Lisa J. Rodriguez
TRUJILLO RODRIGUEZ
& RICHARDS, LLC

258 Kings Highway East Haddonfield, NJ 08033

Telephone: (856) 795-9002 Facsimile: (856) 795-9887

lisa@trrlaw.com

**Attorneys for Plaintiffs** (Additional Counsel on Signature Page)

# UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

In re: LAMICTAL INDIRECT
PURCHASER AND ANTITRUST
CONSUMER LITIGATION

THIS DOCUMENT RELATES TO:

ALL ACTIONS

Master File No. 2:12-cv-05120
William H. Walls, USDJ
Steven C. Mannion, USMJ

CONSOLIDATED AMENDED
CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Carolyn McAnaney, the International Brotherhood of Electrical Workers Local 38, Health and Welfare Fund ("IBEW Local 38"), and the International Brotherhood of Electrical Workers Local 595, Health and Welfare Fund ("IBEW Local 595"), on behalf of themselves and all others similarly situated, for their First Amended Class Action Complaint against Defendants GlaxoSmithKline LLC ("Glaxo"), Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), and Teva Pharmaceuticals USA, Inc. ("Teva USA" and collectively with Teva Ltd., "Teva"), based on (a) personal knowledge; (b) investigations of counsel, including review of various pleadings and rulings in *SmithKline Beecham Corp. v. Teva Pharmaceuticals* USA, Inc., Nos. 02-cv-3779 (D.N.J.) and 02-cv-4537 (D.N.J.), and Teva Pharmaceutical Industries Ltd, et. al v. SmithKline Beecham Corporation, No. 08-cv-03706 (D.N.J.), and In re Lamictal Direct Purchaser Antitrust Litig., Master File No. 2:12-cv-00995-WHW-MCA (D.N.J), discussed herein; (c) public filings and statements by Glaxo and Teva; and (d) information and belief, allege as follows:

#### I. NATURE OF THE ACTION

1. This case is brought on behalf of Plaintiffs and the Classes of Indirect Purchasers (defined *infra* ¶¶25-28) who indirectly purchased, paid, or reimbursed for Lamictal®-brand lamotrigine tablets (25 mg, 100 mg, 150 mg, and 200 mg) ("Lamictal Tablets") from Glaxo and/or a generic version of Lamictal Tablets from Teva, other than for resale, at any time during the Class Period of August 30, 2006, until the effects of Defendants' conduct complained of herein ceased or ceases.

- 2. Since 1994, Glaxo has manufactured, marketed, and sold Lamictal Tablets for the treatment of medical conditions such as epilepsy, other disorders involving seizures, and bipolar disorder, as well as for several off-label uses. For the year ending in March 2008, Glaxo's sales of Lamictal Tablets in the United States exceeded \$2 billion. Glaxo also markets Lamictal® chewable tablets (2 mg, 5 mg, and 25 mg) ("Lamictal Chewables"), which is in most cases a lower-dosage chewable lamotrigine tablet, and had annual domestic sales of about \$50 million during the same time period.
- 3. During the lawful life of U.S. Patent No. 4,602,017 (the "017 patent"), Glaxo had the exclusive right to sell Lamictal Tablets and Lamictal Chewables. In 2002, Teva filed Abbreviated New Drug Applications ("ANDAs") with the U.S. Food and Drug Administration (the "FDA") seeking approval to market its own generic versions of both Lamictal Tablets and Lamictal Chewables. These ANDAs were accompanied by "Paragraph IV" certifications representing that the ANDA products did not infringe any valid or otherwise enforceable patent(s) listed in the FDA publication styled *Approved Drug Products with Therapeutic Equivalent Evaluations* (the "Orange Book") as pertaining to Lamictal Tablets or Chewables, including the '017 patent.
- 4. After Teva filed its ANDAs claiming the '017 patent was not infringed by Teva's generic Lamictal Tablets, or was unenforceable, Glaxo sued Teva in this Court (the "Patent Litigation"). After trial, the Patent Litigation court invalidated the

first and independent claim of the '017 patent. The Patent Litigation court informed the parties that rulings on invalidity of the remaining claims of the '017 patent would be imminently forthcoming.

- 5. Invalidation of the '017 patent would have resulted in the loss of billions of dollars of revenues to Glaxo in Lamictal Tablet and Chewable sales in the United States, the loss of tens of millions of dollars (or more) to Teva as the first generic seller of generic Lamictal Tablets and Chewables, and hundreds of millions of dollars (or more) in savings to those individuals and entities who paid all or part of consumers' cost of purchasing Lamictal Tablets and Chewables ("Indirect Purchasers"), including Plaintiffs.
- 6. To forestall and prevent the Patent Litigation court from ruling on the remaining claims of the '017 patent, on or about February 16, 2005, Glaxo and Teva entered into a series of anti-competitive agreements, none of which were provided to the Patent Litigation court for review or approval. Those agreements were styled the Settlement Agreement and the License and Supply Agreement (collectively, the "Agreements").
- 7. In exchange for Teva's agreement to end the Patent Litigation before further rulings concerning the invalidity of the '017 patent, and to delay not only Teva's sale of generic and substantially-cheaper Lamictal Tablets for more than two years but also all other third-party generic competition for Lamicatal Tablets, the Agreements resulted in cash payments to Teva and the agreement by Glaxo to a

market and territorial allocation agreement for generic Lamictal Tablets and Chewables.

- 8. The Agreements, and Defendants' agreements and conspiracies to enter into the Agreements for their own illicit financial gain to the detriment of Indirect Purchasers and consumers of Lamicatal Tablets, were anticompetitive, unfair, deceptive, and inequitable.
- 9. Plaintiffs, individually and on behalf of four Classes of Indirect Purchasers (defined *infra* ¶25-28), bring claims in this action for violations of the Sherman Act, 15 U.S.C. §§1, 2 (under the Declaratory Judgment Act); the New York Donnelly Act, New York General Business Law ("GBL") §340, *et seq.*; New York GBL §349, *et seq.*; the Michigan Antitrust Reform Act, Mich. Comp. Laws. §445.772; Mich. Comp. Laws. §445.773; the California Cartwright Act, California Business and Professions ("Bus. & Prof.") Code §16700, *et seq.*; California's Unfair Competition Law, California Bus. & Prof. Code §17200, *et seq.*; and the state laws of unjust enrichment.
- 10. For Plaintiffs' and the Classes' state and federal antitrust claims, the Agreements were illegal contracts, combinations, and a conspiracy that were intended to, and which in fact did, restrain trade in the United States comprising two separate and distinct violations of the Sherman Act, Section 1: (i) by fixing prices for the sale of Lamictal Tablets purchased, paid, or reimbursed by the Indirect Purchasers at anticompetitive levels; and (ii) by allocating substantially the entire market and

territory for generic Lamicatal Tablets and Chewables exclusively to Teva for a period of at least six months, during which time Glaxo agreed not to compete with Teva in the allocated market.

- 11. Defendants engaged in additional violations of the federal and state antitrust laws, by and through the unlawful Agreements, by agreeing and conspiring to grant Glaxo a monopoly in the market for Lamical Tablets, during which time Glaxo sold Lamicatal Tablets purchased, paid, and/or reimbursed by Indirect Purchasers at anticompetitive and monopolistic prices.
- 12. To the extent required for Plaintiffs' claims, the Agreements resulted in two separate and distinct "reverse payments" by Glaxo to Teva: (i) cash payments in form of the revenues resulting from the exclusive license granted to Teva beginning in June 2005 to sell Lamictal Chewables in the United States, a market estimated to be valued at \$50 million annually and shared between a duopoly of Teva and Glaxo; and (ii) an exclusive allocation of the market and territory to sell generic Lamictal Tablets and Chewables for at least six months, to the exclusion of all others generic competitiors, and with an agreement by Glaxo not to sell a "branded-generic" version of Lamicatal Tablets or Chewables.
- 13. The Agreements were unfair and/or deceptive and caused injury to Indirect Purchasers, in violation of the New York, Michigan, and California consumer protection statutes.

- 14. The Agreements were inequitable and caused the unjust enrichment of Defendants at the expense, and to the financial detriment, of Indirect Purchasers.
- 15. Plaintiffs, and all others similarly situated, were injured and sustained damages in the form of overcharges, supra-competitive prices, and higher copayments for branded and generic forms of Lamictal Tablets as a direct and proximate result of Glaxo and Teva's unlawful Agreements.

## II. JURISDICTION AND VENUE

- 16. This Complaint is filed and these proceedings are instituted under the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202, to obtain declaratory relief and the costs of suit, including reasonable attorneys' fees, and any other necessary or proper relief for the injuries sustained by Plaintiffs and members of the Classes resulting from Defendants' unlawful conduct. The jurisdiction of this Court is based upon 28 U.S.C. §§1331, 1332(d), 1337(a), and 1367 and 15 U.S.C. §15.
- 17. Defendants are found or transact business within this district, and the interstate trade and commerce hereinafter described is carried out, in substantial part, in this district. Venue is therefore appropriate within this district under 15 U.S.C. §22 and 28 U.S.C. §1391(b) and (c). The Defendants have also consented in the Agreements to the jurisdiction and venue of this Court.

#### III. THE PARTIES

18. Plaintiff Carolyn McAnaney ("Plaintiff McAnaney") is a citizen of Suffolk County, New York. At all relevant times during the Class Period, Plaintiff

McAnaney was a participant, member, or beneficiary of a health insurance plan. Plaintiff McAnaney's health insurance, which provided prescription drug benefits, required her to pay higher co-payments for brand-named drugs, as compared to her financial responsibility and co-payments for AB-rated generic drugs, including branded and generic formulations of Lamictal Tablets. In 2008, during the Class Period, Plaintiff McAnaney began purchasing generic lamotrigine tablets for personal use. Plaintiff McAnanay was injured by the illegal, anticompetitive, unfair, deceptive, and inequitable conducted described herein, both individually and in a manner that was common and typical of the New York Indirect Purchaser Class and the U.S. Indirect Purchaser Class.

19. Plaintiff International Brotherhood of Electrical Workers Local 38 ("IBEW Local 38") is a health and welfare fund located at 1590 East 23rd Street, Cleveland, Ohio 44114. IBEW Local 38 is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. §186(c)(5), and as defined by §§1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §1001, et seq. As such, IBEW Local 38 is an entity entitled to bring suit in its own name pursuant to 29 U.S.C. §1132(d). Beneficiaries of Plaintiff IBEW Local 38 purchased Lamictal Tablets during the Class Period for personal use. Plaintiff IBEW Local 38 is ultimately at risk and responsible for reimbursing or paying for members' purchases of prescription drugs such as Lamictal Tablets. Plaintiff IBEW Local 38

and its beneficiaries have been injured in their business or property by having paid more or reimbursed more for Lamictal Tablets than they would have absent the Defendants' illegal, anticompetitive, unfair, deceptive, and inequitable conduct alleged herein. Plaintiff IBEW Local 38 was injured by the illegal, anticompetitive, unfair, deceptive, and inequitable conduct described herein, both individually and in a manner that was common and typical of the Michigan Indirect Purchaser Class and the U.S. Indirect Purchaser Class.

20. Plaintiff International Brotherhood of Electrical Workers Local 595 ("IBEW Local 595") is a health and welfare fund administrated from Pleasanton, California. IBEW Local 595 is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to Section 302(c)(5) of the LMRA, 29 U.S.C. §186(c)(5), and as defined by §§1002(1) and (3) of ERISA, 29 U.S.C. §1001, et seq. As such, IBEW Local 595 is an entity entitled to bring suit in its own name pursuant to 29 U.S.C. §1132(d). Beneficiaries of Plaintiff IBEW Local 595 purchased Lamictal Tablets during the Class Period for personal use. Plaintiff IBEW Local 595 is ultimately at risk and responsible for reimbursing or paying for members' purchases of prescription drugs such as Lamictal Tablets. Plaintiff IBEW Local 595 and its beneficiaries have been injured in their business or property by having paid more or reimbursed more for Lamictal Tablets than they would have absent the Defendants' illegal, anticompetitive, unfair, deceptive, and inequitable conduct alleged herein. Plaintiff IBEW Local 595 was injured by the illegal, anticompetitive, unfair,

deceptive, and inequitable conduct described herein, both individually and in a manner that was common and typical of the California Indirect Purchaser Class and the U.S. Indirect Purchaser Class.

- 21. Defendant GlaxoSmithKline LLC (again, "Glaxo") is a limited liability company organized under the laws of Delaware. Plaintiffs and Glaxo have stipulated in this case that Glaxo is the express and/or implied successor to SmithKline Beecham Corporation for all matters, agreements, acts, practices, and conduct alleged in this Complaint. Glaxo is in the business, among other endeavors, of developing, manufacturing, distributing, advertising, and selling the Lamictal products thoughout the United States.
- 22. Defendant Teva Ltd. is a corporation organized and existing under the laws of the country of Israel, and having its registered office at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel. Teva Ltd. is the parent company of Teva USA.
- 23. Defendant Teva USA is incorporated under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Teva USA develops, manufactures, and sells generic pharmaceutical products in the United States. Teva USA is an indirect wholly-owned subsidiary of Teva Ltd.
- 24. Teva Ltd. manufactures the generic lamotrigine tablet product that Teva USA began selling in the United States in July 2008.

#### IV. CLASS ACTION ALLEGATIONS

25. Plaintiffs bring this action on behalf of themselves and, under Rule 23 of the Federal Rules of Civil Procedure, as representatives of four Classes. First, Plaintiffs bring this action under Rule 23(b)(2) for Counts One, Two, and Three of this Complaint seeking a declaratory judgment and other equitable relief confirming violations of the federal antitrust laws, and under Rule 23(b)(3) for Count Ten of this Complaint alleging violations of the common laws of unjust enrichment on behalf of a Class defined as:

All persons or entities in the United States and its territories who indirectly purchased Lamictal Tablets from Glaxo or who indirectly purchased a generic version of Lamictal Tablets from Teva at any time during the Class Period of August 30, 2006, until the effects of Defendants' conduct ceases (the "U.S. Indirect Purchaser Class"). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries, and affiliates, and all federal governmental entities.

26. Second, Plaintiff McAnaney brings this action under Rule 23(b)(3) seeking damages and other permissible remedies for violation of New York GBL \$340, et seq. and \$349, et seq. on behalf of a Class defined as:

All persons or entities who indirectly purchased Lamictal Tablets from Glaxo or who indirectly purchased or reimbursed for a purchase of a generic version of Lamictal Tablets from Teva – produced, manufactured, marketed, sold, or purchased in the state of New York – at any time during the Class Period of August 30, 2006, until the effects of Defendants' conduct ceases (the "New York Indirect Purchaser Class"). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries, and affiliates, and all federal governmental entities.

27. Third, Plaintiff IBEW Local 38 brings this action under Rule 23(b)(3) seeking damages and other permissible remedies for violation of the Mich. Comp. Laws. §§445.772 and 445.773 on behalf of a Class defined as:

All persons or entities who indirectly purchased Lamictal Tablets from Glaxo or who indirectly purchased or reimbursed for a purchase of a generic version of Lamictal Tablets from Teva – produced, manufactured, marketed, sold, or purchased in the state of Michigan – at any time during the Class Period of August 30, 2006, until the effects of Defendants' conduct ceases (the "Michigan Indirect Purchaser Class"). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries, and affiliates, and all federal governmental entities.

28. Fourth, Plaintiff IBEW Local 595 brings this action under Rule 23(b)(3) seeking damages and other permissible remedies for violation of the California Bus. & Prof. Code §16700, *et seq.* and §17200, *et seq.* on behalf of a Class defined as:

All persons or entities who indirectly purchased Lamictal Tablets from Glaxo or who indirectly purchased or reimbursed for a purchase of a generic version of Lamictal Tablets from Teva – produced, manufactured, marketed, sold, or purchased in the state of California – at any time during the Class Period of August 30, 2006, until the effects of Defendants' conduct ceases (the "California Indirect Purchaser Class"). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries, and affiliates, and all federal governmental entities.

29. Members of the Classes are so numerous that joinder is impracticable. While the exact number of Class members is unknown to Plaintiffs, it is believed to be at least in the thousands. Furthermore, the Classes are readily identifiable from information and records in possession of the Defendants.

- 30. Plaintiffs' claims are typical of the members of the Classes. Plaintiffs and all members of the Classes were damaged by the same wrongful conduct by the Defendants -i.e., they have paid artificially inflated and supra-competitive prices or higher co-payments for Lamictal Tablets and were deprived of the benefits of competition from cheaper, generic versions of Lamictal Tablets as a result of Defendants' wrongful, anticompetitive, and deceptive conduct.
- 31. Plaintiffs will fairly and adequately protect and represent the interests of the Classes. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Classes.
- 32. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust and consumer litigation, particularly class action antitrust and consumer litigation in the healthcare industry.
- 33. Questions of law and fact common to the members of the Classes predominate over questions, if any, that may affect only individual Class members. Defendants have also acted on grounds generally applicable to the entire Classes. Such generally applicable questions are inherent in Defendants' wrongful conduct.
  - 34. Questions of law and fact common to the Classes include:
    - a. whether the conduct alleged herein constitutes a violation of the federal, and/or New York, and/or Michigan, and/or California antitrust or consumer protection laws;

- b. whether a relevant market needs to be defined in this case in light of the existence of direct evidence of Glaxo's power to exclude generic competition and charge supra-competitive prices for Lamictal Tablets;
- c. if a relevant market needs to be defined, the definition of the relevant market for analyzing Glaxo's monopoly power, and whether Glaxo had monopoly power in the relevant market;
- d. whether Defendants' actions illegally maintained Glaxo's or Defendants' monopoly power in the relevant market;
- e. whether Defendants' actions constituted an unlawful and anticompetitive agreement in restraint of trade;
- f. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Indirect Purchasers and, if so, the appropriate measure of damages;
- g. whether Defendants fraudulently concealed the terms of their Agreements;
- h. whetherDefendants engaged in misleading, unfair and/or deceptive acts and practices;
- i. whether Defendants were unjustly enriched by their wrongful conduct;

- j. whether and to what extent Defendants should disgorge profitswith which they were unjustly enriched; and
- k. whether Defendants acted or refused to act on grounds that apply generally to the Indirect Purchaser classes defined herein.
- 35. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might now be impracticable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.
- 36. Plaintiffs are unaware of any difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

#### V. REGULATORY AND ECONOMIC BACKGROUND

37. A generic drug is a pharmaceutical product that is the bioequivalent to the brand-name drug in terms of dosage, form, strength, route of administration, quality, performance characteristics, and intended use. When a generic drug is completely equivalent to a brand-name drug, the FDA assigns the generic drug an "AB" rating.

- 38. A generic drug is typically sold at a substantial discount from the brandname drug's price. For insured consumers, generic drugs generally require the payment of lower co-payments than the co-payments for their brand-name equivalents.
- 39. Lamictal is a brand-name drug that is available in the United States only by a prescription written by a physician. When a prescription is written for a brand-name drug such as Lamictal, a pharmacist can fill the prescription only by dispensing either the brand-name drug or its AB-rated generic equivalent.
- 40. Pursuant to state generic substitution laws, and under most health insurance plans, a pharmacist can, will, or must substitute an AB-rated generic version of a prescribed brand-name drug when available, unless the prescribing physician has indicated "DAW" or "dispense as written" on the prescription.
- 41. The entry of a generic drug into the market significantly lowers the costs of the drug, by as much as 90% in the first year. The manufacturer of the brand-name drug will typically suffer a substantial decline in its market share immediately after generic alternatives are made available to purchasers. Glaxo has conceded this result for Lamictal Tablets in its annual reports and public filings with the U.S. Securities and Exchange Commission (the "SEC"). In its 2007 Form 20-F, Glaxo stated, "[t]ypically, sales of existing products decline dramatically when generic competition is introduced either on patent expiry or earlier if there is a successful challenge to the

Group's patent." In subsequent Form 20-F filings, Glaxo reported that generic competition had caused a decline of Lamictal sales by 68% in 2008 and 2009.

- 42. The facts in this case arise in the context of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act" or the "Act"), Pub. L. No. 98-417, 98 Stat. 1585. The Act establishes procedures designed to facilitate the entry of lower-priced, generic versions of existing, brand-name drugs while maintaining incentives to invest in new drug development.
- 43. Firms seeking approval from the FDA to market new drugs have long been required to file a New Drug Application ("NDA") demonstrating the safety and efficacy of a new product. 21 U.S.C. §355(b)(1). An ANDA is an abbreviated form of the NDA submitted for generics and relies on the FDA's prior determinations of safety and efficacy in connection with the application for the brand-name drug.
- 44. Under the Hatch-Waxman Act, the NDA must list with the FDA any patent that might reasonably be asserted against the unauthorized manufacture, sale, or use of the drug. 21 U.S.C. §355(b)(1).
- 45. If an ANDA is subject to one or more listed patents, the FDA cannot approve the ANDA before the patent(s)' expiration, unless the generic applicant files one of four types of certifications, including a Paragraph IV certification through which the generic applicant certifies that the patent in question is either invalid or the generic product does not infringe it. 21 U.S.C. §355(j)(2)(A)(vii)(IV).

- 46. The Act makes the filing of a Paragraph IV certification an "artificial act of infringement." 35 U.S.C. §271(e)(1)-(2).
- 47. The Act also requires the ANDA applicant to notify the patent owner and NDA applicant thereto of this patent challenge. 21 U.S.C. §355(j)(2)(B).
- 48. Thus, a generic drug firm that files a Paragraph IV certification may be sued for infringement well before it has undertaken activities to market the generic drug.
- 49. If the branded drug manufacturer files a patent infringement suit within 45 days of receiving a Paragraph IV certification, FDA approval of the generic drug maker's ANDA application is automatically stayed until the earlier of (1) the expiration of the relevant patent, (2) 30 months from the date of the Paragraph IV certification, or (3) there is a judicial determination that the patent in question is invalid or not infringed. 21 U.S.C. §355(j)(5)(B)(iii).
- 50. In turn, the Act encourages challenging branded drug patents and/or designing around them by granting the first Paragraph IV certified ANDA filer a 180-day period to exclusively market the generic version of the drug during which the FDA may not grant final approval to any other generic drug manufacturer's ANDA for the same brand-name drug. 21 U.S.C. §355(j)(5)(B)(iv). This "180-day exclusivity period" does not begin to run until either the first ANDA applicant enters the market with its generic equivalent, or a court enters a final judgment that the

patent(s) subject to the Paragraph IV certification is invalid or not infringed. 21 C.F.R. §314,107(c)(1).

- 51. The introduction of a generic drug, thus, is an event with unique and dramatic economic consequences for purchasers because generics are significantly lower-priced bioequivalents of branded drugs.
- 52. The practical consequences of generic drug economics create a substantial competitive threat and a motive for the manufacturer of the branded drug to settle its patent infringement suit with the Paragraph IV certification filer.
- 53. The branded firm faced with competition from a generic firm's ANDA, including a Paragraph IV certification, runs the risk that pursuing infringement litigation to a conclusion will result in a determination that its patent is invalid or that the generic (and those that follow after the 180-day exclusivity period) does not infringe any of the patents covering its branded drug.
- 54. Moreover, because it is unlikely to recover damages (the requirement to file said infringement suit within 45 days means the Paragraph IV generic will not have even entered the market by the time the suit is filed), the branded drug maker has little to gain from a litigated judgment in its favor if it can protect the lucrative status quo by settlement. And, although an unfavorable judgment as to patent validity will prevent the branded firm from excluding any future challenger, a favorable judgment will not preclude other would-be entrants from later challenging the patent.

55. Thus, there exists anti-competitive dynamics encouraging the execution of reverse payment agreements that preserve patent monopolies that are undeserved, and that harm purchasers by denying them access to significantly-lower priced generic drugs that are the bioequivalent of branded drugs.

#### VI. FACTUAL ALLEGATIONS

#### A. Defendants' Lamictal Products

- 56. Glaxo sells Lamictal Tablets pursuant to NDA No. 20-241, which was approved by the FDA in 1994. Glaxo sells Lamictal Chewables pursuant to NDA No. 20-764, which was approved by the FDA in August 1998. For the 12 months ending March 2008, Glaxo's sales of Lamictal Tablets in the United States exceeded \$2 billion. The lower-dosage Lamictal Chewable product had annual domestic sales of only about \$50 million during the same time period.
- 57. Upon receiving FDA approval of its NDA for Lamictal Tablets on December 27, 1994, Glaxo was awarded a five-year new chemical entity ("NCE") exclusivity, which expired on or about December 27, 1999. During this five-year period, ANDAs could not be given final approval by the FDA, meaning Glaxo's Lamictal Tablets would be free from generic competition for at least a five-year period.
- 58. Subsequently, Glaxo received approval for a new label indication for the adjunctive treatment of Lennox-Gastaut syndrome in pediatric and adult populations. As part of that approval, Lamictal Tablets were awarded a seven-year orphan drug

exclusivity ("ODE"), commencing on August 24, 1998. Congress enacted the Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1982), in order to encourage firms to develop pharmaceuticals to treat rare diseases and conditions. The Orphan Drug Act establishes a seven-year ODE period during which no ANDA for the same use of a generic version of the drug can be approved. 21 U.S.C. §360cc. However, ODE is indication-specific, meaning that the FDA can approve an ANDA for non-ODE protected uses during the seven-year period. The ODE for Lamictal Tablets expired on or about August 24, 2005, although Lamictal Tablets were approved for additional non-ODE protected indications, which allowed for ANDAs to be approved prior to this date.

- 59. The '017 patent, which expired on July 22, 2008, was the only patent listed in the Orange Book for Lamictal Tablets. The '017 patent, along with another patent (U.S. Patent No. 5,698,226), was listed in the Orange Book as pertaining to Lamictal Chewables, although, as alleged below, the '226 patent played no role in the Patent Litigation between Glaxo and Teva.
- 60. In 2007, years after execution of the Agreements between Glaxo and Teva, Glaxo received a six-month Pediatric Exclusivity, which did not extend the '017 patent's expiration date, but did prevent any ANDA applicant for a product claimed by the '017 patent from receiving final regulatory approval until January 22, 2009, assuming that the '017 patent was not invalidated (a risk eliminated by the

Agreements) or there was a showing that a particular ANDA product did not infringe that patent.

- 61. On April 1, 2002, Teva filed ANDA No. 76-388, seeking approval to manufacture and sell AB-rated generic lamotrigine tablets. A short time later, Teva filed ANDA No. 76-420, seeking approval to manufacture and sell generic lamotrigine chewable tablets.
- 62. Teva was the first to file substantially complete ANDAs for AB-rated generic equivalents to Lamictal Tablets and Lamictal Chewables with Paragraph IV certifications to the '017 patent. It also filed a Paragraph IV certification to the second patent listed in the Orange Book regarding Lamictal Chewables.
- 63. Accordingly, Teva was granted the potentially valuable 180-day exclusivity period for generic lamotrigine tablets and lamotrigine chewables, during which time no other manufacturers could sell generic versions of Lamictal Tablets or Lamictal Chewables (except for Glaxo, which had the legal right to sell authorized generic versions).
- 64. The FDA granted final approval to Teva's ANDA for generic lamotrigine chewables on June 21, 2006, and Teva's ANDA application for generic lamotrigine tablets on August 30, 2006. In doing so, the FDA concluded that: (a) Teva's lamotrigine chewables are bioequivalent to Glaxo's Lamictal Chewables that Teva's lamotrigine chewables have the same safety and efficacy as, and are ABrated, to Glaxo's Lamictal Chewables of the same dosage strength; and (b) Teva's

lamotrigine tablets have the same safety and efficacy as, and are AB-rated to, Glaxo's Lamictal Tablets of the same dosage strength.

## B. The Patent Litigation and Resulting Anti-Competitive Settlement

- 65. Soon after Glaxo's receipt of Teva's Paragraph IV certifications to the '017 patent, Glaxo filed Civil Action Nos. 02-3779 and 02-4537 (again the "Patent Litigation") in this Court, alleging that Teva's two ANDAs infringed the '017 patent. Both suits were filed within 45 days of receipt of the Paragraph IV notices from Teva, entitling Glaxo to automatic 30-month stays of approval of both of Teva's ANDAs. Glaxo did not file suit against Teva based upon the second patent listed for Lamictal Chewables.
- 66. Following discovery, the Patent Litigation proceeded to a bench trial from January 18 to January 25, 2005. By this time, the 30-month stays of regulatory approval on both of Teva's ANDAs had either expired or were about to expire.
- 67. On the final day of trial, the Patent Litigation court orally ruled that the first claim (the independent claim) of the '017 patent was invalid. The Patent Litigation court indicated that a ruling on the validity of the three remaining claims (dependant claims) would be issued.
- 68. The imminent adjudication of the '017 patent raised concerns: (i) for Teva, that the ruling could lead to the triggering of its 180-day exclusivity period for its generic version of Lamictal Tablets before Teva had received final FDA approval;

- and (ii) for Glaxo, that generic entry was imminent for the highly lucrative Lamictal Tablets and Lamictal Chewables.
- 69. The outcome of the Patent Litigation would have directly affected the date on which Teva would be legally permitted to commence sales of generic lamotrigine products. If Glaxo were to prevail, then Teva would have been barred from selling its versions of both Lamictal Tablets and Lamictal Chewables until after the expiration of the '017 patent and any additional exclusivities. On the other hand, if Teva prevailed in demonstrating the '017 patent to be invalid and/or not infringed, then Teva would have been permitted to start selling its products immediately upon FDA approvals, which were ulitmately granted in 2006. Because Teva was sued under the same patent claims and patent infringement theories for its generic version of both Lamictal Tablets and Lamictal Chewables, its chances of litigation success were the same for both products.
- 70. The successful invalidation of the '017 patent would dramatically change the competitive landscape for both Glaxo and Teva in two ways. First, the entry of a final court decision invalidating the '017 patent would start the clock on Teva's 180-day exclusivity period for that patent regardless of whether Teva actually had an FDA-approved product to sell during that period. Thus, the invalidation of the '017 patent would open the floodgates of competition for Lamictal Tablets and Lamictal Chewables because within six months after Teva invalidated the '017 patent, other generics would be able to start selling their AB-rate versions once they received FDA

final approval. Second, if the '017 patent were invalid, the six-month Pediatric Exclusivity period could not attach to the end of that patent and, thus, would not be an effective barrier to entry to Teva or the other generic manufacturers that filed ANDAs to sell generic versions of either Lamictal Tablets or Lamictal Chewables.

- 71. If a decision from the Patent Litigation were delayed past August 30, 2006 (the date Teva received final approval from FDA for its generic lamotrigine tablets), then Teva could have entered the market "at-risk," thus, triggering the start of its 180-day period and prohibiting any other approved ANDA filers from coming to market until six months later. The result of a decision in the Patent Litigation being delayed until after August 30, 2006, was unlikely, insofar as the Patent Litigation court provided an oral ruling on the first '017 patent claim in January 2005, and indicated that rulings on the patent's other claims would be forthcoming shortly thereafter.
- 72. The possibility that Teva might have succeeded in invalidating all of the '017 patent claims posed competitive risks to both Glaxo and Teva. Glaxo faced the danger that if the Patent Litigation court invalidated all the '017 patent's claims, there would be a severe reduction in future revenue due to the loss of exclusivity of Lamictal Tablets and Lamictal Chewables years prior to the listed expiration of the '017 patent. The possibility that Teva might achieve that result prior to final FDA approval for its ANDAs placed Teva in a bind, as a successful final court decision would likely start Teva's 180 days of exclusivity for its generic lamotrigine tablets

and chewables prior to FDA approval, meaning that Teva would not be able to take advantage of its 180-day exclusivity period. Teva's ANDA application for generic lamotrigine chewables did not receive final approval until June 21, 2006, and its ANDA application for generic lamotrigine tablets did not receive final approval until August 30, 2006. Therefore, if the January 2005 bench trial resulted in a successful invalidation of the '017 patent before December 2005, then Teva's 180-day exclusivity would be triggered by a court decision and expire for the both generic lamotrigine tablets and generic lamotrigine chewables before Teva could even begin to bring those products to market. Other competitors that had obtained final approval of their ANDAs for generic versions of Lamictal Tablets or Lamictal Chewables as of June 2006 (assuming invalidation of the '017 patent's claims in the Patent Litigation) could then enter the market before (or at the same time) as Teva.

- 73. Glaxo had an interest in delaying Teva's entry, and all other generic manufactures' entry, for as long as possible so that Glaxo could continue to earn monopoly and anticompetitive profits on Lamictal Tablets, and Teva had an interest in preventing and/or delaying a successful court decision until it would be in a position to take advantage of its valuable 180-day exclusivity for generic lamotrigine tablets.
- 74. Following invalidation by the Patent Litigation court of the first claim of the '017 patent, the parties immediately started settlement negotiations, and on February 2, 2005, Defendants had a conference with the Patent Litigation court

during which they asked the court to refrain from ruling on the validity of the remaining '017 patent claims.

- 75. Approximately two weeks following that conference, Glaxo and Teva agreed to the reverse-payment agreements, combinations, and conspiracy challenged in this action. Their Agreements are set forth in a Settlement Agreement between Glaxo and Teva USA and a License and Supply Agreement between Glaxo and Teva Ltd. (again, the "Agreements"), both of which are dated February 16, 2005. The Settlement Agreement expressly provides that both the Settlement Agreement and the License and Supply Agreement are part of the consideration that Glaxo offered Teva "in reaching agreement to settle."
- 76. The Agreements permitted Teva to sell limited amounts of lamotrigine chewables in the United States, starting on June 1, 2005. Teva was supplied by Glaxo with chewable lamotrigine product that Teva began selling as an authorized generic on May 25, 2005.
- 77. Under the Agreements, Glaxo also granted Teva: (a) a royalty-free, non-transferable license under the '017 patent to import, manufacture, have manufactured, and have sold Teva's generic version of Lamictal Tablets in the United States starting on July 21, 2008, at 5:00 p.m. (Pacific), which was when the '017 patent expired; and (b) a waiver of any potential future Pediatric Exclusivity applicable to Teva's generic version of Lamictal Tablets (which did not exist in February 2005).

- 78. Even though Teva had already succeeded in invalidating the '017 patent's primary, independent claim, and even though there was a significant risk that the patent's other claims might be invalidated, the settlement gave little or no discount or reduction to the patent's exclusionary power (*i.e.*, it did not give Teva the right to enter the market with its generic version of Lamictal Tablets significantly prior to the patent's expiration). And even though Teva's generic versions of both Lamictal Tablets and Lamictal Chewables were subject to the exact same patent claims (and, thus, Teva's chances of litigation success were the exact same for both products), Teva was allowed to start selling a version of the smaller-market, \$50 million-a-year chewable product within three months after the settlement while it agreed to wait at least three years to start selling a generic version of the more than \$2 billion-a-year tablet product.
- 79. The differing treatment and entry dates that Glaxo and Teva negotiated for Lamictal Tablets and Lamictal Chewables (both of which were subject to the exact same patent claims and litigation risks) reflects the reality: (a) that Defendants did not choose (nor did they attempt to choose) entry dates for the two products that reasonably reflected the probability that all of the asserted claims of the '017 patent were invalid; and (b) that Defendants were not concerned about whether the Agreements would keep Teva off the market for the larger-market product longer than was warranted by the patent. Instead, the differing treatment and entry dates that Glaxo and Teva negotiated for Lamictal Tablets and Lamictal Chewables reflects the

reality that Teva was paid financial compensation as part of an anticompetitive agreement and conspiracy to delay entry of its generic Lamictal Tablets, and to put the "cork in the bottle" to deny the FDA authority to approve other ANDAs for Lamictal Tablets. Furthermore, while the negotiated deal benefitted Teva and Glaxo, it is clear that it was not done with any concern or interest for Indirect Purchasers of lamotrigine products.

- 80. Because the Lamictal Chewables sold by Teva beginning in June 2005 were either supplied by Glaxo, or AB-rated only to branded Lamictal Chewables, Teva could not, prior to July 2008, provide lower-priced, generic substitutes for Lamictal Tablets that would: (1) be broadly substituted for the higher-priced Lamictal Tablets, or (2) otherwise efficiently compete with Lamictal Tablets. Accordingly, any benefits gained by the licensed sale by Teva of Lamictal Chewables since June 2005 pale in comparison to the harm incurred by Plaintiffs and the Classes caused by the anticompetitive, unfair, deceptive, and inequitable delayed entry date of Teva's less-expensive, generic lamotrigine tablets.
- 81. Teva received significant consideration in exchange for its agreement to:
  (a) abandon its efforts to invalidate the '017 patent; (b) forego competing against
  Glaxo's Lamictal Tablets with a less-expensive, generic version until the '017 patent
  expired; and (c) prevent all other generic competitors from selling competing, lessexpensive, generic versions of Lamictal Tabets. The consideration paid by Glaxo to
  Teva took the form of two separate and distinct reverse payments and anticompetitive

inducements to restrain competition: (i) cash payments in form of the revenues resulting from the exclusive license granted to Teva beginning in June 2005 to sell Lamictal Chewables in the United States, a market estimated to be valued at \$50 million annually and shared between a duopoly of Teva and Glaxo; and (ii) an exclusive allocation of the market to sell generic Lamictal Tablets for at least six months, to the exclusion of all other generic competitiors, and with an agreement by Glaxo not to sell a "branded-generic" version of Lamictal Tablets.

- 82. In the pleadings from a subsequent Teva-Glaxo litigation, Glaxo acknowledged that its agreement allowing Teva to enter the market to sell a Lamictal Chewable product "formed part of the bargain between Glaxo and Teva" and was one of the "benefits" that Teva received for agreeing to abandon its efforts to invalidate the '017 patent and to stay off the market with the larger-market lamotrigine tablet product for at least three years.
- Agreements was a market allocation agreement in which Teva would be virtually guaranteed to be the exclusive seller of both generic Lamictal Tablets and Lamictal Chewables for a period of 180 days. Since the Agreements put the "cork in the bottle" preventing the FDA from finally approving other generic ANDAs, the Agreements forstalled competition from other generic competitors during Teva's first 180 days selling generic Lamictal Tablets and Lamictal Chewables. Just as important, and anticompetitive, the Agreements contained Glaxo's agreement not to

sell "branded generic" formulations of Lamictal Tablets and Chewables during this same six months. The market-allocation agreement between Glaxo and Teva is evidenced in Sections 2.2 and 2.3 of their Licensing Agreement.

- 84. Due to the Agreements, Teva was allocated exclusive sales of generic Lamictal Tablets and Chewables for 180 days, which enabled it to charge anticompetitive, monopolistick, and supra-competitive prices during those periods, and to maximize its longer-term profits by thus obtaining the "first mover advantage." Glaxo also benefitted in that the Agreements as a whole delayed not only the entry of Teva's generic version, but other generics as well. Thus, by and through these Agreements, Teva and Glaxo afforded themselves a guarantee of higher revenues during these periods of time which resulted in anti-competitive overcharges being imposed upon consumers.
- 85. Based on a review of the Agreements, and its analysis of hundreds of other agreements among branded and generic pharmaceutical manufacturers, the U.S. Federal Trade Commission ("FTC") determined that the Agreements were anticompetive, violated the antitrust laws, and resulted in reverse payments from Glaxo to Teva. The FTC provided its conclusions to this Court in *In re Lamictal Direct Purchaser Antitrust Litig.*, U.S. District Court, District of New Jersey, Master File No. 2:12-cv-00995-WHW-MCA (the "Direct Purchasers Action"). According to the FTC's *amicus curiae* brief, filed on October 5, 2012, responding to Defendants' protestations that the Agreements were lawful and competitive:

Both of Defendants' claims are incorrect. First, Teva received more than the right to enter on a negotiated entry date—it is undisputed that it also received commitments that GSK would not market AG [authorized generic] versions of the two Lamictal products. As such, they guaranteed that Teva would be protected from generic competition on each of its generic Lamictal products for at least six months. In the unique context of the Hatch-Waxman Act, such commitments are often quite lucrative to the generic. Thus, as with the cash payment in *K-Dur*, it is logical to conclude that each of these commitments could have acted as the *quid pro quo* for Teva to accept a later entry date than it otherwise would have.

- 86. Plaintiffs adopt and incorporate into this Complaint the FTC's analysis and conclusions contained in its *amicus curiae* brief submitted in the Direct Purchasers' Action. Plaintiffs further allege a reverse payment separate and distinct from the discussion contained in the FTC's *amicus curiae* brief, of the same type and kind discussed in the *K-Dur* decision, in the form of the cash payments generated by revenues from Teva's licensed sale of Lamictal Chewables beginning in or about June 2006.
- 87. On April 4, 2005, Teva and Glaxo drafted and filed a Stipulation and Order of Dismissal in the Patent Litigation seeking the dismissal of all claims and counterclaims. On the same day the Patent Litigation court signed the dismissal, it also entered an order withdrawing the bench ruling that invalidated the first claim of the '017 patent.
- 88. Absent the payment of the anticompetitive "reverse" inducements from Glaxo (the patent holder) to Teva (the generic competitor and patent challenger) to delay the launch of Teva's generic version of Lamictal Tablets, Teva would likely

have prevailed in the Patent Litigation or Teva would have sought (and the Defendants would have agreed to) a settlement allowing Teva to bring to market its generic Lamictal Tablets earlier than the Agreements allowed. Alternatively, absent a settlement, the parties would have continued to litigate, and Teva's success in the Patent Litigation would have allowed for an earlier launch of generic versions of Lamictal Tablets, or allowed for an at-risk launch by Teva of its generic version of Lamictal Tablets during the Patent Litigation after Teva received final FDA approval.

89. It is well known in the industry that Teva is the most prolific launcher of generic versions of brand-name drugs "at-risk." Launching at risk is a core part of its business strategy. Teva possesses the financial power well above and beyond "at-risk" insurance to cover potentially non-insured losses stemming from at-risk launches. It is also well known that most at-risk launches, or threats of them, generally give rise to settlements of the associated patent litigation.

## C. The Launch of Teva's Generic Lamotrigine Tablets

- 90. Even though it received FDA approval to launch lamotrigine tablets almost two years earlier, Teva delayed launching its generic version of Lamictal Tablets until on or about 5:00 p.m. (Pacific) on July 21, 2008, the earliest date permitted under the Agreements.
- 91. Because of Teva's 180-day exclusivity on generic versions of Lamictal Tablets, which was secured by and through the anticompetitive Agreements

challenged in this action, no other generic was allowed to launch, and none, in fact, did launch, prior to January 22, 2009.

- 92. Teva's 180-day exclusivity period for its generic version of Lamictal Tablets would have been triggered earlier if: (a) Teva and Glaxo had settled the Patent Litigation without the provision of illegal financial inducements to Teva from Glaxo, which would have resulted in a settlement that provided for an earlier entry of Teva's less-expensive, generic version of Lamictal Tablets; and/or (b) Teva had launched its generic lamotrigine tablets (as it would have) upon receipt of final FDA approval on August 30, 2006, either "at-risk" or after successfully invalidating the '017 patent. Instead, because of the unlawful Agreements, Teva did not enter the market until July 21, 2008, leaving its 180-day exclusivity in place and, thereby, blocking final FDA approval and entry of other generic versions of Lamictal Tablets until January 2009.
- 93. The Agreements between Glaxo and Teva that delayed Teva's launch of the generic lamotrigine tablets and guaranteed Teva's 180-day exclusivity period were not necessary for the settlement of the Patent Litigation and constitute ancillary restraints of trade.
  - D. Defendants' Agreements Enabled Them to Charge Anti-Competitive and Supra-Competitive Prices for Lamotrigine Tablets
- 94. The Agreements between Teva and Glaxo guaranteed that Teva's 180-day exclusivity period would not be triggered for the lamotrigine tablet ANDA by a

final court decision in the Patent Litigation before Teva received FDA approval of that ANDA, and ultimately provided Teva with a full 180 days of exclusive generic sales on that product.

- 95. The Agreements between Teva and Glaxo guaranteed that Glaxo would have exclusivity on the lucrative Lamictal Tablet product with no generic competition for more than three years from the date of the Agreements, approximately two years after Teva received final FDA approval for its lamotrigine tablets.
- 96. In consideration for Teva delaying its launch of its generic version of the blockbuster Lamictal Tablet until the close of business on July 21, 2008, Teva secured: (1) the right to immediately launch a licensed Lamictal Chewable product, which generated revenues and profits for Teva in the \$50 million Lamictal Chewables market, but created much smaller consumer savings and benefits than an earlier launch of the lucrative lamotrigine tablet product (*i.e.*, the Indirect Purchaser benefits generated by the earlier launch of generic lamotrigine chewables pales in comparison to the consumer harm created by the anti-competitive delay in entry of the generic lamotrigine tablets); and (2) a virtual guarantee on its ability to sell during the 180-day exclusivity period relating to its generic version of Lamictal Tablets.
- 97. Teva's generic market exclusivity and accompanying supra-competitive pricing generated many millions of dollars of additional revenue for Teva during the six-month exclusivity periods at the expense of Indirect Purchasers who would have

otherwise paid or reimbursed lower prices or co-payments for Teva's generic lamotrigine tablets. In addition, higher, anti-competitive and supra-competitive prices for Lamictal Tablets paid by Direct Purchasers were passed-on and borne substantially by Indirect Purchasers.

98. Defendants' unlawful conduct, thus, delayed not only the launch of less-expensive, generic versions of Lamictal Tablets for the benefit of Indirect Purchasers, but allowed both Teva and Glaxo to profit from charging anti-competitive and supracompetitive prices for lamotrigine products in the relevant market absent any competition for Lamictal Tablets.

### VII. FRAUDLENT CONCEALMENT AND EQUITABLE TOLLING

- 99. Defendants have engaged in deceptive, misleading, and fraudulent efforts to conceal the true nature of their unlawful conduct from Plaintiffs and the Classes through acts of omission, partial disclosures omitting material facts, and misrepresentations. Defendants have intended to and have, in fact, accomplished their concealment through misrepresentations and omissions, as described herein.
- another, to withhold from public disclosure material facts concerning their Agreements challenged in this action as unlawful. In the Licensing Agreement, Article I, §1.1, Glaxo and Teva agreed that the terms of their agreements contained in the Licensing Agreement and Settlement Agreement, among any other agreements

among them concerning Lamictal and its generic equivalents, would be deemed "Confidential Information."

- 101. As "Confidential Information," the Licensing Agreement forbade Glaxo and Teva from disclosing the details of their Agreements challenged in this action to the public, including Plaintiffs and the Classes.
- 102. Glaxo and Teva further agreed, and bound themselves, in §6.3 of the Licensing Agreement, to not make any "public announcement" or engage in any "[p]ublicity" concerning the Agreements challenged as unlawful in this action.
- 103. The anti-publicity provision set forth §6.3 of the Licensing Agreement permitted Teva to issue a brief press release concerning Defendants' agreements, and was attached as an exhibit to the Licensing Agreement. That press release was issued by Teva from Jerusalem, Israel, on February 17, 2005. Aside from disclosing that parties had reached agreements resulting in estimated launch dates for generic lamotrigine pursuant to licenses, the press release stated, "Additional terms of the settlement agreement were not disclosed."
- 104. Upon information and belief, Glaxo has not issued any press releases disclosing the terms of the Agreements challenged as unlawful in this action.
- 105. Upon information and belief, upon informing the Patent Litigation court of their settlement in February 2005, neither Glaxo nor Teva filed with the district court copies of the Settlement Agreement or Licensing Agreement. If such

Agreements were provided to the Patent Litigation court, they were not filed in a manner that was available to the public, Plaintiffs, or the Classes.

- 106. The proposed Stipulation and Order of Dismissal drafted by Glaxo and Teva for presentation to the Patent Litigation court in February 2005, and attached as an exhibit to their Settlement Agreement, did not attach the Agreements challenged as unlawful in this action, nor disclose those Agreements' complete and material terms. Concerning the terms of those Agreements, the proposed Stipulation and Order of Dismissal revealed only that: "Plaintiff and Defendant have reached an agreement to settle the Litigation, which is set forth in this Stipulated Order, a separate Settlement Agreement and a separate License and Supply Agreement, each of which is being executed contemporaneously."
- 107. While it is Teva's routine practice to publicly announce when it receives final FDA approval to market or sell generic equivalents in the United States, it made no public statement that the FDA granted final approval for its ANDA for lamotrigine tablets (25mg, 100 mg, 150 mg, and 200 mg) on August 30, 2006. Upon information and belief, Teva did not inform the public of this FDA final approval because it had agreed with Glaxo to maintain Glaxo's monopoly and anti-competitive pricing for Lamictal Tablets until July 2008.
- 108. Since entering into the Agreements challenged as unlawful in this action in February 2005, Glaxo and Teva have each made multiple filings with the SEC, including annual reports issued on Form 20-F. Material terms of the Agreements

challenged as unlawful in this action were omitted and withheld from those filings with the SEC.

- 109. In its 2005 Form 20-F filed with SEC on or about March 20, 2006, Teva briefly discussed the Agreements, omitting disclosure of material facts concerning the anti-competitive nature of the Agreements challenged in this action, and other material facts (including, but not limited to, the Patent Litigation court's ruling that the first claim of Glaxo's '017 patent was unenforceable and not infringed by Teva's ANDA). Teva's disclosure concerning the challenged Agreements in its 2005 Form 20-F was limited to the following statement:
  - In February 2005, as settlement of a patent dispute with GlaxoSmithKline ("GSK") over the generic version of Lamictal<sup>®</sup>, GSK granted Teva an exclusive royalty-bearing license to distribute generic lamotrigine chewable tablets (5 mg and 25 mg) in the United States no later than June 2005. GSK also granted Teva the exclusive right to manufacture and sell its own generic version of lamotrigine tablets (25 mg, 100 mg, 150 mg and 200 mg) in the U.S., with an expected launch in 2008 prior to patent expiry in July 2008 (plus six months of expected pediatric exclusivity).
- 110. In accordance with their agreement to withhold public disclosure of the concerning material terms of the Agreements, neither the Licensing Agreement nor Settlement Agreement were provided as exhibits to this Teva Form 20-F, or any subsequently-filed Form 20-F.
- 111. No details concerning Defendants' challenged Agreements were contained in Teva's 2006 Form 20-F.

- 112. Teva's Forms 20-F filed with SEC for years 2007 and 2008 contained substantially similar statements and material omissions as contained in the 2005 Form 20-F concerning the Agreements challenged as unlawful in this action.
- 113. On July 22, 2008, Teva issued a press release from Jerusalem, Israel, and filed with the SEC on Form 6-K, a statement that disclosed only generalized and partial details of its Agreements with Glaxo, challenged as unlawful in this action, and contained material omissions. Concerning the Agreements, Teva's press release disclosed only that: "In February 2005, GlaxoSmithKline and Teva entered into an agreement to settle patent litigation under which GlaxoSmithKline granted Teva the exclusive right to manufacture and sell a generic version of Lamictal® during the sixmonth pediatric exclusivity which ends on January 22, 2009."
- 114. In its 2005 Form 20-F filed with the SEC on or about March 3, 2006, Glaxo likewise omitted substantive disclosure of the terms of the Agreements, challenged in this lawsuit as unlawful, and other material facts (including, but not limited to, the Patent Litigation court's ruling that the first claim of Glaxo's '017 patent was unenforceable and not infringed by Teva's ANDA). Glaxo's disclosure concerning the challenged Agreements in its 2005 Form 20-F was limited to the following statements:

Lamictal. The patent on lamotrigine is not due to expire until 2009 (USA). Litigation challenging the validity of this patent in the USA has been settled. In Europe, the corresponding patent has expired and generic competition exists.

[Footnotes omitted.]

\* \* \*

#### Lamictal

In August 2002, the Group commenced an action in the US District Court for the District of New Jersey against Teva Pharmaceuticals USA Inc., alleging infringement of the Group's compound patent for lamotrigine, the active ingredient in Lamictal oral tablets. That patent affords protection through January 2009 after giving effect to a grant of paediatric exclusivity by the FDA. Teva had filed an ANDA with the FDA with a certification of invalidity of the Group's patent. The parties reached a settlement agreement pursuant to which the Group has granted Teva an exclusive royalty-bearing license to distribute in the USA a generic version of lamotrigine chewable tablets. In addition, Teva was granted the exclusive right to manufacture and sell Teva's own generic version of lamotrigine tablets in the USA with an expected launch date in 2008.

- 115. In accordance with their agreement to withhold public knowledge concerning material terms of the Agreements, neither the Licensing Agreement nor the Settlement Agreement were provided as exhibits to this Glaxo Form 20-F, or any subsequently-filed Form 20-F.
- 116. Glaxo's Form 20-F filed with SEC for 2006 contained substantially similar statements and material omissions concerning the facts and Agreements challenged as unlawful in this action. The Form 20-F filed by Glaxo for 2007 contained even fewer disclosures concerning the Agreements challenged as unlawful in this action, and subsequent Forms 20-F did not contain any disclosures.
- 117. A September 25, 2006 press release issued by Glaxo in the United States announced a new FDA-approved indication for Lamictal, but was entirely devoid of any disclosure concerning the Agreements challenged as unlawful in this action.

- 118. An October 15, 2007 press release issued by Glaxo in the United States announced research findings concerning extended-release Lamictal, but was entirely devoid of any disclosure concerning the Agreements challenged as unlawful in this lawsuit.
- 119. A June 1, 2009 press release issued by Glaxo in the United States announced FDA approval of Lamictal XRTM, but was entirely devoid of any disclosure concerning the Agreements challenged as unlawful in this action.
- 120. As a result and proximate cause of Defendants' concealment, and because Defendants represent or represented that the unlawful fees are legitimately charged and collected, Plaintiffs learned of the existence of their claims against Defendants shortly prior to becoming parties in this action. For the same reasons, members of the Classes were likely to be reasonably unaware of Defendants' unlawful acts and the claims alleged in this action.
- 121. A reasonably diligent Indirect Purchaser, including Plaintiffs and members of the Classes, could not have learned of their claims alleged in this action, or all the material events giving rise to their claims in this action, prior to various press reports and public accounts concerning the filing of the lawsuit by the Direct Purchasers on or about February 17, 2012. The claims alleged in this action have been tolled since that time.
- 122. Plaintiffs' and the Classes' lack of knowledge as to the existence of their claims against Defendants was not due to any fault or lack of reasonable diligence on

their part, but rather due entirely or substantially to the acts of Defendants designed to conceal and hide the true nature of their unlawful and inequitable conduct. To the contrary, Plaintiffs have been diligent in bringing their claims in this action, both individually and on behalf of the Classes.

123. Plaintiffs' and the Classes' claims alleged in this action were tolled, equitably and/or as a result of Defendants' fraudulent concealment, at least until February 17, 2012.

### VIII. CONTINUING HARM AND INURY

124. Plaintiffs and all members of the Classes were harmed and suffered separate injuries and claims against Defendants each and every time Plaintiff and each member of the Classes purchased Lamictal Tablets (25mg, 100 mg, 150 mg, and 200 mg) during the Class Period.

### IX. THE RELEVANT MARKET

125. Direct proof exists that Glaxo had monopoly power over the price of lamotrigine tablets and their AB-rated generic equivalents. Such direct evidence will include: (i) manufacturers' and/or market-wide transactional data that will show a significant, non-transitory decline in lamotrigine tablet prices upon entry of generic lamotrigine tablets that had not occurred until generic entry; and (ii) abnormally high price-cost margins enjoyed by Glaxo prior to the entry of generic competition. This direct evidence of monopoly power obviates the need to define a relevant product market in determining whether Glaxo had monopoly power.

- 126. Assuming that a relevant market needs to be defined, the relevant product market is all lamotrigine tablet products -i.e., Lamictal Tablets (as defined above) and AB-rated equivalent lamotrigine products. The relevant geographic market is the United States and its territories. A firm that was the only seller of such products in the United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by Glaxo's ability to profitably charge supra-competitive prices during the period in which it lacked generic competition. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which lamotrigine products are prescribed.
- 127. Consistent with the Relevant Market defined in this Complaint, Defendants defined the "Territory" for their Licensing Agreement as the "United States of America (including the Commonwealth of Puerto Rico)." Defendants fixed prices and allocated markets for the marketing and sale of Lamictal Tablets and Chewables, in both branded and generic formulations, for the purpose of increasing the price paid by indirect purchasing consumers and payors to anti-competitive levels within the relevant market, including the "Territory" defined in the Licensing Agreement.
- 128. Through the anti-competitive conduct alleged herein, Defendants were able to profitably charge anti-competitive and supra-competitive prices for lamotrigine tablets without losing substantial sales, and, thus, by definition, maintained monopoly

power with respect to lamotrigine tablets sold in the United States. Those anticompetitive and supra-competitive prices were passed on and borne by Indirect Purchasers in the form of higher prices and co-payments.

- 129. Glaxo's market share of the relevant market throughout the Class Period was 100% until the entry of Teva's generic version of the Lamictal Tablet. Glaxo and Teva's combined market share of the relevant market was 100% from that point until the expiration of Teva's 180-day exclusivity period.
- 130. At all relevant times, Glaxo, and later Glaxo in combination with Teva, benefited from high barriers to entry with respect to this relevant market.

### FIRST CAUSE OF ACTION

## DECLARATORY JUDGMENT ACT CLAIM CONCERNING VIOLATIONS OF SECTION 1 OF THE SHERMAN ACT FOR PRICE FIXING

(15 U.S.C. §1)

- 131. Plaintiffs incorporate and reallege all paragraphs in this Complaint, as though fully set forth below.
- 132. Glaxo and Teva are horizontal competitors in the relevant geographic and product markets for therapeutically-equivalent Lamictal Tablets.
- 133. Beginning in or about January 2005, Glaxo and Teva engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade, the purpose and effect of which was to: (a) fix the price at which Plaintiffs and the other members of the Classes would pay for lamotrigine tablets at the higher, branded price

until at least July 21, 2008; and (b) fix the price at which Plaintiffs and the members of the Classes would pay for generic lamotrigine tablets until at least January 22, 2009.

- distinct reverse payments by Glaxo to Teva: (i) cash payments in the form of the revenues resulting from the exclusive license granted to Teva beginning in June 2005 to sell Lamictal Chewables in the United States, a market estimated to be valued at \$50 million annually and shared between a duopoly of Teva and Glaxo; and (ii) an exclusive allocation of the market and territory to sell generic Lamictal Tablets and Chewables for at least six months, to the exclusion of all other generic competitiors, and with an agreement by Glaxo not to sell a "branded-generic" version of Lamictal Tablets or Chewables.
- 135. By entering into these unlawful conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' Agreements are horizontal price-fixing agreements between actual or potential competitors and, thus, are *per se* violations of Section 1. In the alternative, Defendants' Agreements are unreasonable restraints of trade in violation of Section 1 when viewed under a "quick look" or "rule of reason" mode of analysis.
- 136. Plaintiffs and all members of the U.S. Indirect Purchaser Class have been injured in their business and property by reason of Defendants' unlawful contract,

combination, and conspiracy. During the Class Period, Plaintiffs and the U.S. Indirect Purchaser Class members have paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper, generic alternative for their purchases of the more-expensive Lamictal Tablets and/or Teva's generic equivalent. But for Defendants' violations of Section 1 of the Sherman Act, competitors would have begun marketing AB-rated generic versions of lamotrigine tablets well before July 2008 and/or would have been able to market such versions more successfully.

137. Defendants' actions, as alleged herein, constitute violations of Section 1 of the Sherman Act, 15 U.S.C. §1. Pursuant to the Declaratory Judgment Act, Plaintiffs seek a judgment and decree that Defendants have violated Section 1 of the Sherman Act.

#### SECOND CAUSE OF ACTION

## DECLARATORY JUDGMENT ACT CLAIM CONCERNING VIOLATIONS OF SECTION 1 OF THE SHERMAN ACT FOR ALLOCATION OF MARKETS

(15 U.S.C. §1)

138. Plaintiffs incorporate and reallege all paragraphs in this Complaint, as though fully set forth below.

- 139. Glaxo and Teva are horizontal competitors in the relevant geographic and product markets, comprising the relevant market, for therapeutically-equivalent Lamictal Tablets.
- 140. Beginning in or about January 2005, Glaxo and Teva engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of Lamictal Tablets in the United States to Glaxo until July 21, 2008; and (b) allocate substantially all sales of generic versions of lamotrigine tablets to Teva by preventing the entry of all generic versions other than Teva's (including Glaxo-authorized, produced or licensed generic or generic equivalent versions) until January 22, 2009.
- 141. But for Defendants' market allocation agreement, Glaxo would have sold an authorized, Glaxo-produced or licensed generic or generic equivalent version of Lamictal Tablets starting on or about July 21, 2008 (or earlier if Teva had started selling its generic version of Lamictal tablets earlier).
- 142. To the extent required, the Agreements resulted in two separate and distinct reverse payments by Glaxo to Teva: (i) cash payments in form of the revenues resulting from the exclusive license granted to Teva beginning in June 2005 to sell Lamictal Chewables in the United States, a market estimated to be valued at \$50 million annually and shared between a duopoly of Teva and Glaxo; and (ii) an exclusive allocation of the market and territory to sell generic Lamictal Tablets and Chewables for at least six months, to the exclusion of all other generic competitors,

and with an agreement by Glaxo not to sell a "branded-generic" version of Lamictal Tablets or Chewables.

- 143. By entering into these unlawful conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' Agreements are horizontal market allocation agreements between actual or potential competitors and, thus, are *per se* violations of Section 1. In the alternative, Defendants' Agreements are unreasonable restraints of trade in violation of Section 1 when viewed under a "quick look" or "rule of reason" mode of analysis.
- 144. The U.S. Supreme Court has consistently interpreted market or territorial allocation agreements between horizontal competitors, such as the Agreements between Glaxo and Teva, to violate the Sherman Act, of 15 U.S.C. §1:

In *United States v. Topco Associates, Inc.*, 405 U.S. 596, 31 L. Ed. 2d 515, 92 S. Ct. 1126 (1972), we held that agreements between competitors to allocate territories to minimize competition are illegal: "One of the classic examples of a per se violation of §1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition.... This Court has reiterated time and time again that 'horizontal territorial limitations ... are naked restraints of trade with no purpose except stifling of competition.' Such limitations are *per se* violations of the Sherman Act." *Id.*, at 608 (citations omitted).

Palmer v. BRG of Georgia, Inc., 498 U.S. 46, 49-50 (1990).

145. Plaintiffs and all members of the U.S. Indirect Purchaser Class have been injured in their business and property by reason of Defendants' unlawful contract,

combination, and conspiracy. During the Class Period, Plaintiffs and the U.S. Indirect Purchaser Class members have paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' allocation of markets in violation of the Sherman Act, Section 1, and/or were prevented from substituting a cheaper, generic alternative for their purchases of the more-expensive Lamictal Tablets and/or Teva's generic equivalent. But for Defendants' violations of Section 1 of the Sherman Act, generic competitors would have begun marketing AB-rated generic versions of lamotrigine tablets well before July 2008 and/or would have been able to market such versions more successfully, and Glaxo (or its licensee) would have begun marketing, or marketing substantially more, Glaxo-produced "branded generic" versions Lamicatal Tablets before January 22, 2009.

146. Defendants' actions, as alleged herein, constitute violations of Section 1 of the Sherman Act, 15 U.S.C. §1. Pursuant to the Declaratory Judgment Act, Plaintiffs seek a judgment and decree that Defendants have violated Section 1 of the Sherman Act.

### THIRD CAUSE OF ACTION

# DECLARATORY JUDGMENT ACT CLAIM CONCERNING VIOLATION OF SECTION 2 OF THE SHERMAN ACT FOR MONPOLIZATION AND ATTEMPTS TO MONOPOLIZE AGAINST GLAXO AND TEVA

(15 U.S.C. §2)

- 147. Plaintiffs incorporate and reallege all paragraphs in this Complaint, as though fully set forth below.
- 148. As a result of the unlawful Agreements and the combinations, conspiracies, acts, practices, and conduct in furtherance of enforcing and complying with the Agreements, Glaxo unlawfully restrained and monopolized trade and attempted to monopolize trade with specific intent in violation of Section 2 of the Sherman Act. Glaxo did, in fact, monopolize trade in the United States in the market for lamotrigine tablets and eliminated competition in the sale of Lamictal Tablets and generic equivalents in the United States.
- 149. As a result of the unlawful Agreements and the combinations, acts, practices, and conduct in furtherance of enforcing and complying with the Agreements, Glaxo and Teva conspired to restrain and monopolize trade in the United States in the market for Lamictal Tablets and eliminated competition to the sale of Lamictal Tablets and generic equivalents in the United States, thereby preserving Glaxo's monopoly in the market for Lamictal Tablets for Defendants' mutual financial gain.

- 150. During the Class Period, Plaintiffs and the U.S. Indirect Purchaser Class purchased Lamictal and, by reason of Defendants' violations of Section 2 of the Sherman Act, Plaintiffs and U.S. Indirect Purchaser Class members paid more than they would have paid in the absence of Defendants' Agreements that violated Section 2 of the Sherman Act, 15 U.S.C. §2.
- 151. Defendants' actions, as alleged herein, constitute violations of Section 2 of the Sherman Act, 15 U.S.C. §2. Pursuant to the Declaratory Judgment Act, Plaintiffs seek a judgment and decree that Defendants have violated Section 2 of the Sherman Act.

### FOURTH CAUSE OF ACTION

### VIOLATION OF NEW YORK GBL §340 ET SEQ.

- 152. Plaintiff McAnaney incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.
- 153. The aforementioned practices by Defendants were and are in violation of New York's Donnelly Act, New York GBL §340, *et seq*. The aforementioned practices have a significant impact on commerce within the state of New York.
- 154. As alleged herein, Defendants entered into the Agreements, each and together, constituing a contract, agreement, arrangement, or combination to establish and maintain a monopoly in the conduct of trade or commerce in New York. Glaxo, with the material assistance of Teva, did, in fact, establish a monopoly in the market

for lamotrigine tablets and eliminated competition to the sale of Lamictal Tablets and generic equivalents within New York and throughout the United States.

- and together, constituting a contract, agreement, arrangement, or combination to restrain competition in the conduct of trade or commerce in New York. Beginning in or about January 2005, and continuing through January 2009, Glaxo and Teva engaged in a continuing, illegal contract, combination, and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of Lamictal Tablets in the United States to Glaxo until July 21, 2008; (b) fix the price at which Plaintiff McAnaney and the other members of the Class would pay for Lamictal Tablets at the higher, branded price during that period; and (c) prevent the sale of generic versions of lamotrigine tablets other than Teva's, in the United States until at least January 22, 2009.
- 156. Plaintiff McAnaney and all members of the New York Indirect Purchaser Class have been injured in their business and property by reason of Defendants' unlawful contracts, combinations, and conspiracy. Plaintiff McAnaney and the New York Indirect Purchaser Class members have paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper, generic alternative for their purchases of the more-expensive Lamictal Tablets and/or Teva's generic equivalent.

- 157. As a result of Defendants' illegal conduct, Plaintiff McAnaney and the New York Indirect Purchaser Class paid more than they would have paid for lamotrigine tablets, absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing AB-rated generic versions of lamotrigine tablets well before July 2008 and/or would have been able to market such versions more successfully.
- 158. If manufacturers of AB-rated generic lamotrigine tablets entered the market and competed with Lamictal Tablets in a full and timely fashion (including Glaxo through the launch of an authorized generic), Plaintiff McAnaney and other New York Indirect Purchaser Class members would have substituted lower-priced and lower co-payment generic lamotrigine tablets for the higher-priced, brand-name Lamictal Tablets and/or Teva's generic lamotrigine tablets for some or all of their lamotrigine requirements, and/or would have paid lower prices on some or all of their remaining purchases of Glaxo's Lamictal Tablets and/or Teva's generic equivalent.
- 159. During the relevant period, Plaintiff McAnaney and the other New York Indirect Purchaser Class members purchased Lamictal Tablets indirectly from Glaxo and/or their generic equivalent indirectly from Teva. As a result of the Defendants' illegal conduct alleged herein, Plaintiff McAnaney and the other New York Indirect Purchaser Class members were compelled to pay, and did pay, artificially inflated prices or co-payments for their lamotrigine tablet requirements. Plaintiff McAnaney and the other New York Indirect Purchaser Class members paid prices and co-

payments for lamotrigine tablets that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (i) New York Indirect Purchaser Class members were deprived of the opportunity to purchase lower-priced, generic lamotrigine tablets instead of more-expensive, brand-name Lamictal Tablets; (ii) New York Indirect Purchaser Class members were forced to pay artificially inflated prices for generic lamotrigine tablets; and/or (iii) the price of brand-name Lamictal Tablets was artificially inflated by Defendants' illegal conduct.

- 160. During the period covered by this Complaint and thereafter, Plaintiff McAnaney and the New York Indirect Purchaser Class purchased Lamictal and, by reason of the alleged violation of New York GBL §340, *et seq.*, Plaintiff McAnaney and other New York Indirect Purchaser Class members paid more than they would have paid in the absence of Defendants' conduct. As a proximate result thereof, Plaintiff and members of the New York Indirect Purchaser Class have been injured and have suffered damages in an amount according to proof at trial.
- 161. To the extent New York law so requires, Plaintiff McAnaney hereby forgoes any minimum or punitive damages in order to preserve the right of New York Indirect Purchaser Class members to recover by way of a class action.

# FIFTH CAUSE OF ACTION VIOLATION OF NEW YORK GBL §349 ET SEQ.

162. Plaintiff McAnaney incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.

- 163. By the foregoing conduct, Defendants' anti-competitive conduct constitutes deceptive and misleading practices in the conduct of trade or commerce in New York, which is violative of New York GBL §349. By the foregoing conduct, Defendants have also engaged in deceptive and fraudulent acts or practices in violation of New York GBL §349 in the conduct of trade or commerce in New York.
- 164. As a direct and proximate result of Defendants' anti-competitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff McAnaney and the New York Indirect Purchaser Class were materially misled as to: (i) the inflated price and higher co-payments of brand-name Lamictal Tablets; (ii) the fair market price of brand-name Lamictal Tablets, but for the anti-competitive conduct alleged herein; and (iii) the availability of lower-priced, generic lamotrigine tablets, but for the anti-competitive conduct alleged herein.
- 165. As a direct and proximate result of Defendants' anti-competitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff McAnaney and the New York Indirect Purchaser Class were deprived of the opportunity to purchase lower-priced, generic lamotrigine tablets instead of more-expensive, brand-name Lamictal Tablets, and were forced to pay artificially inflated prices or co-payments for generic lamotrigine tablets. Further, the price of brand-name Lamictal Tablets was artificially inflated by Defendants' illegal conduct.
- 166. Defendants' misleading and deceptive acts and practices adversely impacted Plaintiff McAnaney and members of the New York Indirect Purchaser Class,

and, therefore, constitute consumer-oriented conduct under New York GBL §349, that resulted in an actual and direct harm to Plaintiff McAnaney and New York Indirect Purchaser Class members.

- 167. Plaintiff McAnaney and members of the New York Indirect Purchaser Class have suffered actual losses, damages, and injuries, including financial losses, damages, and injuries as a result of Defendants' violations of New York GBL §349(a).
- 168. Defendants' violations of New York GBL §349(a) have directly, foreseeably, and proximately caused damages and injury to Plaintiff McAnaney and New York Indirect Purchaser Class members.
- 169. Plaintiff McAnaney and members of the New York Indirect Purchaser Class are entitled to pursue claims against Defendants for damages, statutory damages, treble damages, exemplary damages, injunctive relief, costs, and attorneys' fees pursuant to New York GBL §349(h) to redress Defendants' violations of GBL §349(a).
- 170. To the extent New York law so requires, Plaintiff McAnaney hereby forgoes any minimum or punitive damages in order to preserve the right of New York Indirect Purchaser Class members to recover by way of a class action.

### SIXTH CAUSE OF ACTION

# **VIOLATION OF MICH. COMP. LAWS §445.772**

- 171. Plaintiff IBEW Local 38 incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.
- 172. The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws. §445.772, and were undertaken in the market for lamotrigine tablets in the conduct of trade or commerce within the State of Michigan.
- 173. Beginning in or about January 2005, and continuing through January 2009, Glaxo and Teva engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade, the purpose and effect of which was to: (i) allocate all sales of Lamictal Tablets in the United States to Glaxo until July 21, 2008; (ii) fix the price at which Plaintiff IBEW Local 38 and the other members of the Michigan Indirect Purchaser Class would pay or reimburse for Lamictal Tablets at the higher, branded price during that period; and (iii) prevent the sale of generic versions of lamotrigine tablets other than Teva's in the United States until at least January 22, 2009.
- 174. By entering into these unlawful conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Mich. Comp. Laws. §445.772. Defendants' Agreements are horizontal market allocation and price-fixing agreements between actual or potential competitors and, thus, are *per se* violations of

Mich. Comp. Laws. §445.772. In the alternative, Defendants' Agreements are unreasonable restraints of trade in violation of that statute when viewed under a "quick look" or "rule of reason" mode of analysis.

175. Plaintiff IBEW Local 38 and all members of the Michigan Indirect Purchaser Class have been injured in their business and property by reason of Defendants' unlawful contract, combination, and conspiracy. Plaintiff IBEW Local 38 and the Michigan Indirect Purchaser Class members have paid or reimbursed more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper, generic alternative for their purchases of the more-expensive Lamictal Tablets and/or Teva's generic equivalent. But for Defendants' illegal conduct, competitors would have begun marketing AB-rated generic versions of Lamictal Tablets well before July 2008 and/or would have been able to market such versions more successfully.

176. As a result of Defendants' illegal conduct, Plaintiff IBEW Local 38 and the Michigan Indirect Purchaser Class paid more than they would have paid for lamotrigine tablets absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing AB-rated generic versions of Lamictal Tablets well before July 2008 (including Glaxo through the launch of an authorized generic), and/or would have been able to market such versions more successfully.

177. If manufacturers of AB-rated generic lamotrigine tablets entered the market and competed with Lamictal Tablets in a full and timely fashion (including Glaxo through the launch of an authorized generic), Plaintiff IBEW Lcal 38and other Michigan Indirect Purchaser Class members would have substituted lower-priced and lower co-payment generic lamotrigine tablets for the higher-priced, brand-name Lamictal Tablets and/or Teva's generic lamotrigine tablets for some or all of their lamotrigine requirements, and/or would have paid or reimburesed lower prices on some or all of their remaining purchases of Glaxo's Lamictal Tablets and/or Teva's generic equivalent.

178. During the Class Period, Plaintiff IBEW Local 38 and the other Michigan Indirect Purchaser Class members purchased substantial amounts of Lamictal Tablets indirectly from Glaxo and/or their generic equivalent indirectly from Teva. As a result of the Defendants' illegal conduct alleged herein, Plaintiff IBEW Local 38 and the other Michigan Indirect Purchaser Class members were compelled to pay, and did pay, artificially inflated prices for their lamotrigine tablet requirements. Plaintiff IBEW Local 38 and the other Michigan Indirect Purchaser Class members paid prices and co-payments for lamotrigine tablets that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (i) Michigan Indirect Purchaser Class members were deprived of the opportunity to purchase lower-priced, generic Lamictal Tablets instead of expensive, brand-name Lamictal Tablets; (ii) Michigan Indirect Purchaser Class members were forced to pay

artificially inflated prices for generic lamotrigine tablets; and/or (iii) the price of brand-name Lamictal Tablets was artificially inflated by Defendants' illegal conduct.

- 179. The injury to Plaintiff IBEW Local 38 and the other Michigan Indirect Purchaser Class members is the type of injury Michigan state antitrust laws were designed to prevent and the injury flows from Defendants' unlawful conduct.
- 180. During the period covered by this Complaint and thereafter, Plaintiff IBEW Local 38 and the Michigan Indirect Purchaser Class purchased Lamictal and by reason of the alleged violation of the Mich. Comp. Laws. §445.772 Plaintiff IBEW Local 38 and other Michigan Indirect Purchaser Class members paid or reimbursed more than they would have paid in the absence of Defendants' conduct. As a proximate result thereof, Plaintiff IBEW Local 38 and Michigan Indirect Purchaser Class members have been injured and have suffered damages in an amount according to proof at trial.

# SEVENTH CAUSE OF ACTION VIOLATION OF MICH. COMP. LAWS §445.773

- 181. Plaintiff IBEW Local 38 incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.
- 182. Defendant Glaxo unlawfully restrained and monopolized trade and attempted to monopolize trade for the purpose of excluding or limiting competition or controlling, fixing, or maintaining prices in the market for Lamictal Tablets in violation of Mich. Comp. Laws. §445.773.

- 183. Glaxo did, in fact, monopolize trade in the United States in the market for Lamictal Tablets, and eliminated competition to the sale of Lamictal Tablets and generic equivalents in the United States. Glaxo further monopolized trade in the market for Lamictal Tablets to maintain supra-competitive prices for Lamictal.
- 184. The injury to Plaintiff IBEW Local 38 and the other Michigan Indirect Purchaser Class members is the type of injury Michigan antitrust laws were designed to prevent and the injury flows from Defendants' unlawful conduct. During the Class Period, Plaintiff IBEW Local 38 and the Michigan Indirect Purchaser Class purchased Lamictal Tablets, for which, by reason of the alleged violation of the antitrust laws, Plaintiff IBEW Local 38 and the Michigan Indirect Purchaser Class paid or reimbursed more than it would have paid in the absence of Defendants' conduct. As a proximate result thereof, Plaintiff IBEW Local 38 and Michigan Indirect Purchaser Class members have been injured and will continue to be injured in its business and property and have suffered damages in an amount according to proof at trial.

### **EIGHTH CAUSE OF ACTION**

# VIOLATION OF THE CARTWRIGHT ACT (CALIFORNIA BUS. & PROF. CODE §16700, ET SEQ.)

- 185. Plaintiff IBEW Local 595 incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.
- 186. The Agreements and Defendants' combinations, acts, practices, and conduct in furtherance of enforcing and complying with the Agreements violated California's Cartwright Act, California Bus. & Prof. Code §16700, et seq., which

prohibits, among other things, any combination to create or carry out restrictions in trade or commerce, and any agreement to fix the price of a product.

- 187. IBEW Local 595 and California Indirect Purchaser Class members have been injured in their business or property by reason of Defendants' violations of the Cartwright Act. During the Class Period, IBEW Local 595 and California Indirect Purchaser Class members paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper, generic alternative for their purchases of the more-expensive Lamictal Tablets and/or Teva's generic equivalent.
- 188. Pursuant to California Bus. & Prof. Code §16750, IBEW Local 595 and California Indirect Purchaser Class members are entitled to three times the damages sustained by them as a result of Defendants' violations of the Cartwright Act.

#### NINTH CAUSE OF ACTION

# VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW (CALIFORNIA BUS. & PROF. CODE §17200, ET SEQ.)

- 189. Plaintiff IBEW Local 595 incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.
- 190. The Agreements and Defendants' combinations, acts, practices, and conduct in furtherance of enforcing and complying with the Agreements violated California's Unfair Competition Law, California Bus. & Prof. Code §17200, *et seq.*, which prohibits any unlawful, unfair, or fraudulent business act or practice.

- 191. IBEW Local 595 and California Indirect Purchaser Class members have been injured and lost money or property by reason of Defendants' violations of the Unfair Competition Law. During the Class Period, IBEW Local 595 and California Indirect Purchaser Class members paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper, generic alternative for their purchases of the more-expensive Lamictal Tablets and/or Teva's generic equivalent.
- 192. Pursuant to California Bus. & Prof. Code §1704, IBEW Local 595 and California Indirect Purchaser Class members are entitled to equitable relief, including restitution of the amounts they have lost and Defendants have gained as a result of their violations of the Unfair Competition Law.

# TENTH CAUSE OF ACTION UNJUST ENRICHMENT UNDER STATE LAW

- 193. Plaintiffs incorporate and reallege all paragraphs in this Complaint, as though fully set forth below.
- 194. Defendants have violated the common law of unjust enrichment in New York, Michigan, and California, and the laws of unjust enrichment across all the states and territories of the United States.
- 195. Defendants have benefited from the unlawful and inequitable acts alleged in this Complaint.

- 196. Plaintiffs and members of the U.S. Indirect Purchaser Class have conferred upon Defendants a traceable economic benefit in the nature of profits resulting from unlawful overcharges and supra-competitive prices for Lamictal Tablets, to the economic detriment of Plaintiffs and the U.S. Indirect Purchaser Class.
- 197. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments or higher co-payments for Lamictal by Plaintiffs and U.S. Indirect Purchaser Class members.
- 198. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supra-competitive and artificially inflated prices for Lamictal is a direct and proximate result of Defendants' unlawful practices.
- 199. The financial benefits derived from or inuring to the benefit of Defendants resulting from or traceable to anti-competitive and monopolistic prices paid by Plaintiffs and the U.S. Indirect Purchaser Class during the Class Period rightfully and equitably belong to Plaintiffs and the U.S. Indirect Purchaser Class.
- 200. Under the common laws of New York, Michigan, California, and the states of the United States, it would be inequitable and unjust for Defendants to retain any of the overcharges for Lamictal derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.
- 201. Plaintiffs' and the Classes' unintentional conferral of profits onto Defendants was brought about by Defendants' anti-competitive, deceptive, and inequitable methods, acts, and practices alleged in this Complaint.

- 202. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the U.S. Indirect Purchaser Classes all unlawful or inequitable proceeds received by them.
- 203. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and the U.S. Indirect Purchaser Classes.
- 204. It would be futile for Plaintiffs and the U.S. Indirect Purchaser Classes to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiffs and the U.S. Indirect Purchaser Classes.
- 205. It would be futile for Plaintiffs and the U.S. Indirect Purchaser Classes to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Lamictal or its generic equivalents, as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Defendants.
- 206. In the alternative, Plaintiffs and the U.S. Indirect Purchaser Classes have no adequate remedy at law.

### PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Classes, pray for judgment against all Defendants, jointly and severally, as follows:

- A. That the Court declare, adjudge, and decree that the Defendants and each of them have violated Sections 1 and 2 of the Sherman Antitrust Act; New York GBL §§340 and 349; Mich. Comp. Laws §§445.772 and 445.773; California Bus. and Prof. Code §§16700, *et seq.* and 17200, *et seq.*; and the laws of unjust enrichment of all the states of the United States;
- B. That Plaintiff McAnaney and all others similarly situated be awarded damages, and exemplary or statutory damages permitted by New York GBL §§340, *et seq.* and 349, *et seq.*, suffered by reason of Defendants' violations of New York GBL 340, *et seq.* and 349, *et seq.*;
- C. That Plaintiff IBEW Local 38 and all others similarly situated be awarded damages, exemplary or statutory damages, permitted by Mich. Comp. Laws. §§445.772 and 445.773, suffered by reason of Defendants' violations of Mich. Comp. Laws. §§445.772 and 445.773;
- D. That Plaintiff IBEW Local 595 and all others similarly situated be awarded treble damages permitted by California Bus. & Prof. Code §16750, *et seq.* suffered by reason of Defendants' violations of California Bus. & Prof. Code §16700, *et seq.*;
- E. That Plaintiff Local 595 and all others similarly situated be awarded equitable relief, including restitution permitted by California Bus. & Prof. Code §17204, arising from Defendants' violations of California Bus. & Prof. Code § 17200, et seq.;

- F. That Plaintiffs be awarded equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment under the state laws of all the United States;
- G. That the Plaintiffs and the Classes be awarded reasonable attorneys' fees and costs; and
  - H. Such other and further relief as the Court may deem just and proper.

### **JURY TRIAL DEMANDED**

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of all claims and complaints in this Complaint so triable.

DATED: February 5, 2013 TRUJILLO RODRIGUEZ & RICHARDS, LLC

By: s/Lisa J. Rodriguez

Lisa J. Rodriguez 258 Kings Highway East

Haddonfield, NJ 08033

Telephone: (856) 795-9002 Facsimile: (856) 795-9887

lisa@trrlaw.com

Liason Counsel for Plaintiffs and Interim Class Liason Counsel

# SCOTT+SCOTT, ATTORNEYS AT LAW, LLP

David R. Scott

drscott@scott-scott.com

Joseph P. Guglielmo (pro hac vice)

jguglielmo@scott-scott.com

Donald A. Broggi

dbroggi@scott-scott.com

Penelope D. Abdiel (pro hac vice)

pabdiel@scott-scott.com

The Chrysler Building

405 Lexington Avenue, 40th Floor

New York, NY 10174

Telephone: (212) 223-6444

Facsimile: (212) 223-6334

-and-

Christopher M. Burke (pro hac vice)

cburke@scott-scott.com

Walter W. Noss (pro hac vice)

wnoss@scott-scott.com

Jennifer S. Scott (pro hac vice)

jscott@scott-scott.com

707 Broadway, Suite 1000

San Diego, CA 92101

Telephone: (619) 233-4565

Facsimile: (619) 233-0508

Counsel for Plaintiffs McAnaney and IBEW Local 38, Chair of Steering Committee, and Interim Class Counsel

### TUSA P.C.

Joseph S. Tusa (pro hac vice) joseph.tusapc@gmail.com 1979 Marcus Avenue, Ste. 210 Lake Success, NY 11042 Telephone: (516) 622-2212

Facsimile: (516) 706-1373

Counsel for Plaintiffs McAnaney and IBEW Local 38, Plaintiffs Steering Committee, and Interim Class Counsel

### SCHNEIDER WALLACE COTTRELL BRAYTON KONECKY LLP

Todd M. Schneider tschneider@schneiderwallace.com Jason H. Kim jkimschneiderwallace.com 180 Montgomery Street, Suite 2000 San Francisco, CA 94109 Telephone: (415) 421-7100 Facsimile: (415) 421-7105

### SCHNEIDER WALLACE COTTRELL BRAYTON KONECKY LLP

Garrett W. Wotkyns gwotkynsschneiderwallace.com 8501 North Scottsdale Road, Suite 270 Scottsdale, AZ 85253

Telephone: (480) 428-0144 Facsimile: (866) 505-8036

# LEONARD CARDER LLP

Aaron Kaufmann 1330 Broadway, Suite 1450 Oakland, CA 94612 Telephone: (510) 272-0169

Facsimile: (510) 272-0174

Counsel for Plaintiff IBEW Local 595, Plaintiffs Steering Committee, and Interim Class Counsel