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

MYLAN PHARMACEUTICALS, INC., **Plaintiff,** **v.** **WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,** **Defendants.**	:	**Civ. No. 12-3824** **CONSOLIDATED**
ROCHESTER DRUG CO-OPERATIVE, INC., **Plaintiff,** **v.** **WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,** **Defendants.**	:	
MEIJER, INC., et al., **Plaintiffs,** **v.** **WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,** **Defendants.**	:	
AMERICAN SALES COMPANY, LLC, **Plaintiff,** **v.** **WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,** **Defendants.**	:	

DIRECT PURCHASER CLASS PLAINTIFFS'
CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

Plaintiffs Rochester Drug Co-Operative, Inc. ("RDC"), Meijer, Inc. and Meijer Distribution, Inc., and American Sales Company, LLC ("ASC"), on behalf of themselves and all others similarly situated, for their Complaint against Warner Chilcott (US) LLC, Warner Chilcott Public Limited Company, Warner Chilcott Company LLC, and Warner Chilcott Laboratories Ireland Limited (collectively "Warner Chilcott"), and Mayne Pharma Group Limited and Mayne Pharma International Pty, Ltd. (collectively, "Mayne") (Warner Chilcott and Mayne collectively are "the defendants"), allege as follows based on: (a) personal knowledge; (b) the investigation of their counsel; and (c) information and belief:

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages arising out of the defendants' unlawful exclusion of competition from the market for Doryx. Doryx, otherwise known as delayed-release doxycycline hyclate, is a broad-spectrum antibiotic synthetically derived from oxytetracycline in a delayed-release formulation for oral administration. The defendants manufacture and sell branded Doryx; the Warner Chilcott defendants market branded Doryx under an exclusive license from the Mayne defendants. The defendants, acting in concert, used a series of acts and practices as part of an overall scheme to improperly maintain and extend their monopoly power in the market for delayed-release doxycycline hyclate; the unlawful monopolization, in turn, harmed the direct purchasers and the class they seek to represent, causing them to pay significant overcharges for delayed-release doxycycline hydrate. The unlawful acts include a series of predatory product changes, sometimes known in the field as "product hopping."

2. First, in 2004 the defendants changed the formulation of the product from capsules to tablets, but the tablet formulation offered no medical or clinical benefits over the

existing capsules, and medically speaking the tablets were therapeutically identical. The "hopping" of this product from capsules to tablet afforded no economic benefit other than to delay generic entry by forcing would-be generic companies to chase the new formulation by making their own manufacturing changes and seeking further FDA approvals in order to take advantage of the drug substitution laws.

3. Second, in 2006 the defendants timed FDA label changes to be imposed on would-be generic makers, further stalling generic entry. The label change explained how to administer Doryx by breaking up the Doryx tablet and sprinkling the contents over applesauce. Once again, the defendants knew the label change would likely require any would-be generic competitor's formulation of generic Doryx tablets to be labeled as capable of being "sprinkled over applesauce." The change offered no medical or clinical benefits over applesauce-free dosing regimens. Nor did the defendants expect these changes to garner them any additional sales, lower their costs, or increase their efficiency – except by denying generic entry to its competitors.

4. Third, in 2007 the defendants changed the Doryx tablet itself: they began to produce 75 and 100 mg Doryx tablets with a "score," and immediately discontinued producing unscored 75 and 100 mg Doryx tablets, thereby effectuating the removal of unscored 75 and 100 mg tablets from the market. A "score" on the 75 and 100 mg Doryx tablet meant that the tablet was debossed across the tablet's center to facilitate a patient's breaking it in half for half-tablet dosing.

5. Fourth, in 2008, the defendants obtained approval for and began distinguishing 150 mg branded Doryx tablets, and immediately took steps to convert demand to their new dosage strength, irrespective of therapeutic of economic benefit, solely for the purpose of preventing substitution by 75 g and 100 mg generic Doryx tablets. As part of this scheme,

defendants later completely withdrew their branded 75 mg and 100 mg tablets from the market, thus destroying any demand for generic formulations of those dosage strengths.

6. The defendants' use of these "product hopping" techniques successfully delayed generic entry of non-brand delayed-release doxycycline hyclate. The defendants knew that these changes to branded Doryx – from capsules to tablets, and to labels for "sprinkled over apple sauce", and to a scored tablet – would, each time, likely require any would-be generic competitor's formulation of generic Doryx to chase the new manufacturing or label change. Each time the change offered no medical or clinical benefits over the prior product. And each time the defendants did not expect the changes to result in additional sales, lower their costs, or increase their efficiency. But the purpose of the changes – delay of generic entry – was achieved.

II. JURISDICTION AND VENUE

7. This Complaint is filed and these proceedings are instituted under section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover threefold damages and the costs of suit and reasonable attorneys' fees, for the injuries sustained by the Direct Purchaser Class (defined below) of Doryx tablets from the defendants, resulting from violations by the the defendants, as hereinafter alleged, of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

8. The defendants transact business within this district, and they carry out interstate trade and commerce, in substantial part, in this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

9. The direct purchaser Rochester Drug Co-Operative, Inc. ("RDC") is a stock

corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business located at 50 Jet View Drive, Rochester, New York 14624. During the class period, as defined below, RDC purchased branded Doryx tablets directly from the defendants, and suffered antitrust injury as a result of the defendants' unlawful conduct.

10. The direct purchaser Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Meijer") are corporations organized under the laws of the State of Michigan, with their principal place of business located at 2929 Walker Avenue, NW, Grand Rapids, Michigan 49544. Meijer is the assignee of the claims of the Frank W. Kerr Co., which, during the class period, defined below, purchased Doryx directly from the defendants and suffered antitrust injury as a result of the anticompetitive conduct alleged herein. Frank W. Kerr Co. resold to Meijer at least some of the Doryx that it purchased from the defendants during the relevant period.

11. The direct purchaser American Sales Company, LLC ("ASC") is a Delaware limited liability company with its principal place of business in Lancaster, Erie County, New York. ASC brings this action on its own behalf and as an assignee of McKesson Corp. which, during the relevant period, purchased Doryx directly from the defendants. ASC suffered antitrust injury as a result of Defendants' unlawful conduct.

12. Defendant Warner Chilcott Public Limited Company is a company organized and existing under the laws of Ireland, having its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland L2 00000.

13. Defendant Warner Chilcott Company, LLC is a limited liability company organized and existing under the laws of the Commonwealth of Puerto Rico, having its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

14. Defendant Warner Chilcott (US), LLC is a limited liability company organized

and existing under the laws of Delaware, having its principal place of business at 100 Enterprise Drive, Rockaway, NJ 07866.

15. Defendant Warner Chilcott Holdings Company III, Ltd. is a privately-owned, for-profit company organized, existing, and doing business under and by virtue of the laws of Bermuda, with its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866-2129.

16. Defendant Warner Chilcott Laboratories Ireland Limited is a company organized and existing under the laws of the Republic of Ireland, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

17. The five foregoing defendants are sometimes referred to herein as the "Warner Chilcott defendants."

18. Defendant Mayne Pharma Group Limited is a corporation organized and existing under the laws of Australia, having its principal place of business at Level 9, 470 Collins Street, Melbourne, VIC 3000, Australia.

19. Defendant Mayne Pharma International Pty. Ltd. is a corporation organized and existing under the laws of Australia, having its principal place of business at 1538 Main North Road, Salisbury South, SA 5106, Australia.

20. The two foregoing defendants are sometimes referred to herein as the "Mayne defendants."

21. All of the defendants' actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or done by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment,

and/or with the actual, apparent, and/or ostensible authority of the defendants.

IV. CLASS ACTION ALLEGATIONS

22. The direct purchasers bring this action on behalf of themselves and, under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure, as representatives of a class defined as follows:

> All persons or entities in the United States who purchased Doryx tablets directly from any of the Defendants at any time during the period July 2008 through the present (the "Direct Purchaser Class").

Excluded from the Direct Purchaser Class are the defendants, and their officers, directors, management, employees, subsidiaries, and affiliates, and all federal governmental entities.

23. Members of the Direct Purchaser Class are so numerous that joinder is impracticable. The direct purchasers believe the class may number in the hundreds. Further, the Direct Purchaser Class is readily identifiable from information and records in the possession of the defendants.

24. The direct purchasers' claims are typical of the claims of the members of the class. The Direct Purchaser Class was damaged by the wrongful conduct by the defendants, *i.e.*, they paid artificially inflated prices for delayed-release doxycycline hyclate tablets and were deprived of the benefits of competition from cheaper generic versions of Doryx tablets as a result of the defendants' wrongful conduct.

25. The direct purchasers will fairly and adequately protect and represent the interests of the class. The direct purchasers' interests are coincident with, and not antagonistic to, those of the class.

26. The Direct Purchaser Class is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience

with class action antitrust litigation in the pharmaceutical industry.

27. Questions of law and fact common to the members of the Direct Purchaser Class predominate over questions, if any, that may affect only individual class members because the defendants have acted on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in the defendants' wrongful conduct.

28. Questions of law and fact common to the Direct Purchaser Class include:

a. whether the defendants conspired to suppress generic competition to Doryx;

b. whether the defendants' challenged conduct suppressed generic competition to Doryx;

c. whether the defendants' challenged conduct harmed competition in the market(s) in which Doryx is sold;

d. whether there exist legitimate, non-pretextual procompetitive justifications for the defendants' challenged conduct that offset the harm to competition in the market(s) in which Doryx is sold;

e. whether the defendants possessed monopoly power over Doryx;

f. whether the defendants maintained monopoly power by suppressing generic competition to Doryx;

g. whether direct proof of the defendants' monopoly power is available, and if available, whether it is sufficient to prove the defendants' monopoly power without the need to also define a relevant market;

h. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

i. whether the activities of the defendants as alleged herein have substantially affected interstate commerce;

j. whether, and to what extent, the defendants' conduct caused antitrust injury to the business or property of Plaintiffs and the members of the Class in the nature of overcharges; and

k. the quantum of overcharges paid by the Class in the aggregate.

29. 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 the 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 not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

30. The direct purchasers know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. FACTS

A. Characteristics of the Pharmaceutical Marketplace

31. The marketplace for the sale of prescription pharmaceutical products in the United States contains a significant feature that can be exploited by manufacturers in order to extend a monopoly in the sale of a particular pharmaceutical composition. In most industries, the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays a predominant role in the person's choice of products and, consequently, manufacturers have a strong incentive to lower the price of their products to maintain profitability.

32. The pharmaceutical marketplace, by contrast, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including delayed-release doxycycline hyclate, to patients without a prescription written by the patient's physician. The prohibition on dispensing certain products without a prescription introduces a "disconnect" in the pharmaceutical

marketplace between the payment obligation and the product selection. The patient (and in many cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's physician chooses which product the patient will buy.

33. Many pharmaceutical manufacturers, including the defendants here, exploit this feature of the pharmaceutical marketplace. The so-called "brand manufacturers" (*i.e.*, the manufacturers of branded, as opposed to generic, pharmaceuticals) employ large forces of sales representatives, known as "detailers," who visit physicians' offices in an effort to persuade physicians to prescribe the manufacturer's products. Importantly, these detailers do not advise the physicians of the cost of the branded products. Studies show that physicians typically are not aware of the relative costs of branded pharmaceutical products and that, even when physicians are aware of the relative cost, they are insensitive to price differences, including because they do not themselves have the obligation to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

34. In situations in which each of two manufacturers sells a drug that serves a similar medical function and each manufacturer uses a significant detailer force, those products are often sold at very similar, high prices, thus eliminating any consumer benefit from that "competition." This is in stark contrast to the situation in which the competing seller of an AB-rated, bioequivalent drug is a generic company without a detailer force. In that case, the generic price is significantly lower than the brand price, and consumers benefit as Congress intended by the Hatch-Waxman Act, discussed below.

35. When the relative importance of the price between two branded pharmaceuticals, or pharmaceuticals that otherwise are not AB-rated to one another, is low, the price elasticity of demand — the extent to which sales go down when price goes up — is by definition also low,

which in turn gives brand manufacturers the ability to raise or maintain price substantially above competitive levels without losing sales. The ability to raise price above competitive levels without losing sales is referred to by economists and antitrust courts as market power or monopoly power. Thus, the net result of the pharmaceutical industry features and marketing practices described above often is to allow brand manufacturers to gain and maintain monopoly power.

36. Congress sought to mitigate the "disconnect," and to restore some of the normal competitive pressures to the pharmaceutical marketplace, by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Act, discussed below. When a pharmacist receives a prescription for a branded pharmaceutical product, and an AB-rated generic version of that product is available, state law permits (or in some cases requires) the pharmacist to dispense the generic product in lieu of the branded product. In this way, the importance of price is reintroduced to the product selection decision at the pharmacy counter, and the pharmaceutical marketplace "disconnect" is ameliorated between the AB-rated generic product and the corresponding branded product. When an AB-rated generic product is introduced and is not prevented from competing unfettered, branded pharmaceutical manufacturers are no longer able to exploit the features of the pharmaceutical industry, their monopoly power dissipates and some of the normal competitive pressures are restored.

37. If the defendants' unlawful conduct had not prevented generic manufacturers from successfully entering the market with generic versions of Doryx, the Direct Purchaser Class would have saved millions of dollars in the purchase of delayed-release doxycycline hyclate. The defendants' anticompetitive scheme purposely manipulated generic competition to Doryx.

B. The Regulatory Structure For Generic Drug Approval

38. Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301-392), manufacturers who create a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

39. In 1984, Congress amended the Food, Drug and Cosmetics Act with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

40. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

41. The ANDA relies on the scientific findings of safety and effectiveness included by the brand-name drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the generic drug it proposes to market is, among other things, bioequivalent and pharmaceutically equivalent to the brand-name drug.

42. As a counter-balance to this abbreviated process for bioequivalent generic drugs, Hatch-Waxman streamlined the process for a brand-name manufacturer to enforce its patents against infringement by generic manufacturers, and provided that, under conditions not applicable to this case, the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand-name drug for up to 30 months.

43. When the FDA approves a brand-name manufacturer's NDA, the FDA publishes any compound patents which (according to the brand-name manufacturer) claim the approved

drug in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." 21 U.S.C. §355(j)(7)(A)(iii). In the case of method of use patents, the FDA lists in the Orange Book any patents which (according to the brand-name manufacturer) claim the approved drug for its approved method of use. In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand-name manufacturer, but trusts that the manufacturer will be truthful. As here, after the NDA is approved, the brand-name manufacturer may list other new patents in the Orange Book as related to the NDA, if the brand-name manufacturer similarly certifies, *inter alia*, that the new patents claim either the approved drug (for compound patents) or that the patents claim the approved drug for approved methods of use (for method-of-use patents).

44. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand-name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

a. that no patent for the brand-name drug has been filed with the FDA (a "Paragraph I certification");

b. that the patent for the brand-name drug has expired (a "Paragraph II certification");

c. that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

45. If a generic manufacturer files only paragraph I, II, or III certifications, then it is able to take advantage of the expedited Hatch-Waxman approval process, and the FDA must act

on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5)(A).

46. If a generic manufacturer files a Paragraph IV certification claiming that a patent listed in the Orange Book is invalid or will not be infringed, a brand-name manufacturer often has an opportunity to delay the final FDA approval of the ANDA and the sale of the competing generic drug on the market. When a generic drug manufacturer files a Paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of the patent(s) at issue. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the Paragraph IV certification, then in certain cases (inapplicable here) the FDA may not grant final approval to the ANDA until the earlier of either: (a) 30 months; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii). Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand-name drug manufacturer often may delay when the generic drug is finally approved by the FDA, and when generic competition to the brand-name drug enters the market. During the pendency of an applicable 30 month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval but for the stay. FDA does not grant tentative approvals when 30-month stays are inapplicable, however.

47. Several provisions of Hatch-Waxman did not apply to Doryx until October 8, 2008, after the effective date of the so-called "QI Act." Pub. L. No. 110-379, 122 Stat. 4075 (2008) (codified in relevant part at 21 U.S.C. § 355(v)). Prior to that date, drugs like Doryx that contained an active moiety like doxycycline hyclate that had been the subject of a marketing

application received by FDA before November 21, 1997 (and thus known as an "old antibiotic") were exempted from the patent listing, patent certification, and 30-month stay provisions of Hatch-Waxman. The QI Act brought such old antibiotics within the provisions of Hatch-Waxman.

48. Pursuant to the provisions of the QI Act, the defendants listed a patent they had obtained on October 25, 2005 (U.S. Patent No. 6,958,161), in the Orange Book, as covering Doryx. But, by the time the QI Act became effective (October 8, 2008) and the defendants listed their patent (December 5, 2008), Impax, Mylan, and several other generic drug companies had already filed ANDAs seeking approval to market generic versions of 75 and 100 mg Doryx tablets.

49. Those several ANDA filers, including Impax, Mylan, and three others, in response to the defendants' Orange Book listing, filed Paragraph IV certifications with respect to the '161 Patent. In response to those Paragraph IV certifications, the defendants sued each of those ANDA filers for patent infringement under the provisions of Hatch-Waxman.

50. On May 17, 2009, FDA determined that the 30-month stay provisions of Hatch-Waxman did not apply to ANDAs for Doryx or other "old antibiotics." Consequently, when Impax and Mylan received final approval for their generic 75 and 100 mg Doryx tablets on December 8, 2010, they launched them immediately, "at risk," despite the pendency of the defendants litigation against them over the '161 Patent. The '161 Patent thus was not, and but-for the defendants' challenged conduct still would not have been, an impediment to Impax's and Mylan's launching their 75 and 100 mg generic Doryx tablets.

51. In order to be substitutable for a branded product at the pharmacy counter, and approvable by FDA as AB-rated to a particular branded product, a generic product must be,

among other things, "pharmaceutically equivalent" (same dosage form and strength) and "bioequivalent" (exhibiting the same drug absorption characteristics) as the branded product. FDA regulations, which are concerned only with safety and efficacy and not with effects on competition, permit branded manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. *See* 21 C.F.R. § 314.54. Importantly, the regulations do not require the brand manufacturer to make public the fact that the manufacturer is seeking FDA approval for these modifications. As a result, an unscrupulous brand manufacturer that anticipates the onset of generic competition could modify the dosage form, strength, or some other characteristic of its product from, say, A to A_1. Unaware that the branded manufacturer has sought approval to modify its product, the generic manufacturer might continue to seek approval to produce a generic version of A. Before the generic product receives FDA approval and enters the market, the brand manufacturer might get approval for A_1 and use its detailers to encourage physicians to write prescriptions only for A_1 instead of A. The branded manufacturer's modification of A to A_1 may cause FDA to require the generic manufacturer to reformulate its product (a costly and time-consuming process) or, if the FDA does not so require, then when the generic manufacturer later gets approval and enters the market with a generic version of A, the generic manufacturer will make few or no sales because its product is not substitutable for A_1.

C. Generic Drugs are Significantly Less Expensive, and Take Significant Sales From, the Corresponding Brand-Name Version

52. Typically, generic versions of brand-name drugs are priced significantly below the brand-name versions. Because of the price differentials, and other institutional features of the pharmaceutical industry, generic versions are liberally and substantially substituted for their brand-name counterparts. In particular, generic drugs that are bioequivalent to their brand name

counterparts are given an "AB" rating by the FDA. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand-name product unless the doctor has indicated that the prescription for the brand-name product must be dispensed as written. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generic accelerates. Generic competition enables all members of the proposed Direct Purchaser Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand-name drug at a reduced price. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug to compete with the brand-name drug, and therefore the brand-name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand-name sales. Consequently, brand-name drug manufacturers have a strong interest to use various tactics, including those alleged above, to delay the introduction of generic competition into the market.

D. Facts Pertaining to the Defendants' Anitcompetitive Scheme

53. The defendants (and/or their predecessors-in-interest) began marketing a 100 mg capsule version of their brand name drug Doryx in 1985. Mayne received FDA approval for the Doryx 100 mg capsule on July 22, 1985, and began selling the product commercially the same year. In 1997, Mayne granted Warner Chilcott an exclusive license to market and sell the Doryx 100 mg capsule (and later all other Doryx formulations) in the United States. Mayne continues to manufacture Doryx for Warner Chilcott to sell in the United States.

54. The defendants added a 75 mg capsule version to their offerings in September of 2001, when Mayne received FDA approval to sell the product. The defendants quickly garnered

substantial revenues from the sale of Doryx. The defendants, however, recognized the substantial threat to their monopoly profits posed by the potential onset of competition from generic versions of Doryx. Specifically, the defendants learned that various companies were planning to seek FDA approval to manufacture generic versions of 75 and 100 mg Doryx capsules. Since generics are priced significantly below the brand-name drug, such products typically take the vast majority of the brand-name version's sales quickly after their introduction into the marketplace.

55. In response to the serious competitive threat posed by generics, and knowing that Doryx enjoyed no patent protection, the defendants, acting in concert, executed a multifaceted scheme over the course of several years to maintain and extend their monopoly power over delayed-release doxycycline hyclate by illegally preventing generic manufacturers from effectively competing with Doryx. The defendants' scheme was executed through a purposeful and planned manipulation of the complex distribution and regulatory approval systems for pharmaceutical products in the U.S.

1. The first predatory product change

56. Fearing the onset of generic competition to their 75 and 100 mg Doryx capsules, and knowing that they had no patent protection for Doryx, on April 5, 2004, the defendants applied to the U.S. Food and Drug Administration ("FDA") for approval to market a 75 and 100 mg tablet version of Doryx, which was bioequivalent to the 75 and 100 mg Doryx capsules that the defendants were marketing at the time. Bioequivalent means that the rate and extent of absorption of doxycycline hyclate was the same for the tablets as it was for the capsules. The new tablet formulation offered no medical or clinical benefits over the existing capsules. They are therapeutically identical. The purpose and effect of the plan to market the tablets were not to

provide the public with a better or improved product, but rather to protect the defendants' Doryx profits by thwarting, delaying and/or mitigating the impact of generic competition. There were no legitimate efficiencies achieved.

57. The new tablet formulation was more costly and difficult for the defendants to manufacture than the existing capsule formulation, and even required a reformulation of the delayed-release enteric coating on the pellets of doxycycline hyclate that comprise Doryx capsules so that they could withstand the compression force required to manufacture a tablet. The defendants nonetheless expended significant resources developing and seeking FDA approval for their tablet formulation, and changing over their manufacturing processes, solely to use that new formulation as part of a scheme to exclude and minimize generic competition by raising would-be generic companies' costs, delaying their product development efforts, and excluding them from the most efficient means of distributing their products. The tablet formulation was approved by FDA on May 6, 2005, and the defendants proceeded to market the 75 and 100 mg tablets.

58. As part of their scheme to exclude generic competition, the defendants then took affirmative (and costly) steps to (a) destroy the pre-existing demand for Doryx capsules, and (b) shift that demand to the defendants' tablet formulation (since there were no pending tablet ANDAs). The defendants purposely and intentionally sought to convert all Doryx prescriptions from the existing capsule formulation to the tablet formulation by, *inter alia*, instructing representatives to promote only the tablet formulation, while discouraging physicians from writing prescriptions for the older capsule formulation. Within six months of the introduction of the 75 and 100 mg tablets, the defendants had effectuated nearly a complete shift, so that virtually all prescriptions written and dispensed were for the 75 and 100 mg Doryx tablets, not

the capsules. By June 2006, the defendants had withdrawn Doryx capsules from the market altogether.

59. As a result of the defendants' conduct, by the time generic manufacturers would have been able to start selling their generic capsule versions of 75 and 100 mg delayed-release doxycycline hyclate, the demand for such capsules had been switched to the 75 and 100 mg tablet versions of Doryx. Because capsules are a different formulation than tablets, pharmacists and others could not legally substitute generic capsules for prescriptions written for the defendants' branded tablet formulation, even though the capsule and tablet products were bioequivalent. It was for this reason alone that the defendants converted their 75 and 100 mg Doryx capsules to tablets.

2. The second set of predatory product changes

60. The defendants' anticompetitive scheme did not stop with their first illegal, exclusionary product conversion. After the defendants obtained approval for their tablet product, they feared that generic manufacturers would soon seek FDA permission to market generic versions of 75 and 100 mg Doryx tablets. By October 2005, the defendants had obtained a patent (U.S. Patent No. 6,958,161) that covered Doryx (later held to be invalid), but according to the federal Food, Drug and Cosmetics Act (the "Act"), Doryx, as an "old antibiotic," was not yet subject to the patent listing, certification, and 30-month stay provisions of the Hatch-Waxman Amendments to the Act. The defendants knew they could not rely on filing a patent-infringement lawsuit to delay entry of generic versions of 75 and 100 mg Doryx tablets.

61. In response to this threat, the defendants deployed an anticompetitive strategy whose sole value to the defendants was to delay generic competition to Doryx tablets. The strategy consisted of a one-two punch. The first punch was to buy time by disrupting any would-

be generic competitor's development of a suitable formulation of generic 75 and 100 mg delayed-release tablets. The defendants accomplished this disruption using two changes they made to 75 and 100 mg branded Doryx tablets — one change to its labeling and one change to the tablet itself — that would render the delayed-release tablet formulation ANDAs then in development incapable of receiving FDA approval, and force would-be generic competitors to start over again in formulating generic Doryx tablets.

62. Specifically, on February 17, 2006, the defendants proposed a labeling change to explain how to administer Doryx by breaking up the Doryx tablet and sprinkling the contents over applesauce. FDA approved this label change on December 19, 2006. Then, on October 1, 2007, the defendants changed the Doryx tablet itself: they began to produce 75 and 100 mg Doryx tablets with a "score," and immediately discontinued producing unscored 75 and 100 mg Doryx tablets, thereby effectuating the removal of unscored 75 and 100 mg tablets from the market. A "score" on the 75 and 100 mg Doryx tablet meant that the tablet was debossed across the tablet's center to facilitate a patient's breaking it in half for half-tablet dosing, a change which FDA approved in early 2009.

63. The defendants knew that these changes to branded Doryx tablets would likely require any would-be generic competitor's formulation of generic Doryx tablets to be capable of being "sprinkled over applesauce" and taken in halves using a "score" while maintaining a similar drug release profile to that of a whole tablet. Creating that requirement for would-be generic competitors, and associated drug formulation revisions, was precisely the defendants' intent in making these changes to branded Doryx tablets and their labeling, and removing unscored Doryx tablets from the market.

64. The defendants' anticompetitive intent is evident from the timing of their changes.

For instance, the defendants sought and obtained from FDA a "sprinkle over applesauce" dosing regimen for the Doryx capsules label. When it came to Doryx tablets, however, the defendants strategically held back their application to include a "sprinkle over applesauce" dosing regimen on the label until such time as they believed it would maximally disrupt the ongoing efforts of would-be generic competitors to formulate generic Doryx tablets.

65. The changes to branded Doryx tablets offered no medical or clinical benefits over unscored tablets and applesauce-free dosing regimens, nor did the defendants expect these changes to garner them any additional sales, lower their costs, or increase their efficiency. There was no therapeutic demand or advantage to be able to halve a 75mg tablet into two tablet halves of 37 ½ mg each. From the outset, the purpose and effect of these changes were not to provide the public with a better or improved Doryx product. These changes were costly to the defendants, and made economic sense only because they raised would-be generic competitors' costs and delayed generic competition to 75 and 100 mg Doryx tablets.

66. And delay generic competition these changes did; they forced both Impax Labs, Inc. ("Impax") and Mylan Pharmaceuticals, Inc. ("Mylan") to reformulate and extensively test their 75 and 100 mg generic Doryx tablet products merely to ensure they could mimic the defendants' 75mg and 100mg Doryx design, while maintaining a release profile similar to that of a whole tablet. These obstacles, purposely created by the defendants solely to delay generic competition, substantially delayed FDA approval of Impax and Mylan's ANDAs for 75 and 100 mg Doryx tablets, the first of which was filed on March 18, 2008, but which were not finally approved by FDA until 33 months later, on December 28, 2010. On information and belief, other generic manufacturers were similarly delayed due to the defendants' anticompetitive actions.

67. Using the time they bought for themselves by sending Impax and Mylan back to the drawing board, the defendants delivered their second punch: just as they had done with their capsule product, they converted the market again, this time from the 75 and 100 mg tablets to a 150 mg tablet. Thus, on December 18, 2007, just after they began scoring 75 and 100 mg Doryx tablets, the defendants, for no legitimate medical or clinical reason, filed an application with FDA to market a 150 mg dosage strength of Doryx tablets. Six months later, on June 20, 2008, FDA approved the application, and the defendants began to market 150 mg branded Doryx tablets.

68. The defendants' new tablet strength offered no medical or clinical benefits over the existing 75 and 100 mg strengths. Indeed, nowhere on the Doryx label is any instruction for a patient to take a dose in the amount of 150 mg. The usual adult dose as described in the product label is 200 mg on the first day of treatment (administered 100 mg every 12 hours), followed by a maintenance dose of 100 mg daily. The label indicates that the maintenance dose may be administered as a single dose or as 50 mg every 12 hours. A dose of 100 mg every 12 hours is recommended for more severe infections.

69. When the defendants launched the 150 mg tablet in June 2008, it was available with a single score (allowing it to be cut into two 75 mg halves). This was the case until at least September 2011. Therefore, not only was there no benefit to replacing the existing 75 and 100 mg dosage strengths with a 150 mg dosage strength, but the 150 mg dosage strength switch actually made patient dosing *less* convenient. In order for a patient to take the usual dose of 100 mg per day when prescribed 150 mg tablets, the patient would be required to break off a 100 mg piece (or break off two 50 mg pieces) from the tablet each day. This would be more difficult to do with a tablet that is scored to be broken into two 75 mg pieces. The defendants' 150 mg

"improvement" actually *eliminated* a convenient way to take the usual dose of 100 mg per day. Instead, it required patients taking the usual dose to do more work and take extra care in order to get the correct dosage amount, and face greater risk that they would not get the intended dose.

70. Even after a second score was added to the 150 mg tablets in 2011, it continued to be *less convenient* (compared to when the 100 mg tablet existed) for patients to take the usual dose of 100 mg. Patients would still be required to break off at least 50 mg from the tablet before taking it.

71. The defendants nonetheless expended significant resources developing and seeking FDA approval for their 150 mg tablet strength, simply to use that new strength as part of the scheme to exclude and minimize generic competition. The defendants introduced a 150 mg dosage strength with the sole goal of giving themselves a dosage strength to which they could shift physicians and prescriptions before their 75 and 100 mg Doryx tablets were exposed to generic competition from Impax, Mylan, and others. The defendants knew that generic versions of 75 and 100 mg Doryx tablets could not be substituted by pharmacists who were presented with prescriptions for Doryx tablets in a 150 mg dosage strength.

72. Thus, once the defendants launched their 150 mg tablet they immediately took active steps to, once again, convert demand, this time from 75 and 100 mg Doryx tablets to the newly-approved 150 mg dosage strength, before Impax and Mylan could obtain FDA approval to sell generic versions of the 75 and 100 mg tablets. The defendants took affirmative steps to (a) destroy the pre-existing demand for 75 and 100 mg Doryx tablets, and (b) shift that demand to the defendants' 150 mg tablet strength (since there were no pending ANDAs on that strength). The defendants purposely and intentionally sought to convert all 75 and 100 mg Doryx prescriptions to the 150 mg tablet strength by, *inter alia*, instructing its sales representatives to

promote only the 150 mg tablet strength, while discouraging physicians from writing prescriptions for the 75 and 100 mg tablet strengths. These efforts were very costly to the defendants and made economic sense only because they raised would-be generic competitors' costs and delayed and impeded generic competition to 75 and 100 mg Doryx tablets.

73. The defendants' scheme worked just as the defendants planned. By the time Impax and Mylan's ANDAs for 75 and 100 mg Doryx tablets were finally granted on December 28, 2010, approximately 95% of Doryx prescriptions were being written for the 150 mg dosage strength. Generic versions of 75 and 100 mg Doryx tablets could not be substituted when pharmacists were presented with prescriptions for 150 mg Doryx tablets.

74. The defendants then discontinued sales of 75 and 100 mg Doryx tablets altogether, in December of 2010 and August of 2011, respectively, further ensuring that Impax and Mylan's generic 75 and 100 mg Doryx tablets would get no sales.

75. The defendants have made no secret of their desire to manipulate the regulatory and competitive processes to avoid generic competition for Doryx. Indeed, the President and Chief Executive Officer of Warner Chilcott, Roger Boissonneault, has publicly boasted about the company's ability to move the market to new formulations of Doryx — on the eve of generic entry — in order to delay and/or prevent generic competition to Doryx. Defendant Mayne has also expressly acknowledged its continuous plans to thwart generic competition by continuing to launch new formulations of Doryx: "Lifecycle management of Doryx has been a focus for Mayne Pharma since the launch of Doryx capsules in the US and Australia in 1985. The Company has successfully reformulated Doryx from capsules into tablets in 2005 and subsequently released a new Doryx 150mg tablet in 2008. In order to protect Doryx market position, Mayne Pharma is continuing to work with Warner Chilcott on a number of lifecycle

management activities." (Announcement of FY2011 Final Results, Mayne Pharma Group Ltd., at p. 4)

76. For instance, in an earnings conference call last year, the defendants admitted their strategy to thwart generic competition to Doryx through "multiple strategies" to shift the market for delayed-release doxycycline hyclate. In that call, Mr. Boissonnault was asked the following question by an investor: "[O]n Doryx, I guess usually by now in typical Warner Chilcott fashion, we would have already had a new Doryx approved in some formulation or dose that would be a life cycle extension strategy for the old one. I was curious what was going on there and what are you thinking about that franchise right now with respect to protection from potential generic competition." Mr. Boissonnault candidly responded: "[W]e don't have *a* strategy, we have *multiple* strategies and what we're looking is seeing how the situation has developed and what we best do. So I wouldn't be overly concerned at this particular moment is there a new Doryx out there or what is it" (Q2 2011 Warner Chilcott Earnings Conference Call Q&A Transcript at 6-7) (emphasis added).

77. Defendant Mayne, Warner Chilcott's supplier, admitted to "relentlessly" working with Warner Chilcott to use "life cycle strategies" to prevent generics from competing in the market: "One of the challenges of achieving visible success with a key proprietary product such as Doryx® tablets is that the competition is keenly seeking ways to access the market. We remain relentless in defending our proprietary position and market share with our marketing partners [such as Warner Chilcott in the U.S. market] and maintain a lifecycle management programme to stay ahead of potential competition." (Mayne (at the time named Halcygen Pharmaceuticals Limited) 2010 Annual Report at 16). The defendants note their achievements using life-cycle management strategies to "protect the market position of Doryx®" by

"successfully reformulating Doryx® from capsules into tablets in 2005 and then subsequently releasing a new 150 mg tablet in July 2008." (Mayne 2011 Annual Report at 11). Mayne's press release announcing its September 14, 2011 FDA Approval of the dual-scored Doryx 150 mg tablet similarly highlights its role thwarting generic entry, noting its "expectation that the FDA is likely to ask companies with a single-scored 150 mg generic tablet to develop and gain approval for a dual-scored 150 mg generic tablet prior to launch." (Mayne Press Release (Sept. 14, 2011) at 1).

78. The defendants' concerted scheme, as a whole and in its individual parts, was intended to, and did, disrupt the normal channels, and the statutory and regulatory mechanisms, by which generic competition takes place and was prescribed by Congress to take place, and exclude would-be generic competitors from the most efficient means of distributing their products.

79. The defendants cannot justify their scheme with any offsetting consumer benefit, as the enormous cost savings offered by generic drugs (and, correspondingly, the anticompetitive harm caused by suppressing generic competition to Doryx) outweigh any nonpretextual procompetitive justifications the defendants could offer for the changes they made to Doryx. To the contrary, the anticompetitive harm from the product changes clearly outweighed any consumer benefit they conceivably conferred.

80. The defendants' exclusionary motive is additionally illustrated by their willingness to sacrifice profits as part of their product change strategy: the defendants' decisions to incur the extra costs necessary to change Doryx's dosage form from capsules to tablets, to add a score to 75 and 100 mg Doryx tablets, to change Doryx's labeling to include applesauce dosing, to introduce a 150 mg Doryx tablet, and to launch promotional campaigns to shift

demand from Doryx capsules to tablets (and discontinue capsules), and then from Doryx 75 and 100 mg tablets to the 150 mg tablet (and discontinue unscored 75 and 100 mg tablets), were economically rational only because those changes had the exclusionary effect of suppressing generic competition. But for the impact on generic competition, the defendants would not have invested the resources necessary to make any of these changes, because it would have been economically irrational to do so. This willingness to sacrifice profits is not necessary to establish anti-competitive harm, but is more than sufficient to do so.

81. The defendants' scheme was concerted. Specifically, the Mayne defendants, and each of them, and the Warner-Chilcott defendants, and each of them, agreed to perform each element of the scheme and to effectuate the scheme in its entirety.

82. As a result of their illegal, concerted scheme, the defendants: (1) illegally maintained and extended their monopoly in the market for delayed-release doxycycline hyclate in the United States; (2) fixed, raised, maintained, and/or stabilized the price of extended-release doxycycline hyclate at supra-competitive levels; and (3) overcharged the Direct Purchaser Class of Doryx tablets from the defendants by millions of dollars by depriving them of the benefits of competition from cheaper generic versions of Doryx.

83. The defendants' monopoly power, as described above, was maintained through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a superior product, business acumen or historic accident. The defendants' conduct did not constitute competition on the merits.

84. As alleged in more detail below, the defendants violated § 1 and § 2 of the Sherman Act through their conspiracy to engage in an overarching scheme to improperly maintain and extend their market and monopoly power by foreclosing or delaying competition

from lower-priced generic versions of Doryx.

E. Effect on Interstate Commerce

85. At all material times, Doryx manufactured and sold by the defendants, was shipped across state lines and sold to customers located outside its state of manufacture.

86. During the relevant time period, in connection with the purchase and sale of Doryx, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

87. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of the defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

F. Monopoly Power

88. At all relevant times, the defendants had monopoly power over delayed-release doxycycline hyclate because they had the power to raise and/or maintain the price of delayed-release doxycycline hyclate at supracompetitive levels without losing substantial sales.

89. A small but significant, non-transitory price increase by the defendants to Doryx would not have caused a significant loss of sales.

90. Doryx does not exhibit significant, positive cross-elasticity of demand with respect to price, with any doxycycline, antibiotic, or other product other than AB-rated generic versions of Doryx.

91. Because of, among other reasons, its unique side effect profile, Doryx is differentiated from all doxycycline products, and all antibiotics, other than AB-rated generic versions of Doryx.

92. The defendants needed to control only Doryx and its AB-rated generic equivalents, and no other products, in order to maintain the price of Doryx profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Doryx would render the defendants unable to profitably maintain their prices for Doryx without losing substantial sales.

93. The defendants also sold branded Doryx prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

94. The defendants have had, and exercised, the power to exclude generic competition to branded Doryx.

95. The defendants, at all relevant times, enjoyed high barriers to entry with respect to branded and generic Doryx.

96. To the extent that the Direct Purchaser Class is legally required to prove monopoly power circumstantially by first defining a relevant product market, the Direct Purchaser Class alleges that the relevant market is all delayed-release doxycycline hyclate products — *i.e.*, Doryx (in all its forms and dosage strengths) and AB-rated bioequivalent doxycycline hyclate products. During the period relevant to this case, the defendants have been able to profitably maintain the price of Doryx well above competitive levels.

97. The relevant geographic market is the United States and its territories.

98. The defendants' market share in the relevant market is and was 100% prior to the sale of Impax and Mylan's launch of 75 and 100 mg generic Doryx tablets, and has been over 90% thereafter.

G. Effects on Competition and Damages to the Direct Purchaser Class Claimed in this Action

99. The defendants' overarching anticompetitive scheme to suppress generic competition to Doryx has, both as a whole and in its individual parts, delayed and prevented the sale of generic Doryx, both by delaying its availability and, through the defendants' successive destruction of demand for extant versions of Doryx vulnerable to generic competition, by suppressing the ability of generic Doryx to compete by depriving would-be generic versions of the most efficient means of competition under the governing statutory and regulatory regime.

100. The defendants' overarching anticompetitive scheme delayed or prevented the sale of generic 75 and 100 mg Doryx tablets in the United States, and unlawfully enabled the defendants to sell Doryx at artificially inflated prices. But for the defendants' illegal conduct, generic competitors would have been able to compete, unimpeded, with generic versions of 75 and 100 mg Doryx tablets. Generic competitors would also have been able to compete earlier, and additional generic competitors would have entered the market thereafter. The defendants' challenged conduct thereby delayed and prevented the savings that purchasers of Doryx tablets would have experienced from unfettered generic competition.

101. Specifically, if manufacturers of generic 75 and 100 mg Doryx tablets had been able to enter the marketplace and effectively compete with the defendants earlier or without the defendants' having switched the market to the 150 mg Doryx tablet, as set forth above, the Direct Purchaser Class would have substituted lower-priced generic 75 and 100 mg Doryx tablets for the higher-priced brand-name Doryx tablets for some or all of their delayed-release doxycycline hyclate requirements, and/or would have paid lower prices for some or all of their remaining branded Doryx purchases.

102. During the relevant period, the Direct Purchaser Class purchased substantial amounts of Doryx tablets directly from the defendants. As a result of the defendants' illegal

conduct as alleged herein, the Direct Purchaser Class was compelled to pay, and did pay, artificially inflated prices for their delayed-release doxycycline hyclate requirements. The Direct Purchaser Class paid prices for delayed-release doxycycline hyclate that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic Doryx tablets instead of expensive brand-name Doryx tablets; (2) class members paid artificially inflated prices for generic Doryx tablets and/or (3) the price of branded Doryx tablets was artificially inflated by the defendants' illegal conduct.

103. As a consequence, the Direct Purchaser Class has sustained substantial losses and damage to its business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

VI. CLAIMS FOR RELIEF

Claim I: Violation of 15 U.S.C. § 2 (Monopolization and Monopolistic Scheme)

104. The Direct Purchaser Class hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

105. This claim is pled as to the Warner Chilcott defendants and the Mayne defendants.

106. At all relevant times, the Warner Chilcott defendants and the Mayne defendants possessed substantial market power (*i.e.*, monopoly power) in the relevant market. The Warner Chilcott defendants and the Mayne defendants possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

107. Through the overarching anticompetitive scheme, as alleged extensively above, the Warner Chilcott defendants and the Mayne defendants willfully maintained their monopoly

power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured the Direct Purchaser Class thereby.

108. It was the Warner Chilcott defendants' and the Mayne defendants' conscious object to further their dominance in the relevant market by and through the overarching anticompetitive scheme.

109. The defendants' scheme harmed competition as aforesaid.

110. There is and was no legitimate, nonpretextual procompetitive justification for the defendants' actions comprising the anticompetitive scheme that outweighs the scheme's harmful effects. Even if there were some conceivable such justification, the scheme is and was broader than necessary to achieve such a purpose.

111. As a direct and proximate result of the Warner Chilcott defendants' and the Mayne defendants' illegal and monopolistic conduct, as alleged herein, the Direct Purchaser Class was harmed as aforesaid.

Claim II: Violation of 15 U.S.C. § 1
(Conspiracy in Restraint of Trade)

112. The Direct Purchaser Class hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

113. This claim is pled as to the Warner Chilcott defendants and the Mayne defendants.

114. Warner Chilcott defendants and the Mayne defendants consciously agreed with one another to deploy the overarching anticompetitive scheme alleged above, and in concert did deploy the scheme, whose objectives were unlawful.

115. By so agreeing, and by each taking steps in furtherance thereof, the Warner Chilcott defendants and the Mayne defendants engaged in concerted action (*i.e.*, entered into a

contract, combination and/or conspiracy) that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which were to suppress generic competition to Doryx.

116. The conspiracy harmed the Direct Purchaser Class as set forth above.

117. The conspiracy covered a sufficiently substantial percentage of the relevant market to harm competition and did, in fact, harm competition as aforesaid.

118. The Warner Chilcott defendants and the Mayne defendants are each *per se* liable for the conspiracy and its effects.

119. Alternatively, the Warner Chilcott defendants and the Mayne defendants are liable for the conspiracy and its effects under a "quick look" and/or rule of reason standard.

120. There is and was no legitimate, nonpretextual procompetitive justification for the defendants' actions comprising the anticompetitive scheme that outweighs their harmful effect. Even if there were some conceivable such justification, the scheme is and was broader than necessary to achieve such a purpose.

121. As a direct and proximate result of the Warner Chilcott defendants' and the Mayne defendants' anticompetitive conduct, as alleged herein, the Direct Purchaser Class was harmed as aforesaid.

Claim III: Violation of 15 U.S.C. § 2
(Conspiracy to Monopolize)

122. The Direct Purchaser Class hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

123. This claim is pled as to the Warner Chilcott defendants and the Mayne defendants.

124. Through the overarching anticompetitive scheme, as alleged extensively above,

the Warner Chilcott defendants and the Mayne defendants conspired to maintain and enhance their monopoly power in the relevant market.

125. The Warner Chilcott defendants and the Mayne defendants knowingly and intentionally conspired to maintain and enhance their monopoly power in the relevant market.

126. The Warner Chilcott defendants and the Mayne defendants specifically intended that the overarching anticompetitive scheme would maintain their monopoly power in the relevant market, and injured the Direct Purchaser Class thereby.

127. The Warner Chilcott defendants and the Mayne defendants each committed at least one overt act in furtherance of the conspiracy.

128. The conspiracy harmed the Direct Purchaser Class as set forth above.

129. There is and was no legitimate, nonpretextual procompetitive justification for the defendants' actions comprising the anticompetitive scheme that outweighs their harmful effect. Even if there were some conceivable such justification, the scheme is and was broader than necessary to achieve such a purpose.

130. As a direct and proximate result of the Warner Chilcott defendants' and the Mayne defendants' illegal and monopolistic conduct, the Direct Purchaser Class was harmed as aforesaid.

Claim IV: Violation of 15 U.S.C. § 2
(Attempted Monopolization)

131. The Direct Purchaser Class hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

132. This claim is pled as to the Warner Chilcott defendants and the Mayne defendants.

133. The Warner Chilcott defendants and the Mayne defendants, through their

overarching anticompetitve scheme, specifically intended to maintain monopoly power in the relevant market. It was the Warner Chilcott defendants' and the Mayne defendants' conscious objective to control prices and/or to exclude competition in the relevant market.

134. The natural and probable consequence of the Warner Chilcott defendants' and the Mayne defendants' overarching anticompetitive scheme, which was intended by them, and plainly foreseeable to them, was to control prices and exclude competition in the relevant market, to the extent it did not succeed.

135. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that the Warner Chilcott defendants and the Mayne defendants would succeed in and achieve their goal of maintaining monopoly power in the relevant market.

136. As a direct and proximate result of the Warner Chilcott defendants and the Mayne defendants' illegal and monopolistic conduct, the Direct Purchaser Class was harmed as aforesaid.

VII. DEMAND FOR JUDGMENT

WHEREFORE, the plaintiffs, on behalf of themselves and the proposed Direct Purchaser Class, respectfully prays that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Direct Purchaser Class, and declare the plaintiffs the representatives of the Direct Purchaser Class;

B. Enter joint and several judgments against the defendants and in favor of plaintiffs and the Direct Purchaser Class;

C. Award the Direct Purchaser Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and

D. Award plaintiffs and the Direct Purchaser Class their costs of suit, including reasonable attorneys' fees as provided by law.

VIII. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiffs, on behalf of themselves and the proposed Direct Purchaser Class, demands a trial by jury on all issues so triable.

Respectfully submitted,

/s/ Thomas M. Sobol

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Dated: August 13, 2012

CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of the foregoing to be served this day upon all counsel of record via the Court's CM/ECF filing system and upon all parties for which an appearance of counsel has not been made by email to their counsel.

August 13, 2012

/s/ David S. Nalven
David S. Nalven