

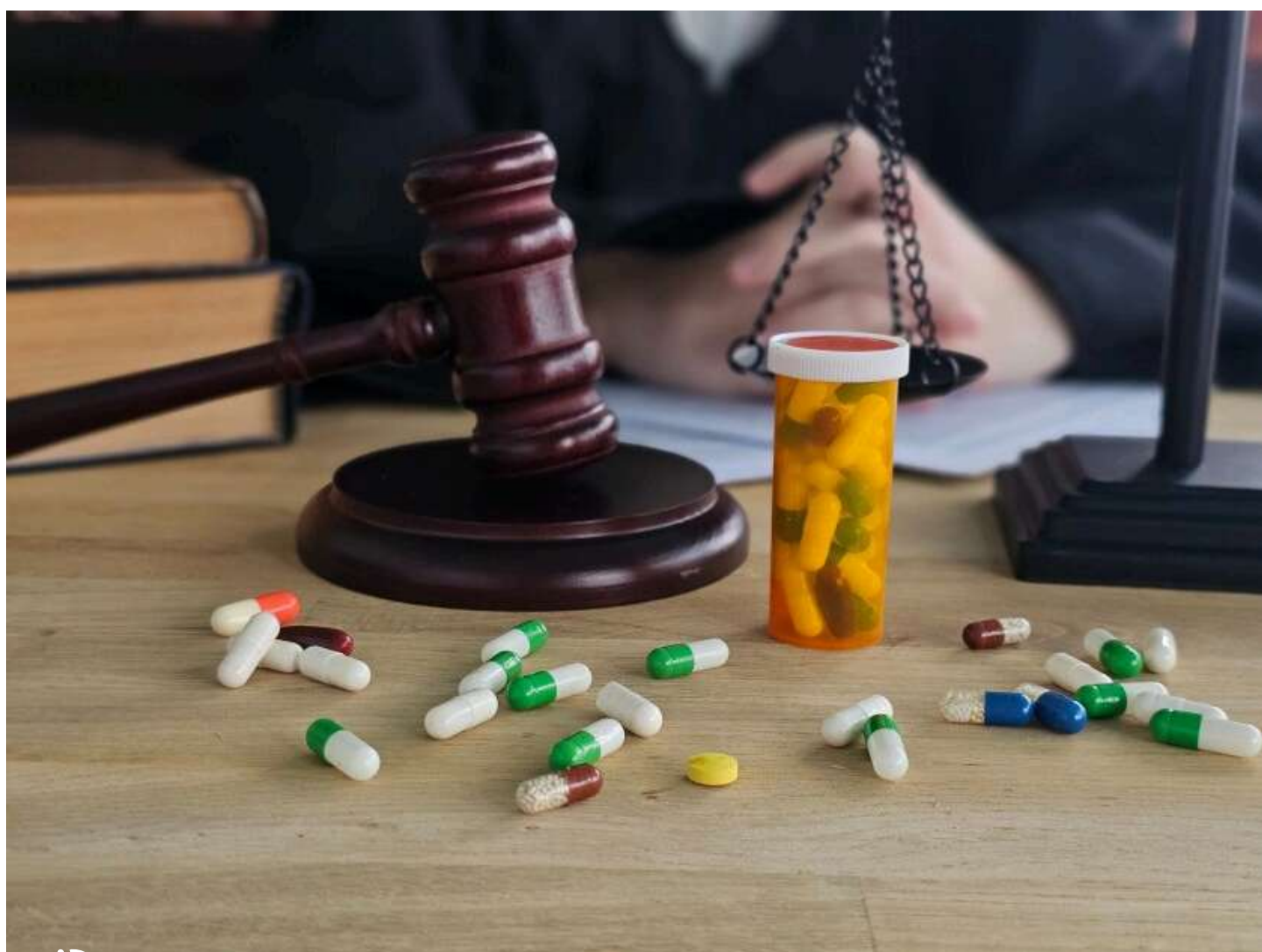
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Book review: Pharmaceutical, Biological and Chemical Patents

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Xenia Boergen March 23 2026



The handbook tackles the challenging task of making German life sciences patent law accessible to international practitioners. Xenia Boergen of Boergen Legal & Patents reviews an impressive undertaking by Marco Stief, Maximilian Haedicke, and Annelie Wünsche

The most valuable specialist books are not necessarily those that advance an ambitious new thesis. More often, they solve a concrete professional problem so well that they become indispensable in practice. *Pharmaceutical, Biological and Chemical Patents* falls into that category.

Its central achievement is to make German patent law in the pharmaceutical, chemical, and life sciences fields genuinely accessible to an international readership without reducing the subject to slogans or over-simplified summaries. That is no small contribution.

German patent case law in these sectors is both influential and technically demanding, but for many non-German readers it remains difficult to approach directly. This handbook addresses that difficulty head-on. It presents the relevant statutory framework, distils the governing principles from the case law, explains the underlying technical setting, and, crucially, adds English translations of the most important decisions and provisions. The result is much more than an ordinary handbook. It is a working bridge into a body of jurisprudence that has long mattered well beyond Germany.

That practical orientation gives the book its character from the outset. Rather than treating chemical, pharmaceutical, and biological inventions as just another branch of general patent doctrine, the authors recognise that these sectors raise recurring issues that demand sector-specific analysis.

Questions of novelty, inventive step, sufficiency, added matter, infringement, and interim relief do not arise here in a vacuum. They arise against a background of experimental uncertainty, regulatory overlay, formulation science, biologics, dosage features, second medical use claims, and, increasingly, high-stakes launch disputes involving generic and biosimilar competition. A handbook in this field therefore succeeds only if it can combine doctrinal precision with technical sensitivity. This one does.

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Structure and approach: built for practitioners

The book's structure is one of its major strengths. It is divided into three main parts:

- Patentability and validity;
- Infringement and enforceability; and
- Compulsory licensing.

That division is sensible not merely from a pedagogical perspective, but because it reflects the way real disputes develop. In a pharmaceutical or biotechnology case, validity, claim scope, infringement

theory, regulatory context, launch timing, and public interest arguments often form part of one continuous litigation story. The handbook captures that reality well.

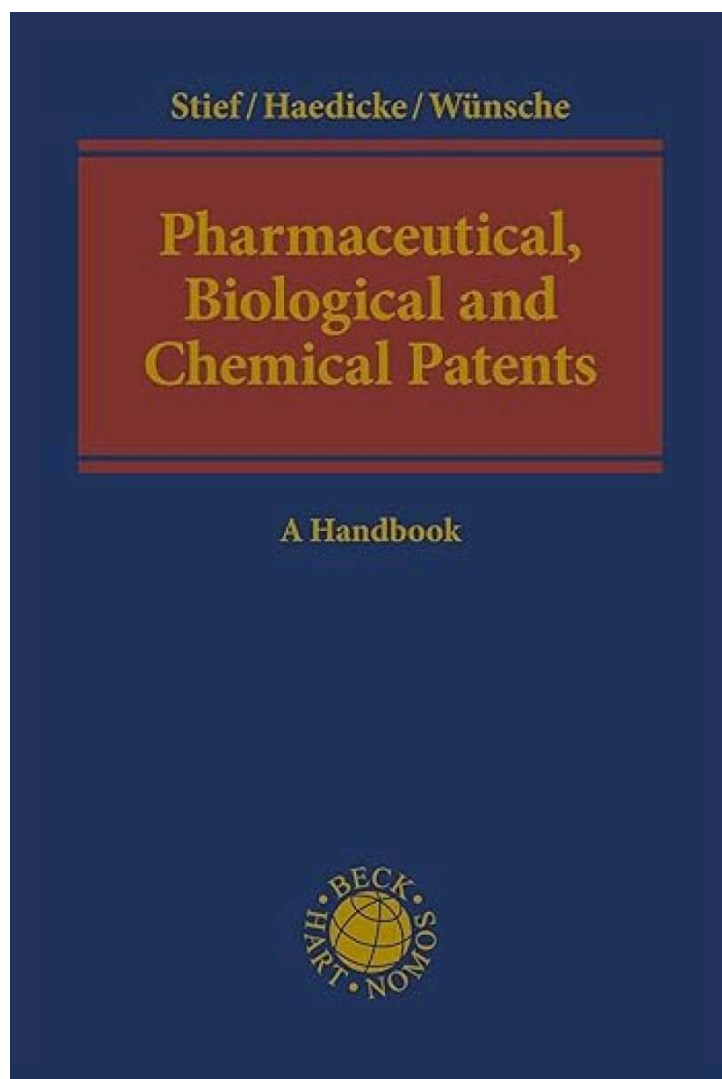
Within the individual chapters, the presentation is methodical and reader-friendly. The relevant statutory provisions are introduced first, the guiding principles derived from the case law are then stated in a compact form, and only thereafter do the authors move to the case summaries themselves. This gives the reader several levels of access to the material: quick orientation where needed, but enough depth for serious research.

Patentability and inventive step in practice

Part I, dealing with patentability and validity, is particularly rich. It does not remain at the level of abstract doctrine. Instead, it addresses the concrete invention types and recurring factual patterns that dominate life sciences patent litigation. The discussion covers, among other things, dosage regimens, second and further medical uses, enantiomers, polymorphs, selection inventions, biological material, and gene-related inventions. These are precisely the areas in which broad formulas are least helpful and where the interaction between law and science becomes most acute.

The authors are careful to explain not only the legal holding of the relevant cases but also the technical contribution claimed by the patent and the court's reasoning in relation to the skilled person, the technical problem, and the expectation of success. That makes the analysis particularly useful for practitioners who need more than just a doctrinal label.

The treatment of inventive step deserves separate mention. In pharmaceutical and chemical disputes, inventive step is very often the decisive battleground, and it is also the area in which hindsight can most easily distort legal analysis. The handbook does a good job of showing how German courts approach the question in sector-specific settings. Instead of reducing the inquiry to formulaic statements, it illustrates how the courts work through motivation, reasonable expectation of success, routine experimentation, and technical prejudice in different factual constellations. That kind of structured presentation is valuable because it helps the reader understand not only what the courts have decided but why particular outcomes followed in particular technical settings.



“The book speaks to litigators, patent attorneys, in-house counsel, and academically minded readers without becoming trapped in any one professional idiom”

Litigation realities: infringement and enforcement

Part II, on infringement and enforceability, is likely to be the section many practitioners will consult most often. Here the handbook’s litigation focus becomes especially visible.

It addresses claim interpretation, scope of protection, direct and indirect infringement, equivalence, legal consequences, and injunction proceedings in a way that is closely tied to the realities of pharmaceutical enforcement. That is important. Patent infringement in the pharmaceutical sector is rarely a purely abstract exercise in claim construction. The relevant questions frequently involve therapeutic purpose, labelling, cross-label use, supply chains, biosimilar launch scenarios, and the interaction between patent rights and regulatory market practice. The handbook does not shy away from those complications. On the contrary, it seems strongest where the legal analysis is inseparable from the market context.

The discussion of preliminary injunctions is a good example. German interim relief practice in pharmaceutical cases has become a matter of European significance, particularly in originator-versus-generic and biosimilar disputes. The handbook’s treatment of urgency, first infringement, secured validity, and the practical asymmetry of harm in launch situations is therefore highly relevant. The same is true of the sections dealing with second medical use claims and the special difficulties of proving infringement in such cases.

By placing those issues within the wider framework of German infringement law, the book gives the reader something more useful than a collection of isolated case notes: it offers a coherent map of the current enforcement landscape.

Compulsory licensing

The third part, devoted to compulsory licensing, is narrower in scope but far from peripheral. In the life sciences field, compulsory licensing remains exceptional, yet it carries obvious practical and political significance whenever public health concerns, supply shortages, or exceptional therapeutic need are invoked.

The handbook's discussion of the statutory requirements under German law, and of the modern case law on public interest and prior licensing efforts, is therefore a welcome inclusion. The renewed debate surrounding access to medicines and the legal limits of exclusivity has made this topic more visible again, and the book treats it with appropriate sobriety. It neither exaggerates the practical availability of compulsory licences nor relegates them to a purely academic corner of patent law.

Another important strength lies in the architecture of the book as a research tool. This is not simply a monograph to be read from start to finish; it is designed for repeated consultation. The combination of statutory text, guiding principles, case summaries, and translated decisions makes it possible to move quickly between overview and detail.

Practical relevance and audience

For non-German readers, the annex containing English translations of the principal decisions is particularly valuable. It allows users to engage directly with the language and reasoning of German courts rather than relying solely on second-hand paraphrase. That feature alone significantly increases the practical utility of the work for cross-border litigation, internal advice, and comparative analysis. In a field where subtle doctrinal differences can have major commercial consequences, direct access to the relevant decisions in English is a major asset.

The book also benefits from the breadth of perspective reflected in its treatment of the subject. It speaks to litigators, patent attorneys, in-house counsel, and academically minded readers without becoming trapped in any one professional idiom. It is plainly informed by litigation practice, but it is not merely tactical. It is doctrinally careful but not academic in the pejorative sense of being detached from the way disputes actually unfold. That balance is difficult to achieve in a field as technical as this one. Here, however, the combination of careful structure, technical clarity, and practical focus makes the book consistently useful.

No serious review should ignore the fact that this is a substantial and unapologetically specialist work. At more than 1,200 pages, it is not an introductory primer and not intended to be one. Readers looking for a short, entry-level explanation of patent law will not find it here. But that is not a criticism. The field covered by the book is too important and too demanding for superficial treatment.

What matters is whether the length is justified and whether the material is presented in a way that rewards use. On both counts, the answer is yes. The handbook is comprehensive without becoming shapeless, detailed without losing direction, and ambitious without losing sight of the needs of practice.

Taken as a whole, *Pharmaceutical, Biological and Chemical Patents* is best understood as a major English-language gateway into German patent law for the life sciences industries. It covers the full spectrum of issues that matter in practice, from patentability and validity to infringement, enforcement, and compulsory licensing, and it does so in a format that is unusually accessible for such a dense and technically exacting subject. Its value lies not only in the range of topics covered but in the disciplined way in which the material is organised and made usable.

For anyone working seriously with German or European pharmaceutical, chemical, or biotechnology patent disputes, this handbook is likely to become a very helpful and frequently consulted reference.

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