

---

# 15 Legal and Legislative Hurdles to Generic Drug Development, Approval, and Marketing

*Arthur Y. Tsien*

## CONTENTS

Introduction.....	334
Citizen Petitions and Legal Challenges to Generic Drug Approvals .....	335
Exclusivity Issues.....	337
Five-Year New Chemical Entity Exclusivity .....	337
Three-Year Exclusivity for Product “Improvements” .....	338
Seven-Year Orphan Drug Exclusivity .....	340
180-Day Generic Drug Exclusivity.....	340
General Considerations .....	340
Pre-MMA Rules .....	341
MMA Rules.....	343
Six-Month Pediatric Labeling Exclusivity.....	345
Antibiotics .....	347
Differences between Innovator and Generic Products.....	347
ANDA Suitability Petitions.....	347
“Same” Active Ingredient.....	348
“Same” Dosage Form.....	350
“Same” Labeling.....	350
Bioequivalency .....	351
Prescription-to-OTC Switches .....	352
505(b)(2) NDAs .....	352
Patent-Related Issues .....	355
Scope of Hatch–Waxman Patent Listing Provisions .....	355
30-Month Delay of ANDA and 505(b)(2) NDA Final Approval .....	357
Hatch–Waxman Patent Infringement Litigation .....	358
Declaratory Judgment Actions .....	358
Bolar-Type Considerations.....	359
Authorized Generics .....	360
Biosimilars .....	361