IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., et al.,)
Plaintiffs,	Civil Action No. 12-3824
) CONSOLIDATED
V.)
WARNER CHILCOTT PUBLIC LIMITED)
COMPANY, et al.,)
Defendants.)
)

FEDERAL TRADE COMMISSION BRIEF AS AMICUS CURIAE

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TABLE OF AUTHORITIES

Cases

Abbott Labs v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408 (D. Del. 2006)
Aspen Skiing Co. v. Aspen Highlands Corp., 472 U.S. 585 (1985)
Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007)
Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263 (2d Cir. 1979)
Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297 (3d Cir. 2007)
C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340 (Fed. Cir. 1988)
Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, — U.S. —, 132 S. Ct. 1670 (2012)
eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006)
LePage's Inc., v. 3M, 324 F.3d 141 (3d Cir. 2003)
Mannington Mills, Inc. v. Congoleum Indus., Inc., 610 F.2d 1059 (3d Cir. 1979)
SmithKline Corp. v. Eli Lilly & Co., 575 F.2d 1056 (3d Cir. 1978)
United States v. Dentsply Int'l, Inc., 399 F.3d 181 (3d Cir. 2005)
United States v. Grinnell Corp., 384 U.S. 563 (1966)
United States v. Microsoft, 253 F.3d 34 (D.C. Cir. 2001)
Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976) 4
Xerox Corp. v. Media Scis. Int'l, Inc., 511 F. Supp. 2d 372 (S.D.N.Y 2007)
Statutes
15 U.S.C. § 46
15 U.S.C.§§ 41-58
21 U.S.C. § 355
H.R. Rep. No. 98-857, Pt. 1, p. 14-17 (1984)5
The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 3
Other Authorities



Allison Masson & Robert L. Steiner, FTC, Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws (September 1985)
Department of Justice & Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property (1995)
Drug Product Selection, Staff Report to the FTC, Bureau of Consumer Protection (Jan. 1979)
FDA Center for Drug Evaluation and Research, Approved Drug Products with Therapeutic Equivalence Evaluations (32d ed.)
FDA, Facts About Generic Drugs
Federal Trade Commission, <i>The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition</i> (2011)
Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (2003)
Fiona M. Scott Morton, Barriers to Entry, Brand Advertising, and Generic Entry in the US Pharmaceutical Industry, 18 Int'l J. Indus. Org. 1085 (2000)
FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact (2011) 4, 7, 8
FTC, Emerging Health Care Issues: Follow-on Biologic Drug Competition (June 2009) 4
FTC, Pay-For-Delay: How Drug Company Pay-offs Cost Consumers Billions (2010)
G. Michael Allen et al., <i>Physician Awareness of Drugs Cost: A Systematic Review</i> , 4 PLOS Med. 1486 (2007)
Generic Pharmaceutical Association, Generic Drug Savings in the U.S. (4th ed. 2012)
Hovenkamp et al, <i>IP and Antitrust</i> , 2d. Ed. (2010) § 15.3
KaiserEDU.org, Prescription Drug Costs
Marc-André Gagnon, Joel Lexchin, <i>The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States</i> , 5 PLoS Med 32 (Jan. 2008) 9
Michael A. Carrier, A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping, 62 Fla. L. Rev. 1009 (Sept. 2010)
Overview of FTC Antitrust Actions in Pharmaceutical Services and Products (June 2012) 2
Report of the American Bar Association Section of Antitrust Law Special Committee to Study the Role of the Federal Trade Commission, 58 Antitrust L. I. 43 (1989)



The Use of Medicines in the United States: Review of 2010, IMS Institute for Healthcare Informatics (April 2011)	. 8
U.S. Department of Justice & Federal Trade Commission, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition (2007)	. 3
William H. Shrank et al., <i>The Consequences of Requesting "Dispense as Written</i> ," 124 Am. J. Med. 309 (2011)	. 7



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