New Book Review

Introduction

Pharmaceutical, Biological and Chemical Patents – A Handbook –

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When selecting books to feature in this new publications review, the reviewer visits bookshops with the hope that these titles might serve as a useful reference for members as they occasionally look up from their day-to-day specialist work to observe developments in adjacent fields or areas that may at first glance seem unrelated, thereby further deepening and broadening their expertise.However, this book is an exception: as its title suggests, it is an authoritative, systematic and practical reference work on German case law, intended directly for readers who are experts in 'pharmaceutical, biotechnology and chemical patents'. It was recommended by Yuko Matsutoya, a patent attorney and long-standing member of our Association who specialises in this field.

One of the book's distinctive features is that, rather than beginning with a general explanation of German patent law, it directly addresses and meticulously analyses how German courts have tackled the specific issues arising in the life sciences sector (discussed below) and how they have developed the law in response.The authors—Dr Stief, Dr Haedicke and Dr Wünsche—combine legal practice, academic research, judicial analysis and technical context from the perspectives of a lawyer with extensive litigation experience, a university professor and judge, and a patent attorney, respectively, to provide a comprehensive overview of the legal framework in this field as of March 2025.

A further distinctive feature of this book is that it enables non-German speakers to directly understand, in English, the raw reasoning of German courts, which is otherwise difficult to access.This is a major intended benefit of the book's structure, which follows the main text (approximately 300 pages)—which explains points of practical importance whilst highlighting guiding principles embedded in relevant legislation and judgements—with an appendix (approximately 950 pages) containing full English translations of each judgement listed in alphabetical order by case name, thereby enabling readers to efficiently access the necessary source materials.

The main body of this book is divided into three parts: Part I (Patentability), Part II (Patent Infringement) and Part III (Compulsory Licences). Part I covers [A] Patentability (including medical treatment and diagnostic methods, and assessments regarding recommended dosages and methods of use, etc.), [B] Novelty (enantiomers, inventions relating to pharmaceutical uses, numerical limitations, etc.), [C] Inventive Step (methods of assessment, bonus effects, etc.), [D] Insufficient Disclosure (functional limitations, etc.), and [E] Addition of New Matter. Part II [§ 4] Claim Construction (gene sequence patents, second pharmaceutical uses, 'skinny label' (cross-label)claims, the doctrine of equivalents, etc.), [§ 5] Direct and indirect infringement, [§ 6] Exceptions for research and development (scope of the Bolar exception, etc.), and prior user rights, [§ 7] Claims for injunctions and destruction, and [§ 8] Interim relief (disputes involving generic medicines, etc.) are discussed.

Part III is devoted entirely to compulsory licences, which hold significant practical and political importance in this field. It includes judgments of particular interest to those in the Japanese pharmaceutical industry, such as the ruling granting a compulsory licence for Shionogi & Co.'s anti-HIV drug patent, and the ruling in the case where Sanofi sought a compulsory licence against Amgen's globally contested patent for PCSK9 antibodies.As disputes over patents between innovator pharmaceutical companies are expected to increase in the future, this volume offers important insights into how such disputes should be handled from the perspective of the public interest.

Judgments by German courts in this field have a significant influence on the decisions of the Court of Justice of the European Union, the European Patent Office and the Unified Patent Court, and readers can also glean useful insights into issues where debate in Japan has not yet reached maturity. This is an indispensable reference work that practitioners in this field should keep to hand and consult repeatedly.

[Bibliographic Details]

Pharmaceutical, Biological and Chemical Patents – A Handbook – Authors Marco Stief, Maximilian Haedicke, Annelie Wünsche

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