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

INTERNATIONAL BROTHERHOOD OF ELECTRICAL WORKERS LOCAL 38, HEALTH AND WELFARE FUND on behalf of itself and all others similarly situated, Plaintiff, v. WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT COMPANY, LLC; WARNER CHILCOTT (US), LLC; WARNER CHILCOTT HOLDINGS COMPANY III, LIMITED; WARNER CHILCOTT LABORATORIES IRELAND LIMITED; MAYNE PHARMA GROUP LIMITED; and MAYNE PHARMA INTERNATIONAL PTY. LTD., Defendants.	Civil Action No. CLASS ACTION JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff, International Brotherhood of Electrical Workers Local 38, Health and Welfare Fund ("Plaintiff") on behalf of itself and all others similarly situated, for its Complaint against the above-captioned defendants, alleges as follows based on: (a) personal knowledge; (b) the investigation of its counsel, which includes a review of court filings in *Mylan Pharmaceuticals Inc., v Warner Chilcott Public Limited Company, et al.,* No. 2:12-cv-03824-PD (E.D.P.A.), *Warner Chilcott Company LLC et al., v. Heritage Pharmaceuticals Inc.,* No. 2:10-cv-01401-WJM-MF (D.N.J.) and *Warner Chilcott Company LLC et al., v. Sandoz Inc.,* No. 2:09-cv-00228-WJM-MF (D.N.J.); (c) public news filing and other public documents including filings with the Food and Drug Administration ("FDA") and the Securities and Exchange Commission ("SEC"); and (d) information and belief.

I. NATURE OF THE ACTION

1. This action challenges Defendants' obstruction of competition through an unlawful, self-described "anti-generic strategy." Through multiple, concerted and deliberate anti-competitive tactics, and blatantly anti-competitive agreements, commenced as early as 2005, Defendants have harmed Plaintiff and all other indirect purchasers of the prescription drug Doryx, by preventing generic competition in the market for delayed-release doxycycline hyclate products. As discussed more fully below, Defendants have accomplished their anti-competitive goals through the use of various strategies that were designed to unlawfully interfere with the regulatory process, cause delays in the approval of generic versions of Doryx, and disrupt the market for delayed-release doxycycline hyclate products. The Defendants' conduct constitutes an agreement to unreasonably restrain trade and a conspiracy to monopolize the market for delayed-release doxycycline hyclate products in violation of, and pursuant to, the Sherman Act, Sections 1 and 2, 15 U.S.C. §§1 and 2, the Nevada Unfair Trade Practices Act, NEV. REV. STAT. §§598A.060, *et. seq.* and 598A.210, the Nevada Deceptive Trade Practices Act, NEV. REV. STAT. §§41.600 and 598.0903, *et. seq.*, and unfair methods of competition and unconscionable, unfair, and deceptive acts and practices in violation of the Florida Deceptive and Unfair Trade Practices Act, FLA. STAT. §§501.204 and 542.22.

2. Doxycycline hyclate is tetracycline-class antibiotic that is widely prescribed for the adjunctive treatment of severe acne, and that is also indicated for (1) rickettsial infections, (2) sexually transmitted infections, (3) respiratory tract infections, (4) specific bacterial infections, (5) ophthalmic infections, (6) anthrax, including inhalational anthrax (post-exposure), (7) alternative treatment for selected infections when penicillin is

contraindicated, (8) adjunctive therapy in acute intestinal amebiasis, and (9) prophylaxis of malaria. Doryx is the branded version of delayed-release doxycycline hyclate.

3. Defendants manufacture and sell branded Doryx; the Warner Chilcott defendants market and sell branded Doryx under an exclusive license from the Mayne defendants.

4. Defendants agreed to use anti-competitive tactics such as "product hopping", referred to by Defendants themselves as an "anti-generic strategy" or "Swap-out Strategy" with the intention of foreclosing generic competition in the market for delayed-release doxycycline hyclate. As described in detail below, "switching" or "swapping-out" the market generally involved Defendants making immaterial changes to branded Doryx, i.e., changes in dosage form, strength, or tablet scoring, which provided no therapeutic benefit, followed by ceasing the promotion of the prior version of branded Doryx, removing already-distributed product from the market, and undertaking additional efforts to delay approval of competing generic versions of these products. Because a generic drug must be identical in dosage form and route of administration to its reference listed drug, these switches, along with other carefully-timed exclusionary conduct, prevented generic manufacturers from launching commercially viable competing generic versions of delayed-release doxycycline hyclate products.

5. Defendants' monopolistic activities did not stop at product switches. Defendants also entered into blatantly anti-competitive agreements with generic drug manufacturers seeking to enter the market with generic Doryx products. Defendants, faced with generic competition, decided to share their monopoly rents of Doryx products with these would-be competitors, in exchange for the manipulative agreements to defer the entry of generic doxycycline hyclate products into the market. The agreements further perpetuated Defendants' monopoly in the

market for delayed-release doxycycline hyclate products and ensured that Plaintiff and other end-users would continue to pay inflated prices for branded Doryx.

6. Defendants' plan to prevent generic entry through anti-competitive agreements and product switches - first from capsules to tablets, then in dosage strength, then through tablet scoring - was set into motion well in advance of generic entry. As generic competitors to Doryx were preparing to enter the market as early as 2005, Defendants effectuated the "swap-out" of tablets for capsules, converting the market within six months. Then, after generic manufacturers were forced to forego efforts to develop the capsules and started to develop generic versions of the then-available Doryx 75 mg and 100 mg tablet strengths, Defendants undertook additional efforts to delay entry of the generic versions of these tablets. For example, in 2006, Defendants released a study for the administration of Doryx with applesauce and sought a corresponding labeling change that required generic manufacturers to develop tablets that could be broken into pieces and sprinkled over applesauce. This change provided no additional benefit in safety or efficacy for consumers of Doryx but further delayed development of generic Doryx tablets.

7. As generic competitors were close to entering the market with generic Doryx 75 mg and 100 mg tablets, Defendants again switched formulations, this time from 75 mg and 100 mg tablets to 150 mg tablets. As a result, by the time the FDA approved the 75 mg and 100 mg generic tablets, Defendants had again shifted the market, to 150 mg tablets, leaving the generic manufacturers' 75 mg and 100 mg generic tablets commercially unviable. Generic manufacturers thereafter reformulated their 75 mg and 100 mg delayed-release doxycycline hyclate products to meet the 150 mg dosage that Defendants had switched to. In 2009 and 2010, Heritage Pharmaceuticals Inc. ("Heritage") and Sandoz Inc. ("Sandoz") sought to enter the market for delayed-release doxycycline hyclate by filing ANDAs with the FDA for generic

150 mg Doryx tablets. Defendants immediately filed patent infringement suits against both companies. Instead of pursuing their allegedly legitimate suits, or allowing consumers the benefit of generic doxycycline hyclate products, Defendants entered into settlement agreements with Heritage and Sandoz that required the generic manufacturers to delay entry of the generic products until ***December 2016.***

8. Paying two generic drug manufacturers to stay out of the market was insufficient to keep generic doxycycline hyclate products from threatening Defendants' monopoly in the market for delayed release doxycycline hyclate products. In September 2011, as generic manufacturers grew closer to launching a generic doxycycline hyclate 150 mg product, Defendants attempted a ***third*** switch, from a single scored version of Doryx 150 mg tablets to a dual-scored version of Doryx 150 mg tablets. Soon after approval of the dual-scored Doryx 150 mg tablets, Defendants discontinued sales of the single-scored 150 mg tablet and filed a baseless citizen petition with the FDA requesting that the agency not approve any ANDA applicant's 150 mg generic delayed-release doxycycline hyclate tablet until the generic tablet was changed to dual-scoring. Defendants claimed that marketing different scoring configurations at the same time would cause customer confusion despite the fact that Defendants themselves had introduced dual-scored tablets while still marketing single-scored tablets.

9. The FDA rejected Defendant Warner's petition on February 8, 2012, finding that "[c]oncurrent marketing of products with different scoring configurations by the ANDA applicant and the RLD under these circumstances would be expected to cause no more confusion than the RLD concurrently marketing the old configuration and the new configuration as it did here." FDA Letter to Warner Chilcott Responding to September 23, 2011 Citizen

Petition (Feb. 8, 2012) at 7. The FDA also criticized the timing of Defendants' scoring changes made "on the eve of expected generic approval." (*Id.* at 8).

10. In addition, on information and belief, Defendants are (or were) plotting a fourth switch whereby they planned a switch from Doryx 150 mg tablets to yet another version of Doryx in furtherance of their scheme to deny purchasers a lower-priced generic alternative to Defendants' branded Doryx.

11. Defendants knew that because a generic drug must be the same dosage strength and form as the reference listed branded drug to be automatically substitutable at the pharmacy, these immaterial product modifications, which provided no therapeutic benefit, have had the effect of preventing competing generic products from entering the market.

12. Defendants admit that they engaged in an "anti-generic strategy." They trumpet it. Indeed, both Warner Chilcott and Mayne have publicly boasted about their strategies to shield Doryx from potential generic competition. In a 2007 earnings call, the President and Chief Executive Officer of Warner Chilcott, Roger Boissoneault, boasted that the company has "been successful in moving the product along and creating the next generation Doryx" and that, as a result, "***there has never been a generic.***" (Q4 2007 Warner Chilcott Earnings Conference Call Q&A Transcript) (Emphasis added.). Four years later, in a 2011 earnings conference call, Mr. Boissoneault further boasted that Warner Chilcott has "multiple strategies" to provide Doryx with "protection from potential generic competition." (Q2 2011 Warner Chilcott Earnings Conference Call Q&A Transcript). Defendant Mayne, Warner Chilcott's supplier, noted in 2010 that "one of the challenges…with…Doryx® tablets is that the competition is keenly seeking ways to access the market." Mayne 2010 Annual Report at 16. Mayne further acknowledged that it had worked with Warner Chilcott to "protect the market position of

Doryx®" by "successfully reformulating Doryx® from capsules into tablets in 2005 and then subsequently releasing a new 150mg tablet in July 2008." Mayne 2011 Annual Report at 11.

13. As these strategies and anti-competitive agreements have netted Defendants hundreds of millions of dollars in monopoly profits, it is not surprising that they would brag to investors about their steps to prevent generic competition to Doryx. However, these tactics provide no corresponding benefit to consumer welfare. As a result of this conduct, purchasers have been denied the substantial benefits of lower-priced generic competition to Doryx and forced to pay overcharges for delayed-release doxycycline hyclate products.

14. This scheme and the concerted activities alleged in this complaint constitute conspiracies to unreasonably restrain trade, attempted monopolization, conspiracies to monopolize, and actual monopolization in violation of federal and state antitrust laws. Such conduct also constitutes unfair and deceptive trade practices under state law.

II. JURISDICTION AND VENUE

15. This Court has subject matter over this action pursuant to 15 U.S.C. §26, and 28 U.S.C. §§1331 and 1337. This Court also has jurisdiction over this class action pursuant to 28 U.S.C. §1332(d). The amount in controversy, exclusive of interest and costs, exceeds $5 million.

16. Defendants transact business within this District. Venue is appropriate within this District under 28 U.S.C. §1391(b) because a substantial part of the events or omissions giving rise to the claim occurred in this District.

III. THE PARTIES

17. Plaintiff International Brotherhood of Electrical Workers No. 38 ("IBEW") is a health and welfare fund located at 1590 East 23rd Street, Cleveland, Ohio 44114. IBEW is an

"employee welfare benefit plan" and "employee benefit plan" maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act, 29 U.S.C. §186(c)(5) and as defined by Sections 1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §1001, *et seq.* As such, IBEW is entitled to bring suit in its own name pursuant to 29 U.S.C. §1132(d). Beneficiaries of Plaintiff IBEW purchased Doryx during the Class Period, for personal use. IBEW is responsible for reimbursing or paying for members' purchases of prescription drugs such as Doryx. Plaintiff IBEW reimbursed its beneficiaries for purchases of Doryx in a number of states including the states of Nevada and Florida. Plaintiff IBEW and its beneficiaries (collectively "Plaintiff IBEW") have been injured in their business or property by having paid more for Doryx than they would have absent the Defendants' illegal and anti-competitive conduct alleged herein. Plaintiff IBEW was injured by the illegal, anti-competitive, and deceptive conduct described herein, both individually and in a manner that was common and typical of the Indirect Purchaser Class members.

18. 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.

19. 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.

20. 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, New Jersey 07866.

21. 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.

22. 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.

23. The five foregoing defendants are referred to herein as the "Warner Chilcott Defendants" or "Warner Chilcott".

24. 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.

25. 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.

26. The two foregoing defendants are referred to herein as the "Mayne Defendants" or "Mayne".

27. The foregoing seven defendants are collectively referred to herein as "Defendants."

28. All of Defendants' actions described in this complaint are part of, and in furtherance of, the illegal monopolization, restraints of trade and unfair, unconscionable, and deceptive acts and practices alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged

in the management of 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 Defendants.

IV. LEGAL AND REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand-Name Drugs

29. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §301-92. A NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. §355(a) and (b).

30. When the FDA approves a brand-name manufacturer's NDA, the brand manufacturer may list any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand-name drug prior to the expiration of the listed patents in the FDA's Orange Book. Patents issued after NDA approval may be listed within 30 days of issuance. 21 U.S.C. §355 (b)(l) and (c)(2).

31. The FDA relies completely on the brand-name manufacturer's truthfulness about patents' validity and applicability; the FDA does not have the resources to check the manufacturer's representations for accuracy or trustworthiness.

B. The Hatch-Waxman Amendments

32. Enacted in 1984, the Hatch-Waxman Amendments simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand-name drug may

file an abbreviated new drug application ("ANDA"). ANDAs rely on the scientific findings of safety and effectiveness included in the brand-name drug manufacturer's original NDA, but must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand-name drug — that is, that the generic drug is bioequivalent to the brand-name drug. The FDA assigns generic drugs that are bioequivalent to branded drugs an "AB" rating.[1]

33. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients in the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity, are therapeutically equivalent and may be substituted for one another. Thus, bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart.

34. Throughout the Hatch-Waxman Amendments, Congress sought to expedite the entry of generic drugs, thereby reducing healthcare expenses nationwide. Congress also wanted to protect pharmaceutical companies' incentives to create new and innovative products.

35. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches and ushering in an era of historic high profit margins for brand-name pharmaceutical companies. In 1983, before enactment of the Hatch-Waxman Amendments,

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[1] Generic manufacturers can also seek approval of non-AB-rated generics. The FDCA permits "hybrid" applications that are neither full NDAs containing safety and efficacy data, nor ANDA applications showing that the proposed product is the "same" as the NDA product. 21 U.S.C. §505(b)(2). Drug products approved under this section use a safe and effective active pharmaceutical ingredient, but modify the drug product in some way so that it differs from the original NDA product, either in dosage form, strength, route of administration, formulation, dosing regimen, or indication. These non-AB-rated generics are not bioequivalent to the innovator product. *See* 21 C.F.R. §314.54.

only 35% of the top-selling drugs with expired patents had generic versions available; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generics totaled $21.6 billion and generic drugs accounted for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion and generic drugs accounted for 75% of prescriptions.

C. Paragraph IV Certifications

36. To obtain FDA approval of an ANDA, 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:

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

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

iii. 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

iv. 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").

37. If a generic manufacturer files a Paragraph IV certification, a brand-name manufacturer has the ability to delay FDA approval of an ANDA simply by suing the ANDA applicant for patent infringement. If the brand-name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (i) the passage of 30 months, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval" but cannot authorize the generic manufacturer to go to market before the passage of 30 months or a court decision of invalidity or non-infringement.

38. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification gets a period of protection from competition with other generic versions of the drug. For Paragraph IV certifications made prior to December 2003, the first generic applicant is entitled to 180 days of market exclusivity, i.e., all generics (other than one marketed by the branded manufacturer) are kept off the market for at least six months.

39. Once a generic drug has entered into the market, sales switch quickly from the brand to the generic. Thus the high profit margins on brand-name drugs and the predictable effects of generic entry create powerful financial incentives for brand-name manufacturers to list patents in the Orange Book and sue any generic competitor that files an ANDA with Paragraph IV certifications. This is so because, even if such patents are not eligible for listing or if the competitor's product does not actually infringe the listed patent(s) and/or the patent is invalid and unenforceable, such suits automatically delay final FDA approval of an ANDA for up to 30 months.

40. By creating a statutory mechanism to enable early infringement litigation following paragraph IV certifications, the Hatch-Waxman Amendments foster patent litigation between generic and branded drug companies as a method to test the validity of outstanding pharmaceutical patents and encourage generic manufacturers to invent around branded patents. The notion is that bona fide litigation will result in rulings that either confirm legitimate patent protection or ferret out illegitimate use of invalid or unenforceable drug patents.

D. Citizen Petitions

41. Section 505(j) of the FDCA creates a mechanism by which a person may file a petition with the FDA requesting, among other things, that the agency take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a Citizen Petition.

42. Citizen Petitions were created to provide an opportunity for individuals to express genuine concerns about legitimate safety, scientific, or legal issues regarding a product any time before, or after, its market entry. Other than the form of such Citizen Petition, the regulations place no restrictions on the subject matter of a Citizen Petition.

43. The Citizen Petition must contain a statement of what action is being requested, and why. Such justification, if appropriate, includes scientific data and other technical information. The submitter is required to provide a certification that the petition includes all information and views on which the petition relies, and it must also include representative data known to the petition that is unfavorable to the position advocated in the Citizen Petition.

44. FDA regulations concerning Citizen Petitions require the FDA commissioner to respond to, but not necessarily to resolve, each Citizen Petition within 180 days of receipt. The Commissioner may approve the request in whole or in part, deny the request, or provide a tentative response with an estimate as to when it will issue a final response.

45. Reviewing and responding to Citizen Petitions is a resource-intensive and time-consuming task because the FDA must research the petition's subject, examine scientific, medical, legal, and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. These activities strain the FDA's limited resources. For these reasons, the FDA's final response to a Citizen Petition typically takes much longer than 180 days.

46. Abusive and anti-competitive Citizen Petitions have become an increasingly common problem in the last several years as brand name companies have come to realize the immense profits that result from delaying generic competition by even a few months. In some such cases, Citizen Petitions have been filed with respect to ANDAs that have been pending for a year or more, long after the brand name manufacturer received notice of the ANDA filing. Lawful or not, delaying competition is a lucrative strategy for an incumbent manufacturer. Given the market's preference for generic products over brand products, the cost of filing an improper Citizen Petition is usually trivial compared to the value of securing a few months delay in generic competition.

47. FDA officials have acknowledged abuses of the Citizen Petition process. FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency, he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before." Speech before the Generic Pharmaceutical Association Annual Policy Conference (Sept. 19, 2005).

48. Specifically in reference to Citizen Petitions that address the approval of generic drug products, Gary Buehler, RPh., Director of the Office of Generic Drugs, Center for Drug Evaluation and Research ("CDER") at FDA, remarked in July 2006 that "very few . . . have presented data or analysis that significantly altered FDA's policies." Mr. Buehler went on to observe that of forty-two citizen petitions raising issues regarding the approvability of generic products, only three petitions led the FDA to change its policy on the basis of data or information actually submitted with the Citizen Petition.

49. The abuse of the Citizen Petition process by brand name manufacturers led Congress to enact FDA Amendments Act of 2007, 21 U.S.C. §355(q) (the "2007 Amendments"). In relevant part, the 2007 Amendments require the FDA to not delay approval of a pending ANDA because of a Citizen Petition unless such a delay is necessary to protect the public health. The 2007 Amendments also enabled the FDA to deny summarily any Citizen Petition where the primary purpose of the petition is to delay competition entering the market.

E. The Benefits of Generic Drugs

50. Generic drugs are typically sold at substantial discount to the reference listed branded drug. The first generic drug that enters the market is generally priced at a significant discount to the referenced listed branded drug and, as additional generic drugs enter the market, generic drug prices fall even further in comparison to the referenced listed branded drug.

51. Generic drug competition generates large savings for purchasers. A 1998 Congressional Budget Office Report estimates that, in 1994 alone, consumers saved $8 to $10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the corresponding brand name products. The FDA has found that consumers whose needs can be fully satisfied with generic drugs could enjoy reductions of 52% in their daily medication costs. Savings From Generic Drugs Purchased From Retail Pharmacies, http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134205.htm (Last visited September 17, 2012). Most recently, a September 2011 study commissioned by the Generic Pharmaceutical Association found that generic drugs saved the U.S. health care system more than $931 billion from 2001-10 and that the savings for 2010 alone were nearly $158 billion. The study also cites data from the federal Centers for Medicare and Medicaid Services establishing that, a mere 2% increase in generic utilization, would save Medicare an

additional $1.3 billion annually. As a result of Defendants' unlawful tactics and agreements to delay generic competition to Doryx, prescription drug purchasers have been unable to enjoy similar savings with respect to purchases of delayed-release doxycycline hyclate products.

V. RELEVANT MARKET AND MARKET POWER

52. Doxycycline hyclate is a tetracycline-class oral antibiotic that is widely prescribed for the adjunctive treatment of severe acne and other specifically indicated bacterial infections. Doryx is the branded version of delayed-release doxycycline hyclate. Defendants have marketed various iterations of Doryx, including: (1) a 75 mg delayed-release doxycycline hyclate capsule; (2) a 100 mg delayed-release doxycycline hyclate capsule; (3) a 75 mg delayed-release doxycycline hyclate tablet; (4) a 100 mg delayed-release doxycycline hyclate tablet; and (5) a 150 mg delayed-release doxycycline hyclate tablet.

53. Generic manufacturers Mylan Pharmaceuticals, Inc. ("Mylan") and Impax Laboratories, Inc. ("Impax") obtained approval for a generic 75 mg delayed-release doxycycline hyclate tablet that is an AB-rated equivalent to the Doryx 75 mg tablet and a 100 mg delayed-release doxycycline hyclate tablet product that is an AB-rated equivalent to the Doryx 100 mg Tablet. In addition, Mylan has gained final approval for and launched a generic 150 mg delayed-release doxycycline hyclate tablet product that is an AB-rated equivalent to the Doryx 150 mg Tablet.

54. The generic delayed-release doxycycline hyclate products are AB-rated to their Doryx branded equivalents only. Thus, under most automatic substitution laws and rules, they are automatically substitutable for their Doryx branded equivalents only. For example, the generic doxycycline hyclate 75 mg Tablet is AB-rated to the branded Doryx 75 mg Tablet and is, thus, automatically substitutable only for the Doryx 75 mg Tablet. However, because it is not the same

strength or dosage form, the generic doxycycline hyclate 75 mg Tablet is not AB-rated to, and, therefore, not automatically substitutable for, other Doryx dosage forms and strengths.

55. Delayed-release doxycycline hyclate products are not automatically substitutable for other treatments, and, therefore, replaceable products, at the pharmacy counter. Thus, the presence of other products indicated for the treatment of similar conditions, but not AB-rated to delayed-release doxycycline hyclate products, is not sufficient to prevent the anti-competitive effects of Defendants' conduct relating to delayed-release doxycycline hyclate.

56. Generic delayed-release doxycycline hyclate products are priced substantially below Doryx. Upon entry of AB-rated generic delayed-release doxycycline hyclate products, these lower-priced products, within a matter of months, divert the overwhelming majority of sales from branded Doryx products.

57. Because of the competitive relationship between branded drugs and their generic competitors, such products comprise a distinct product market for antitrust purposes. Thus, the product market in which to assess the effects of Defendants' conduct is the market for Doryx and its AB-rated equivalents, i.e., the delayed-release doxycycline hyclate market.

58. The relevant geographic market in which to assess the effects of Defendants' conduct is the United States. The FDA's regulatory process for approving drugs for sale only in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals occur on a nationwide basis, establish the boundaries of the geographic market.

59. There are substantial barriers to entry in the relevant market, including the FDA's regulatory requirements. Moreover, through their anti-competitive, exclusionary conduct, Defendants have erected additional, artificial barriers to entry in the relevant markets.

60. At all relevant times, Defendants possessed monopoly power in the relevant market.

VI. DEFENDANTS' UNLAWFUL CONDUCT

A. Background on Delayed-release Doxycycline Hyclate Products

61. Mayne Defendants received FDA approval for the branded Doryx 100 mg Capsule on July 22, 1985, and began selling the product commercially the same year.

62. 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.

63. Mayne Defendants received FDA approval for the Doryx 75 mg Capsule on August 13, 2001 and Warner Chilcott Defendants introduced the Doryx 75 mg Capsule in the United States in January 2002. Mayne Defendants received FDA approval for the Doryx 75 mg and 100 mg Tablets on May 6, 2005 and began commercialization of these products soon thereafter.

64. On October 25, 2005, the U.S. Patent and Trademark Office issued United States Patent No. 6,958,161 ("the '161 Patent"), entitled "Modified Release Coated Drug Preparation." The '161 Patent claims, *inter alia*, modified release preparations of doxycycline hyclate. Mayne listed the patent in the FDA's Orange Book as covering Doryx Delayed-Release Tablets ("Doryx®"). Due to its licensing agreement with Mayne, Warner Chilcott asserted that it had the exclusive right to market and sell the products covered by the patent.

65. By June 2006, Warner Chilcott Defendants had discontinued the marketing of the Doryx 75 mg and 100 mg Capsules.

66. Mayne Defendants received FDA approval for the Doryx 150 mg Tablet on June 20, 2008, and soon thereafter Warner Chilcott Defendants stopped promoting the Doryx 75 mg and 100 mg Tablets.

67. Sales for the Doryx franchise for the twelve months ending December 31, 2011 were approximately $173 million.

B. Defendants' Efforts to Suppress Generic Competition

68. Defendants have made no secret of their desire to manipulate the regulatory and competitive processes to avoid generic competition in the relevant market. Indeed, the President and Chief Executive Officer of Warner Chilcott, Roger Boissoneault, 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 suppress generic competition.

69. Defendants admitted their strategy to thwart generic competition to Doryx through multiple strategies to shift the market by changing formulations in an earnings call with stock analysts. Defendant Mayne, Warner Chilcott's supplier, admitted to collaborating with Defendant Warner Chilcott to use "life cycle strategies" to prevent generic competition in their annual reports.

70. Defendants have relentlessly conspired and agreed to prevent competition and to maintain and extend their monopoly power in the relevant market. As referenced in Defendants' September 2011 petition, designed to further delay generic entry into the relevant market, Warner Chilcott described itself as the "U.S. agent for Mayne Pharmaceuticals International Pty. Ltd., the sponsor of the Doryx (doxycycline hyclate delayed-release tablets, USP) new drug application (NDA) 50-795 that was originally approved on May 6, 2005." (Warner Chilcott Citizen Petition (Sept. 23, 2011) at 1). Indeed, as Mayne's U.S. agent, Warner Chilcott filed the citizen petition on behalf of both Defendants. As a result of this anti-competitive conduct, Defendants have prevented or delayed lower-priced generic competition to Doryx for years, and continue to take steps to thwart or delay generic competition in the relevant market at every turn, at the expense of manufacturers of generic doxycycline hyclate and purchasers of Doryx alike.

C. Defendants' First Market Switch: Capsules to Tablets

71. Defendants faced the possibility of generic competition to their Doryx franchise as early as 2005. Generic companies, including Mylan, were developing generic formulations of the Doryx 75 mg and 100 mg Capsules and seeking FDA approval to sell their lower-priced generic versions of Doryx Capsules. These manufacturers had expended substantial efforts and expense to develop and test generic doxycycline hyclate 75 mg and 100 mg Capsules.

72. Given the threat posed by impending generic competition, Defendants acted to prevent competition to their Doryx franchise. Defendants first obtained FDA approval to market the Doryx 75 mg and 100 mg Tablets on May 6, 2005 and launched the Doryx 75 mg and 100 mg Tablets shortly after approval. This undertaking converted the delayed-release doxycycline hyclate market from Doryx Capsules to Doryx Tablets within approximately six months. Indeed, by June 14, 2006, Defendants had completely discontinued marketing Doryx Capsules.

73. Defendants' strategy to switch the market from Doryx Capsules to Doryx Tablets was executed to perfection. Generic firms pursuing generic versions of the Doryx 75 mg and 100 mg Capsules, recognizing Defendants' development of Doryx 75 mg and 100 mg Tablets, were forced to forego their efforts to develop and/or effectively commercialize this product and, instead, switch their development efforts to doxycycline hyclate 75 mg and 100 mg Tablets. As a result of the development of Doryx Tablets, the opportunity to effectively commercialize a generic version of Doryx Capsules no longer existed and, therefore, generic manufacturers ceased development of such products.

74. Defendants' switch from Doryx 75 mg and 100 mg Capsules to Doryx 75 mg and 100 mg Tablets delayed generic entry without any improvement to the therapeutic character of the product or consumer welfare, generally.

75. While firms pursuing generic doxycycline hyclate were forced to forego their efforts to commercialize generic versions of the Doryx 75 mg and 100 mg Capsules, they continued their efforts to attempt to bring lower-priced generic alternatives to the delayed-release doxycycline hyclate market by developing generic versions of the Doryx 75 mg and 100 mg Tablets. These manufacturers made substantial investments into the development, testing, manufacture, and launch of a delayed-release tablet form of doxycycline hyclate. In response, Defendants again erected obstacles, creating additional time to effectuate their next unlawful switch strategy.

D. Defendants' Applesauce Study

76. In 2006, Defendants released studies and sought a labeling change regarding the use of their Doryx 75 mg and 100 mg Tablets when broken into pieces and sprinkled over applesauce for patient consumption (the "Tablet Applesauce Study"). Because a generic product must be identical in labeling to its reference listed drug equivalent, Defendants' conduct required the generic manufacturers to undertake similar studies and to formulate a product that could achieve the necessary delayed-release properties when broken into pieces and sprinkled over applesauce.

77. Defendants timed the release of the Tablet Applesauce Study and label change request to suppress competition. Defendants completed a similar applesauce study for the Doryx 75 mg and 100 mg Capsules (the "Capsule Applesauce Study") and sought a corresponding labeling change for these products in December 2002, obtaining approval for the labeling change in June 2003. But Defendants waited until February 2006, over three years later and after the generic manufacturers had already made significant investments in developing an externally coated tablet, to release the results of the Tablet Applesauce Study and seek a labeling change, obtaining approval in December 2006. Defendants' change in labeling to include the Tablet Applesauce Study was

designed to, and had the effect of, delaying generic manufacturers' ANDAs for their generic Doryx 75 mg and 100 mg Tablets, providing Defendants with additional time to effectuate their second market switch from the 75 mg and 100 mg tablets to 150 mg tablets.

78. Despite that the Tablet Applesauce Study delayed development and approval of their generic doxycycline hyclate 75 mg and 100 mg Tablets, generic manufacturers were able to successfully formulate products bioequivalent to branded Doryx 75 mg and 100 mg Tablets and filed ANDAs for 75 mg and 100 mg doxycycline hyclate delayed-release tablets in 2008.

E. Defendants' Scoring Change

Defendants sought to further delay the FDA's approval of ANDAs for generic doxycycline hyclate 75 mg and 100 mg Tablets by filing citizen petitions to the FDA and tweaking their Doryx 75 mg and 100 mg formulations. For example, in February 2009, Defendants launched a "scored" version of the Doryx 100 mg Tablet and, in March 2009, launched a "scored" version of the Doryx 75 mg Tablet. The scored versions of these products, which allow patients to break the tablets into halves, were designed to force generic manufacturers to modify their product to create "scored" versions of its generic doxycycline hyclate 75 mg and 100 mg Tablets in order to obtain FDA approval. This tactic resulted in further stalled generic competition.

F. Defendants' Second Market Switch: 75 mg and 100 mg Tablets to 150 mg Single Scored Tablets

79. Again, in response to the threat of potential generic competition and having bought time through the erection of anti-competitive obstacles to ANDA approval for the 75 mg and 100 mg tablet strengths, Defendants implemented their next switch from the Doryx 75 mg and 100 mg Tablets to the Doryx 150 mg Tablet.

80. After seeking and obtaining FDA approval for 150 mg single-scored delayed-release tablet version of Doryx, in June 2008, Defendants again shifted the delayed-release

doxycycline hyclate market, this time from the Doryx 75 mg and 100 mg Tablets to the Doryx 150 mg Tablets. Defendants accomplished this goal by quickly phasing out the Doryx 75 mg and 100 mg Tablets through eliminating all promotional activities regarding the Doryx 75 mg and 100 mg Tablets and then discounting the sale of the Doryx 75 mg and 100 mg Tablets.

81. Defendants' second market switch had the intended anti-competitive effect, furthering their scheme to maintain their monopoly in the delayed-release doxycycline hyclate market. By the time that Mylan received final FDA approval for its generic versions of the Doryx 75 mg and 100 mg Tablets on December 28, 2010, and subsequently launched and sought to commercialize these products, once again there was no commercially viable market left in which to compete. Just as purchasers were set to enjoy the benefits of generic competition, Defendants eliminated the market for the generic products, shifting prescriptions from Doryx 75 mg and 100 mg Tablets to the 150 mg Tablets.

82. Defendants incurred significant expenses to switch from Doryx 75 mg and 100 mg Tablets to Doryx 150 mg Tablets, a switch that in and of itself provided no commercial advantage to Defendants other than to exclude generic competition from the market.

83. Defendants admit the Doryx 150 mg dosage strength provides no additional therapeutic benefit. Defendants' own prescribing information for Doryx 150 mg Tablets does not provide for a dosage administration in an amount equal to 150 mg. Instead, it instructs that the "usual dose is 200 mg on the first day of treatment (administered 100 mg every 12 hours) followed by a maintenance dose of 100 mg daily. In the management of more severe infections (particularly chronic infections of the urinary tract), 100 mg every 12 hours is recommended."

84. Notably, while Warner Chilcott Defendants have switched the U.S. market (1) from capsules to tablets, (2) from 75 mg and 100 mg tablets to single-scored 150 mg tablets, and

(3) from single-scored 150 mg tablets to dual-scored 150 mg tablets, Mayne has continued to sell Doryx capsules for the past 25 years in Australia as well as for an extended period of time in Singapore.

G. Defendants Enter Into Agreement with Generic Drug Manufacturers to Delay Entry of Generic Doxycycline Hyclate Products

85. Generic manufacturers, forced to switch to manufacturing 150 mg tablets, began efforts to obtain FDA approval for generic versions of the new dosage. In or around January 2009, Sandoz filed an ANDA for 75 mg and 100 mg delayed-release doxycycline hyclate tablets with the FDA containing a Paragraph IV certification that the '161 Patent was invalid, unenforceable, and/or would not be infringed by the manufacture, use, or sale of Sandoz's proposed products. After Defendants' product switch, Sandoz amended its ANDA and Paragraph IV certification to request approval for a 150 mg product. In or around March 2010, Heritage filed an ANDA for 75 mg, 100 mg, and 150 mg delayed-release doxycycline hyclate tablets with the FDA with Paragraph IV certifications that the patent for Defendants' 75 mg, 100 mg, and 150 mg tablet would not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generics.

86. In response, Defendants promptly filed patent infringement litigation against the two generic manufacturers, Heritage and Sandoz, alleging *inter alia,* that the proposed generics "will be administered to human patients for the treatment of infections, which administration constitutes direct infringement of the '161 Patent." Complaint at ¶20, *Warner Chilcott Company LLC et al., v. Heritage Pharmaceuticals Inc.,* No. 2:10-cv-01401-WJM-MF (D.N.J.)

87. Without attempting to have the court uphold the validity of their patent, Defendants entered into settlement agreements with Heritage and Sandoz, which prohibited the two manufacturers from marketing or selling a generic 150 mg Doryx product until ***December 16,***

2016. On information and belief, Defendants made reverse payments worth millions of dollars to Heritage and Sandoz in exchange for the would-be competitors' agreement to halt their efforts to introduce a generic Doryx into the market. This blatantly anti-competitive agreement further enabled Defendants to perpetuate their monopoly in the market for delayed-release doxycycline hyclate tablets and maintain inflated and supra-competitive prices for their products.

H. Defendants' Third Market Switch: 150 mg Single Scored Tablets to 150 mg Dual Scored Tablets

88. In response to Defendants' switch from the Doryx 75 mg and 100 mg Tablets to the Doryx 150 mg Tablets, generic manufacturer Mylan filed an ANDA for a generic Doryx 150 mg Tablet in December 2008 and received tentative approval for this product on June 10, 2011. Again, in direct response to the threat of generic competition, Defendants sought to further delay generic competition by changing the scoring configuration on their Doryx 150 mg Tablet from a "single score" to a "dual score."

89. This tactic provided no additional therapeutic benefit. To the extent a patient was prescribed a 200 mg dose, the patient already had the option of taking two 100 mg tablets. Furthermore, to the extent a patient was prescribed a 50 mg dose, the patient already had the option of breaking a 100 mg scored tablet into two 50 mg tablets. In other words, switching from a 150 mg "single-scored" tablet to a 150 mg "dual-scored" tablet provided no new dosage amount that was not already offered through previous versions of Doryx.

90. Defendants' intent to use this change in scoring as a means to delay generic entry is further evidenced by Mayne's press release announcing its September 14, 2011 FDA Approval of the dual-scored Doryx 150 mg Tablet, highlighting Defendants' commitment "to continue its strategy to lifecycle manage Doryx® into new dose strengths and formulations" and its "expectation that the FDA is likely to ask companies with a single score 150mg 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). Indeed, Defendants attempted to time the manipulation of the FDA regulatory processes to coincide with expected generic entry, which Defendants expected to occur at the end of September 2011 upon expiration of the 30-month regulatory stay of approval. In a further attempt to impede generic entry, Warner Chilcott "asked its major customers to return inventory of the single-scored product as they receive shipments of the dual-scored product" when the company introduced the dual-scored Doryx 150 mg Tablet into the market on September 21, 2011. Warner Chilcott Citizen Petition (Sept. 23, 2011) at 2. Defendants have characterized the scoring change as a change in tablet "design" – to "replace" the current tablet design – not a change affecting the safety and effectiveness of the drug. Warner Chilcott Letter to Pharmacists Regarding Doryx 150 mg (Sept. 2011) at 1.

91. The FDA stated that the scoring change yielded no safety or dosing benefits.

92. On September 23, 2011, Defendants filed yet another citizen petition contending that Mylan' s doxycycline hyclate 150 mg Tablet should not be approved unless and until modified from a "single-scored" to a "dual-scored" tablet.

93. On February 8, 2012, the FDA rejected Defendants' citizen petition. FDA Letter to Warner Chilcott Responding to September 23, 2011 Citizen Petition (Feb. 8, 2012). The FDA was not persuaded by Defendants' argument that a generic single-scored Doryx 150 mg Tablet should not be approved because having two products with different scoring configurations on the market could lead to patient confusion and suboptimal dosing. In addition to finding that dosing errors were unlikely to occur, the FDA found it significant that Defendants themselves had introduced their dual-scored tablets while still marketing their single-scored tablets, without initiating a recall of the single-scored tablets or including any additional warnings to the Doryx labeling. In

condemning the legitimacy of Defendants' citizen petition, the FDA criticized the suspect timing of Defendants' scoring changes, made "on the eve of expected generic approval." (Id. at 8).

94. On the same day as the FDA rejected Defendants' citizen petition, it approved Mylan's generic version of the single-scored Doryx 150 mg Tablet, with a post-approval requirement to double score Mylan's next manufacturing run.

I. Defendants' Plans for a Fourth Market Switch

95. On information and belief, Defendants plotted their next switch from dual-scored 150 mg Doryx Tablets to the next formulation of Doryx.

96. Specifically, on information and belief, Defendants undertook clinical trials related to a new formulation of Doryx in addition to pursuing other "multiple strategies" to thwart generic competition.

97. Defendants' efforts to convert the delayed-release doxycycline hyclate market, on the eve of generic entry, to delay and prevent generic competition to Doryx, have suppressed generic competition in the delayed-release doxycycline hyclate market. Defendants' product changes have conferred no therapeutic benefit over previous formulations of Doryx. Instead, they have imposed overcharges on Plaintiff and the Indirect Purchaser Class in connection with their purchases of delayed-release doxycycline hyclate products.

VII. THE ANTI-COMPETITIVE EFFECTS OF DEFENDANTS' CONDUCT

98. As a result of the Defendants' conspiracy to maintain monopoly control over the relevant market through anti-competitive conduct, generic manufacturers have been blocked from competing in the delayed-release doxycycline hyclate market.

99. Because competing delayed-release doxycycline hyclate products would be AB-rated equivalents to Defendants' branded Doryx products (and therefore eligible for automatic

substitution) and priced below Defendants' branded Doryx products, Plaintiff and the Indirect Purchaser Class would have substituted generic delayed-release doxycycline hyclate products for the more expensive branded Doryx immediately upon entry into the market.

100. Defendants' agreements and anti-competitive conduct allowed the Warner Chilcott Defendants to set the cost of Doryx at artificially inflated monopoly prices in the United States. This conduct has harmed Plaintiff and all indirect purchasers of delayed-release doxycycline hyclate products by preventing access to less-expensive generic substitutes for Doryx and forcing indirect purchasers to pay inflated prices for the branded drug. Defendants' conduct has had the direct anti-competitive effects of foreclosing competition in the market for delayed-release doxycycline hyclate products and maintaining supra-competitive and monopolistic prices for Doryx.

101. There is no pro-competitive justification, countervailing efficiency, increase to consumer welfare, or legitimate business reason for Defendants' conduct. Defendants' conduct has precluded, rather than expanded, competition.

102. Generic manufacturers of delayed-release doxycycline hyclate products had extensive experience in the pharmaceutical industry, including having successfully obtained approval for ANDAs and successfully selling generic pharmaceutical products.

103. Generic manufacturers of delayed-release doxycycline hyclate products had sufficient financial capacity to manufacture product and were ready, willing, and able to do so.

VIII. CLASS ACTION ALLEGATIONS

104. Plaintiff, on behalf of itself and the classes of indirect purchasers it seeks to represent, demand monetary, equitable, injunctive, and declaratory relief against Defendants based

on allegations of anti-competitive conduct in the market for Doryx and AB-rated generic equivalents.

105. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(2) as representative of an United States Indirect Purchaser Class, defined as follows:

> All persons or entities in the United States and its territories who purchased Doryx indirectly from any of the Defendants at any time during the period May 6, 2005 to the present. Excluded from the United States Indirect Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

106. Injunctive relief is appropriate under Rule 23(b)(2) because, as alleged herein Defendants have acted on grounds generally applicable to the United States Indirect Purchaser Class, thereby making appropriate final injunctive relief with respect to the Indirect Purchaser Class as a whole.

107. Plaintiff brings this action on behalf of itself and, under Fed. R Civ. P. 23(a) and (b)(3) as representative of a Nevada Indirect Purchaser Class, defined as follows:

> All persons or entities in the United States and its territories who purchased, other than for resale, Doryx, that was manufactured, produced, marketed, sold or purchased, in the state of Nevada, indirectly from any of the Defendants at any time during the period May 6, 2005 through and until the anti-competitive effects of Defendants' conduct cease (the "Class Period"). Excluded from the Nevada Indirect Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, fully-insured health plans, i.e. plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members, and all governmental entities.

108. Plaintiff brings this action on behalf of itself and, under Fed. R Civ. P. 23(a) and (b)(3) as representative of a Florida Indirect Purchaser Class, defined as follows:

> All persons or entities in the United States and its territories who purchased, other than for resale, Doryx, that was manufactured, produced, marketed, sold or purchased, in the state of Florida, indirectly from any of the Defendants at any time during the period May 6, 2005 through and until the anti-competitive effects of Defendants' conduct cease (the "Class Period"). Excluded from the Florida Indirect Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, fully-insured health

plans, i.e. plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members, and all governmental entities.

109. Members of the United States, Nevada, and Florida Indirect Purchaser Classes (collectively "Indirect Purchaser Classes") are so numerous and geographically dispersed that joinder is impracticable. Further, the Indirect Purchaser Classes are readily identifiable from information and records that are required by law to be maintained by pharmacies, drugstores, pharmaceutical benefit managers, and managed care organizations, as well as records in the possession of the Defendants.

110. Plaintiff's claims are typical of the claims of the members of the Indirect Purchaser Class. Indirect Purchaser Plaintiff and all members of the Indirect Purchaser Class were damaged by the same wrongful conduct of Defendants, i.e., they paid artificially inflated prices for delayed-release doxycycline hyclate products and were deprived of the benefits of competition from cheaper generic versions of Doryx as a result of Defendants' wrongful conduct.

111. Plaintiff will fairly and adequately protect and represent the interests of the Indirect Purchaser Classes. The interests of the Plaintiff are coincident with, and not antagonistic to those of, the Indirect Purchaser Classes.

112. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation and have particular experience with indirect purchaser class action antitrust litigation involving pharmaceutical products.

113. Questions of law and fact common to the members of the Indirect Purchaser Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to all the Indirect Purchaser Classes, thereby making monetary and equitable relief with respect to the Indirect Purchaser Class as wholes appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

114. Questions of law and fact common to the Indirect Purchaser Classes include:

a. whether Defendants conspired to suppress competition in the market for delayed-release doxycycline hyclate products;

b. whether Defendants unlawfully prevented or delayed generic manufacturers from coming to market with a generic doxycycline hyclate product in the United States through their actions and conduct;

c. whether Defendants maintained and conspired to maintain monopoly power by delaying generic entry or harming competition in the market for delayed-release doxycycline hyclate products;

d. whether there is a non-pretextual pro-competitive justification for Defendants' product hopping and other exclusionary conduct;

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

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

g. whether Defendants' product hopping strategy was improper and prevented or delayed competition;

h. whether Defendants' citizen petitions were improper and prevented or delayed competition;

i. whether Defendants' settlement agreements with Heritage and Sandoz constituted unlawful anti-competitive agreements;

j. whether Defendants unlawfully excluded competitors and potential competitors from the market for Doryx and AB-rated generic bio-equivalents;

k. whether Defendants' conduct caused antitrust injury to the business or property of Plaintiff and the members of the Indirect Purchaser Classes; and

l. whether Defendants' conduct constituted unfair, unconscionable, and deceptive acts and practices.

115. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. 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, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweigh potential difficulties in management of this class action.

116. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

CLAIMS FOR RELIEF

COUNT I

Contract, Combination or Conspiracy in Restraint of Trade, Sherman Act Section 1, 15 U.S.C. §1

117. Plaintiff repeats the allegations of the preceding paragraphs as if set forth herein.

118. During the relevant period, Defendants Warner Chilcott and Mayne entered into a contract, conspiracy, and combination to restrain trade, and have taken affirmative acts in furtherance of their contract, conspiracy, and combination to restrain trade, by suppressing

competition in the relevant market through their continued efforts (l) to convert the relevant market to new versions of Doryx, on the eve of generic entry, to delay or prevent generic competition to Doryx, thereby preventing competition from the relevant markets; (2) to enter into anti-competitive settlement agreements with generic manufacturers to delay their introduction of generic doxycycline hyclate products into the market; and (3) to manipulate the FDA regulatory processes to delay or prevent generic competition to Doryx, thereby preventing competition in the relevant market. Such acts constitute a violation of Sherman Act, Section 1, 15 U.S.C. §1.

119. Defendants' conduct was intended to suppress rather than promote competition on the merits and has had precisely the intended effect.

120. Defendants' conduct has impeded the sale of generic delayed-release doxycycline hyclate, and thus allowed Defendants to sell their branded Doryx at artificially inflated prices.

121. Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

122. As a direct and proximate cause of Defendants' unlawful, anti-competitive conduct, Plaintiff and the United States Indirect Purchaser Class have been injured by paying more for Doryx than they would have absent Defendants' misconduct and anti-generic strategies. Their injury further consists of being deprived of the ability to purchase cheaper generic substitutes to Doryx. Plaintiff continues to suffer and will suffer this injury in the future because of Defendants' commitment to ongoing anti-generic strategies, designed to keep generic AB-rated substitutes for Doryx off the market.

123. The injury suffered by the Plaintiff and the Indirect Purchaser Class is the type the antitrust laws were designed to prevent and flows from Defendants' unlawful conduct.

124. Plaintiff and the Class seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. §26, to correct for the anti-competitive market effects caused by the unlawful conduct of Defendants and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

COUNT II

Monopolization, Attempted Monopolization and Conspiracy to Monopolize, Sherman Act, Section 2, 15 U.S.C. §2

125. Plaintiff repeats the allegations of the preceding paragraphs as if set forth herein.

126. At all relevant times, Defendants have possessed monopoly power in the relevant market.

127. During the relevant period, Defendants have willfully and unlawfully attempted to, conspired to, and actually maintained and extended their monopoly power through their continued efforts (1) to convert the relevant market to new versions of Doryx, on the eve of generic entry, in order to delay or prevent generic competition to Doryx, thereby foreclosing generic manufacturers from the relevant market; (2) to enter into anti-competitive settlement agreements with generic manufacturers to delay their introduction of generic doxycycline hyclate products into the market; and (3) to manipulate the FDA regulatory processes to delay or prevent generic competition to Doryx, thereby preventing competition in the relevant market.

128. Defendants' conduct was intended to suppress rather than promote competition on the merits, and it has had precisely the intended effect. Defendants have a specific intent to conspire to monopolize and actually monopolize the market for delayed-release doxycycline hyclate and have taken affirmative exclusionary steps in furtherance of their attempt to monopolize the relevant market.

129. Defendants' conduct has impeded the sale of generic delayed-release doxycycline hyclate in the relevant market, and thus has allowed Defendants to sell Doryx at artificially inflated prices.

130. Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

131. As a direct and proximate cause of Defendants' unlawful, anti-competitive conduct, Plaintiff and the United States Indirect Purchaser Class have been injured by paying more for Doryx than they would have absent Defendants' misconduct and anti-generic strategies. Their injury further consists of being deprived of the ability to purchase cheaper generic substitutes to Doryx. Plaintiff continues to suffer and will suffer this injury in the future, because of Defendants' commitment to ongoing anti-generic strategies, designed to keep generic AB-rated substitutes for Doryx off the market.

132. The injury suffered by the Plaintiff and the Indirect Purchaser Class is the type the antitrust laws were designed to prevent and flows from Defendants' unlawful conduct.

133. Plaintiff and the Class seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. §26, to correct for the anti-competitive market effects caused by the unlawful conduct of Defendants and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

COUNT III

Contract, Combination, and Conspiracy In Restraint of Trade NEV. REV. STAT. §§598A.060 and 598A.210

134. Plaintiff repeats the allegations of the preceding paragraphs as if set forth herein.

135. During the relevant period, Defendants Warner Chilcott and Mayne entered into a contract, conspiracy, and combination to restrain trade, and have taken affirmative acts in

furtherance of their contract, conspiracy, and combination to restrain trade, by suppressing competition in the relevant market through their continued efforts (l) to convert the relevant market to new versions of Doryx, on the eve of generic entry, to delay or prevent generic competition to Doryx, thereby preventing competition from the relevant markets; (2) to enter into anti-competitive settlement agreements with generic manufacturers to delay their introduction of generic doxycycline hyclate products into the market; and (3) to manipulate the FDA regulatory processes to delay or prevent generic competition to Doryx, thereby preventing competition in the relevant market. Such acts constitute agreements to perpetuate and stabilize monopoly prices for Doryx, agreements to allocate the market for delayed-release doxycycline hyclate, and agreements to otherwise suppress or eliminate generic competition and unreasonably restrain trade in the market for delayed-release doxycycline hyclate in violation of NEV. REV. STAT. 598A.060(1).

136. Defendants' conduct was intended to suppress rather than promote competition on the merits and has had precisely the intended effect.

137. Defendants' conduct has impeded the sale of generic delayed-release doxycycline hyclate and thus allowed Defendants to sell their branded Doryx at artificially inflated prices.

138. Defendants' conduct occurred in part, and has had a substantial effect, on trade and commerce in the state of Nevada.

139. As a direct and proximate cause of Defendants' unlawful, anti-competitive conduct, Plaintiff and the Nevada Indirect Purchaser Class have been injured and have suffered damage to their business and property by reason of Defendants' misconduct and anti-generic strategies. Such injury consists of paying more for Doryx during the Class Period than they would have absent Defendants' misconduct. Such injury further consists of being deprived of the ability to purchase cheaper generic substitutes to Doryx.

140. The injury suffered by the Plaintiff and the Nevada Indirect Purchaser Class is the type the antitrust laws were designed to prevent and flows from Defendants' unlawful conduct.

141. For the misconduct alleged herein, Plaintiff and the Nevada Indirect Purchaser Class seek treble damages and injunctive relief pursuant to Nev. Rev. Stat. §598A.210.

COUNT IV

Monopolization, Attempted Monopolization, and Conspiracy to Monopolize, NEV. REV. STAT. §§598A.060(1) and 598A.210

142. Plaintiff repeats the allegations of the preceding paragraphs as if set forth herein.

143. At all relevant times, Defendants have possessed monopoly power in the relevant market.

144. During the relevant period, Defendants have willfully and unlawfully attempted to, conspired to, and actually maintained and extended their monopoly power through their continued efforts (1) to convert the relevant market to new versions of Doryx, on the eve of generic entry, in order to delay or prevent generic competition to Doryx, thereby foreclosing generic manufacturers from the relevant market; (2) to enter into anti-competitive settlement agreements with generic manufacturers to delay their introduction of generic doxycycline hyclate products into the market; and (3) to manipulate the FDA regulatory processes to delay or prevent generic competition to Doryx, thereby preventing competition in the relevant market.

145. Defendants' conduct was intended to suppress rather than promote competition on the merits, and it has had precisely the intended effect. Defendants have a specific intent to conspire to monopolize and actually monopolize the market for delayed-release doxycycline hyclate, and have taken affirmative exclusionary steps in furtherance of their attempt to monopolize the relevant market.

146. Defendants' conduct has impeded the sale of generic delayed-release doxycycline hyclate in the relevant market, and thus has allowed Defendants to sell Doryx at artificially inflated prices.

147. Defendants' conduct occurred in part, and has had a substantial effect, on trade and commerce in the state of Nevada.

148. As a direct and proximate cause of Defendants' unlawful, anti-competitive conduct, Plaintiff and the Nevada Indirect Purchaser Class have been injured and have suffered damage to their business and property by reason of Defendants' misconduct and anti-generic strategies. Such injury consists of paying more for Doryx during the Class Period than they would have absent Defendants' misconduct. Such injury further consists of being deprived of the ability to purchase cheaper generic substitutes to Doryx.

149. Plaintiff continues to suffer and will suffer this injury in the future because of Defendants' commitment to ongoing anti-generic strategies, designed to keep generic AB-rated substitutes for Doryx off the market.

150. The injury suffered by the Plaintiff and the Nevada Indirect Purchaser Class is the type the antitrust laws were designed to prevent and flows from Defendants' unlawful conduct.

151. For the conduct alleged herein, Plaintiff and the Nevada Indirect Purchaser Class seek treble damages and injunctive and declaratory relief pursuant to Nev. Rev. Stat. §598A.210.

COUNT V

Deceptive Trade Practices, NEV. REV. STAT. §§41.600 and 598.0903, *et. seq.*

152. Plaintiff repeats the allegations of the preceding paragraphs as if set forth herein.

153. During the relevant period, Defendants have willfully and unlawfully engaged in deceptive trade practices, by: (1) fraudulently representing to consumers and the FDA that their

multiple reformulations of Doryx, including changes from capsules to tablets, from 75 mg to 100 mg tablets to single-scored 150 mg tablets, and from single-scored 150 mg tablets to dual-scored 150 mg tablets of Doryx, added some therapeutic benefit for consumers justifying the changes; (2) by fraudulently representing to consumers and the FDA that the Tablet and Capsule Applesauce Studies were designed to improve consumption of Doryx, justifying a change in labeling, but only releasing the results of these studies years later on the eve of generic entry; and (3) fraudulently representing to consumers and the FDA, that dual scoring of its 150 mg tablets provided "greater flexibility and treatment options for patients" when 50 mg and 100 mg dosage options were had already been available to consumers via 100 mg versions of Doryx.

154. Defendants' fraudulent and deceptive trade practices were designed with the specific intent to injure competing generic drug manufacturers by preventing their entry into the market for delayed-release doxycycline hyclate products. Defendants' deceptive trade practices had the intended and actual effect of (1) forcing their generic competitors to spend millions of dollars reformulating their generic delayed-release doxycycline hyclate products and (2) actually foreclosing generic competition to Doryx.

155. Defendants' fraudulent and deceptive trade practices were undertaken with the specific intent to destroy or substantially lessen competition in the market for delayed-release doxycycline hyclate products. Defendants' deceptive trade practices had the intended and actual effect of forcing consumers to pay supra-competitive and artificially inflated prices for Doryx in the absence of a competing generic doxycycline hyclate product.

156. The foregoing conduct constitutes deceptive trade practices within the meaning of NEV. REV. STAT. §§598.0915 and 598.0923 that are *prima facie* evidence of Defendants' intent to

injure their generic drug competitors and substantially lessen competition in the market for delayed-release doxycycline hyclate products pursuant to NEV. REV. STAT. §598.0953.

157. Defendants' conduct occurred in part, and has had a substantial effect on, trade and commerce in the state of Nevada.

158. As a direct and proximate cause of Defendants' unlawful and deceptive trade practices, Plaintiff and the Nevada Indirect Purchaser Class have been injured and have suffered damage to their business and property by reason of Defendants' misconduct and anti-generic strategies. Such injury consists of paying more for Doryx during the Class Period than they would have absent Defendants' misconduct. Such injury further consists of being deprived of the ability to purchase less expensive generic substitutes to Doryx.

159. Plaintiff continues to suffer and will suffer this injury in the future because of Defendants' commitment to ongoing anti-generic strategies designed to keep generic AB-rated substitutes for Doryx off the market.

160. For the conduct alleged herein, constituting deceptive trade practices that have injured competitors and destroyed or substantially lessened competition, Plaintiff and the Nevada Indirect Purchaser Class seek damages, interest, and injunctive and declaratory relief, pursuant to NEV. REV. STAT. §41.600.

COUNT VI

Unfair Methods of Competition and Unconscionable, Unfair and Deceptive Acts and Practices, FLA. STAT. §§542.22 and 501.204

161. Plaintiff repeats the allegations of the preceding paragraphs as if set forth herein.

162. During the Class Period, Defendants Warner Chilcott and Mayne have intentionally engaged in unfair methods of competition and unconscionable, unfair, and deceptive acts and practices against consumers of delayed-release doxycycline hyclate products by (l) replacing

existing versions of Doryx with new versions of Doryx, on the eve of generic entry, to delay or prevent generic competition to Doryx, thereby preventing competition from the relevant markets; (2) to enter into anti-competitive reverse payment settlement agreements with generic manufacturers to delay their introduction of generic Doryx products into the market; and (3) to manipulate the FDA regulatory processes to delay or prevent generic competition to Doryx, thereby preventing competition in the relevant market. Such acts constitute violations of FLA. STAT. §501.204.

163. Defendants engaged in the foregoing acts and practices in the conduct of trade and commerce in the state of Florida.

164. As a direct and proximate cause of Defendants' unlawful, anti-competitive conduct, Plaintiff and the Florida Indirect Purchaser Class have been injured and have suffered damage to their business and property by reason of Defendants' unfair methods of competition and unconscionable, unfair and deceptive acts and practices. Such injury consists of paying more for Doryx during the Class Period than they would have absent Defendants' misconduct. Such injury further consists of being deprived of the ability to purchase cheaper generic substitutes to Doryx.

165. The injury suffered by the Plaintiff and the Florida Indirect Purchaser Class as a direct result of Defendants' unfair methods of competition, unconscionable acts or practices and unfair or deceptive acts and practices offend established public policy and are oppressive, unscrupulous, and substantially injurious to consumers.

166. For the conduct alleged herein, Plaintiff and the Florida Indirect Purchaser Class seek injunctive and declaratory relief and damages pursuant to FLA. STAT. §§ 542.22 and 501.211.

IX. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the Indirect Purchaser Class, respectfully prays that the Court:

1. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2), 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 Class and declare the Plaintiff as the representative of the Indirect Purchaser Classes;

2. Enter joint and several judgments against Defendants in favor of Plaintiff and the Indirect Purchaser Classes;

3. Adjudge the acts alleged herein, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. §2201(a), to be unlawful pursuant to Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1 and 2; NEV. REV. STAT. §§598A.060, 598A.210, 598.0903, *et. seq.*, and 41.600 and FLA. STAT. §§501.204 and 542.22;

4. Award the Nevada and Florida Indirect Purchaser Classes three-fold damages in an amount to be determined at trial;

5. Permanently enjoin the Defendants pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C §§15(a) and 26, from continuing their unlawful contract, so as to assure that similar anti-competitive conduct does not occur in the future;

6. Award Plaintiff and the Indirect Purchaser Class their costs of suit, including reasonable attorneys' fees as provided by law; and

7. Grant such other further relief as is necessary to correct for the anti-competitive market effects caused by the unlawful conduct of Defendants and as the Court deems just.

Dated: September 21, 2012

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