

Summary of Contents

- Chapter 1. Prosecution of Biologic Patents
- Chapter 2. Overview of BPCIA Litigation
- Chapter 3. The FDA Approval Process for Biosimilar and Interchangeable Biological Products
- Chapter 4. BPCIA Patent Litigation
- Chapter 5. Post-Grant Proceedings and BPCIA Litigations
- Chapter 6. ITC Section 337 Actions
- Chapter 7. Discovery in the United States for Use in Foreign Litigation
- Chapter 8. Antitrust Actions
- Chapter 9. Product Liability Claims Against Biosimilars

Appendices

- Appendix A. Compilation of Relevant Statutes (42 USC 262 and 35 USC 271)
- Appendix B. Compilation of Relevant Regulations (21 CFR 10.115, 21 CFR Part 600, 37 CFR 42)
- Appendix C1. Assessing User Fees Under the Biosimilar User Fee Amendments of 2022
- Appendix C2. Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed
- Appendix C3. Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act
- Appendix C4. Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products
- Appendix C5. Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product

GUIDE TO BIOSIMILARS LITIGATION AND REGULATION IN THE U.S.

- Appendix C6. Considerations in Demonstrating Interchangeability With a Reference Product
- Appendix C7. The “Deemed To Be a License” Provision of the BPCI Act Questions and Answers
- Appendix C8. Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations
- Appendix C9. Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products
- Appendix C10. Guidance for Industry Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act
- Appendix C11. Interpretation of the “Deemed to be a License” Provision of the Biologics Price Competition and Innovation Act of 2009
- Appendix C12. Labeling for Biosimilar Products Guidance
- Appendix C13. New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 3)
- Appendix C14. Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products— Questions and Answers, Guidance for Industry
- Appendix C15. Questions and Answers on Biosimilar Development and the BPCI Act, Guidance for Industry
- Appendix C16. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product
- Appendix C17. Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act
- Appendix C18. Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product
- Appendix C19. Considerations in Demonstrating Interchangeability With a Reference Product: Update

SUMMARY OF CONTENTS

- Appendix C20. Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products Questions and Answers, Guidance for Industry
- Appendix C21. Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations
- Appendix C22. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies
- Appendix D. FDA Approvals and U.S. Launches of Biosimilars
- Appendix E. BPCIA Litigations
- Table of Laws and Rules**
- Table of Cases**
- Index**