from, for example, the case law of the Boards of Appeal of the EPO, this handbook is simply a must-have.

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