

TABLE OF CONTENTS

TABLE OF AUTHORITIESii

INTRODUCTION 1

BACKGROUND 3

 I. The Related Litigation..... 3

ARGUMENT..... 4

 I. The Statute Does Not Authorize the Court to Order a 30-Month
 Stay. 4

 II. The Doctrine of Equitable Tolling Does Not Apply to the 45-Day
 Period..... 9

 A. The 45-Day Period in 21 U.S.C. § 355(j)(5)(B)(iii) Is Not a
 Statute of Limitation. 9

 B. If Equitable Tolling Were to Apply to the 45-Day Period,
 Purdue’s Repeated Failures to Take Action to Protect Its Interests
 Would Bar Purdue from the Benefit of the Doctrine..... 11

 III. Mallinckrodt Violated No Regulation by Not Filing a New Paragraph
 IV Certification and Serving a New Notice Letter. 14

 IV. If the Court Denies Purdue’s Motion, the Court Should Order Purdue
 to Withdraw Purdue’s Petition to FDA to Stay Action on Mallinckrodt’s
 ANDA..... 17

CONCLUSION 17

TABLE OF AUTHORITIES

Cases

<i>Additive Controls & Measurement Systems, Inc.</i> , 986 F.2d 476 (Fed. Cir. 1993)	12
<i>Bayer AG v. Elan Pharm. Research Corp.</i> , 212 F.3d 1241 (Fed.Cir 2000)	5
<i>Blonder-Tongue Laboratories, Inc. v. Univ. of Ill. Foundation</i> , 402 U.S. 313 (1971)	13
<i>Bowers v. Transportacion Maritima Mexicana</i> , S.A., 901 F.2d 258 (2d Cir. 1990)	11
<i>Bresgal v. Brock</i> , 843 F.3d 1163 (9th Cir. 1987)	12
<i>Bristol-Myers Squibb Co. v. Royce Lab</i> , 69 F.3d 1130 (Fed.Cir. 1995)	5, 7, 9
<i>DuPont Merck Pharm. Co. v. Bristol-Myers-Squibb Co.</i> , 894 F. Supp. 804 (D.Del. 1995)	7
<i>Growth Horizons, Inc. v. Delaware County, Pa.</i> , 983 F.2d 1277 (3rd Cir. 1993).....	7
<i>Johnson v. Nyack Hospital</i> , 86 F.3d 8 (2d Cir. 1996)	10, 11
<i>Keene Corp. v. United States</i> , 508 U.S. 200 (1983)	5
<i>Lee v. Criterion Ins. Co.</i> , 659 F. Supp. 813 (S.D.Ga. 1987)	13
<i>Novartis Corp. v. Dr. Reddy's Labs, Ltd.</i> , 2004 WL 236807 (S.D.N.Y. 2004)	5
<i>Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.</i> , 410 F.3d 690 (Fed. Cir. 2005)	3
<i>Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.</i> , 438 F.3d 1123 (Fed. Cir. 2006)	3, 4
<i>Steen v. United States</i> , 468 F.3d 1357 (Fed. Cir. 2006)	5

Warner-Lambert Co. v. Purepac Pharmaceuticals Co.,
2000 WL 34213890 (D.N.J. 2000).....6

Statutes

19 U.S.C. § 35017
21 U.S.C. § 355(j)(2)(B)(i).....15
21 U.S.C. § 355(j)(5)(B).....5, 6
35 U.S.C. § 1547
35 U.S.C. § 271(3)(4)(A).....5
35 U.S.C. § 271(e)(2)6, 7
35 U.S.C. § 28610

Regulations

21 C.F.R. § 10.35.....17
21 C.F.R. § 314.94(c)(12)(c).....16
21 C.F.R. §§ 314.95(e)15

