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Book Review

Book Review: *Infringement of Second Medical Use Claims: A Global Study Focusing on Skinny Labels*, edited by Marco Stief and Tobias Matschke

Published in 2024 by Verlag C.H.Beck oHG, *Infringement of Second Medical Use Claims: A Global Study Focusing on Skinny Labels*, edited by Marco Stief and Tobias Matschke, offers a timely and comprehensive analysis of one of the most complex and jurisdictionally fragmented issues within patent law as it applies to pharmaceutical inventions.

In recent years, second medical use claims have gained increasing significance in patent filings and infringement litigation. However, the legal treatment of such claims varies considerably across jurisdictions. These differences involve not only the interpretation of claim scope and the conditions for asserting rights, but also the more fundamental issue of whether a second medical use claim would be considered infringed by a “skinny label” product.

A “skinny label” is a regulatory strategy employed by generics manufacturers to seek approval before all of the originator’s patents have expired, particularly those covering specific therapeutic uses. By deliberately excluding patented indications from the drug’s product information, such as the Summary of Product Characteristics (SmPC), package leaflet, or label, the generic applicant aims to avoid infringing use patents while gaining earlier market access.

Nonetheless, whether such an exclusion is sufficient to eliminate the risk of infringement remains legally uncertain. Jurisdictions differ significantly in their assessment of this strategy, especially in scenarios where a generic drug, although approved only for non-patented indications, may still be prescribed or used for patented ones in clinical practice.

Against this backdrop, the present volume brings together contributions from highly qualified and experienced patent litigators multiple jurisdictions crossing Europe (covering jurisdictions including Austria, Denmark, France, Germany, Ireland, Italy, The Netherlands, Poland, Portugal, Spain, Türkiye, United Kingdom, and European Unified Patent Court and Unitary Patent), the United States, Australia, and Asia (including China, Japan, Singapore, and Taiwan). Each of whom provides an in-depth analysis of the legal framework and enforcement strategies applicable in their respective countries. The result is a collaborative and practice-oriented reference work that offers valuable guidance for both originator and generic pharmaceutical companies.

This global compendium applies a uniform, practitioner-focused

approach to second-medical-use patents across all jurisdictions. Each country section begins with a succinct executive summary outlining the legal regime and practical implications, followed by a clear discussion of claim drafting (e.g. Swiss-type, EPC 2000 “purpose-limited product,” or “use” formats) and patentability benchmarks. The text then outlines the standards and evidence required to prove direct or indirect infringement, including scenarios where patented indications are omitted from product labels—commonly known as “skinny label” cases—and addresses parallel concerns for biosimilars. Drawing on expertise from both originator and generic sectors, it offers grounded enforcement and defense strategies. Readers also gain structured insight into available remedies—such as injunctive relief and damages—as well as full statutory texts and translated judicial excerpts that illustrate real-world rulings on second-medical-use and labeling disputes.

This harmonized structure not only facilitates efficient cross-jurisdictional comparisons, but also delivers jurisdiction-specific insights that enhance the book’s value as a practical reference, particularly for legal practitioners navigating pharmaceutical patent issues across multiple legal systems. The book, priced at €169,00, can be purchased at the following website: <https://www.beck-shop.de/stief-matschke-infringement-of-second-medical-use-claims/product/36696452>.

Declaration of competing interest

I have no interests to declare.

George J. H. Huang is the founder of Wisdom International Patent & Law Office. George is the first Attorney at Law with a solid technical background who qualified as a Patent Attorney in Taiwan. Having over 27 years of experience in the intellectual property field, George is skilled at handling patent, trademark and design matters, from prosecution to contentious work. George has also been individually ranked and recognized in the Gold Tier in the IAM Patent 1000, the Silver Tier in the WTR 1000, and other international rankings.

Before becoming an IP attorney, George worked at a multinational pharmaceutical company. Leveraging his technical and legal background, he specializes in biochemistry-related patent matters, with a strong focus on the pharmaceutical sector. George is fluent in English and Japanese, and regularly assists international and Japanese clients across a wide range of industries, including semiconductor, chemical mechanical, pharmaceutical, cosmetics, luxury goods, financial services and software industries, in securing and enforcing IP rights worldwide.

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<https://doi.org/10.1016/j.wpi.2025.102384>

Received 3 July 2025; Received in revised form 6 August 2025; Accepted 7 August 2025

Available online 20 August 2025

0172-2190/© 2025 Published by Elsevier Ltd.