1. Record Nr. UNINA9910255190803321 Autore Shaikh Owais H Titolo Access to Medicine Versus Test Data Exclusivity: Safeguarding Flexibilities Under International Law / / by Owais H. Shaikh Pubbl/distr/stampa Berlin, Heidelberg: .: Springer Berlin Heidelberg: .: Imprint: Springer. , 2016 **ISBN** 3-662-49655-0 Edizione [1st ed. 2016.] Descrizione fisica 1 online resource (XVI, 256 p. 78 illus., 56 illus. in color.) Collana Munich Studies on Innovation and Competition, , 2199-7470 ; ; 4 Disciplina 340.9 Soggetti Information technology - Law and legislation Mass media - Law and legislation Private international law Conflict of laws International law Comparative law Trade regulation Law and economics IT Law, Media Law, Intellectual Property Private International Law, International and Foreign Law, Comparative Law International Economic Law, Trade Law Law and Economics Inglese Lingua di pubblicazione **Formato** Materiale a stampa Livello bibliografico Monografia Nota di bibliografia Includes bibliographical references. Nota di contenuto Introduction -- Test Data Exclusivity: Raison d'être -- Test Data Exclusivity and Art 39(3) TRIPS -- Test Data Exclusivity in the US and the EU -- Index of Data Exclusivity and Access (IDEAS) - Free Trade Agreements -- Index of Data Exclusivity and Access (IDEAS) - National Laws -- Test Data Exclusivity in FTAs and Access to Originator Pharmaceuticals -- Conclusions and Recommendations. Sommario/riassunto This book explores the concept of test data exclusivity protection for pharmaceuticals. Focusing on Art 39(3) of the WTO Agreement on

Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

and relevant provisions in selected free trade agreements (FTA) and national laws, it combines normative, historical, comparative and economic analysis of test data exclusivity protection. At the heart of this book is the novel and original Index of Data Exclusivity and Access (IDEAS), which analyzes the effectiveness of test data exclusivity provisions in FTAs and national laws both on the strength of exclusivity as well as on access to medicine. IDEAS provides a framework for the assessment of current test data exclusivity protection standards on the basis of their proximity to Article 39(3) of the TRIPS Agreement, the scope of exclusivity and the flexibilities in FTAs, and subsequently in national laws. This book aims to broaden national and international policy makers' grasp of the various nuances of test data exclusivity protection. Furthermore, it provides practical recommendations with regard to designing an appropriate legal system with a strong focus on promoting access to medicine for all.