

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

_____)	
MYLAN PHARMACEUTICALS INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. _____
)	
WARNER CHILCOTT PUBLIC LIMITED)	
COMPANY, WARNER CHILCOTT COMPANY,)	
LLC, WARNER CHILCOTT (US),)	
LLC, MAYNE PHARMA GROUP LIMITED,)	
AND MAYNE PHARMA INTERNATIONAL)	
PTY. LTD.,)	JURY TRIAL DEMANDED
)	
Defendants.)	
_____)	

COMPLAINT

I. Nature of the Action

1. This action is brought as a result of Defendants’¹ relentless efforts to obstruct and constrain competition through an admittedly “anti-generic strategy.” Through multiple, concerted, and deliberate anticompetitive tactics commenced as early as 2005, Defendants have harmed Mylan Pharmaceuticals Inc. (“Mylan”) and the public by preventing and/or delaying generic competition to Doryx—a delayed-release doxycycline hyclate product prescribed for the treatment of severe acne and other bacterial infections—years earlier. Defendants have accomplished their anticompetitive goals through the use of various strategies that were intentionally designed to unlawfully interfere with the regulatory process, cause delays in the

¹ “Defendants” refers to the following entities collectively: Warner Chilcott Public Limited Company; Warner Chilcott Company, LLC; Warner Chilcott (US), LLC; Mayne Pharma Group Limited; and Mayne Pharma International Pty. Ltd.

approval of generic versions of Doryx, and disrupt the market for generic Doryx. This conduct violates Sections 1 and 2 of the Sherman Act, as Defendants have monopolized and restrained trade in the market for delayed-release doxycycline hyclate products.

2. On at least three occasions, Defendants have engaged in anticompetitive tactics known in the pharmaceutical industry as the “switch strategy” or “product hopping” and referred to by Defendants themselves as an “anti-generic strategy” or “Swap-out Strategy.” (Doryx Trial Tr. at 78; 86).² These tactics were intended by Defendants to obstruct or restrain competition. As described in detail below, “switching” or “swapping-out” the market generally involved Defendants making relatively minor changes to branded Doryx—a dosage form, strength, or tablet scoring modification—with little or no therapeutic benefit, followed by ceasing the promotion of the prior version of branded Doryx and efforts to delay approval of competing generic versions of these products. Because of regulatory requirements that generic drugs generally be the “same” as the reference listed drug, these switches forced generic manufacturers such as Mylan to change their products in development since the switches devastated the market for the prior versions of Doryx. In addition to their “swap-out” scheme, Defendants engaged in carefully timed exclusionary conduct in order to exacerbate the generic delays and lost investments created by the switches themselves.

3. Defendants’ plan to switch the market—first from Doryx capsules to Doryx tablets—was set into motion well in advance of generic entry. According to Defendants’ own internal documents, “[t]hey [did] not expect to have any increase in sales as a part of the switch

² Transcript of Proceedings at 78, *Warner Chilcott Labs v. Mylan Pharm. Inc.*, 2:09-cv-2073-WJM MF (D.N.J.), *Warner Chilcott Labs v. Impax Labs, Inc.*, 2:08-cv-6304-WJM MF (D.N.J.) (Feb. 8, 2012) (“Doryx Trial Tr.”). The portions of the Doryx Trial Tr. cited in this complaint have not been sealed by the Defendants and are part of the public record.

[from capsules to tablets],” rather it was “merely [] an anti-generic strategy.” (Doryx Trial Tr. at 86). Defendants further explained that a key objective of the tablet launch was to “[s]wap out the capsules to preserve the [Doryx] franchise.” (Doryx Trial Tr. at 81). 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 greater than 90 percent of the market within approximately six months. Then, after generic manufacturers, including Mylan, 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 carefully designed 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 administered by breaking the tablets into pieces and sprinkling the pieces over applesauce. This scheme delayed Mylan’s development of its generic Doryx tablets anywhere from 6 to 12 months. Defendants then further delayed entry of generic manufacturers’ 75 mg and 100 mg tablets by introducing scoring to the branded versions of these dose strengths, which, in conjunction with Defendants’ other tactics, delayed Mylan’s generic approval for these dose strengths until the end of 2010.

4. As generic competitors were close to entering the market with generic Doryx 75 mg and 100 mg tablet products, Defendants again pulled the rug out from underneath the generics by switching the market from Doryx 75 mg and 100 mg tablet strengths to a Doryx 150 mg tablet strength. Indeed, by the time Mylan was able to obtain FDA approval for its 75 mg and 100 mg tablet products—after wading through the additional regulatory and manufacturing impediments erected by Defendants—Defendants had achieved a shift of approximately 90

percent of the delayed-release doxycycline hyclate market to Doryx 150 mg tablets, leaving generics with only a small segment of the market in which to compete.

5. In September 2011, Defendants attempted to switch the market for a third time from a single scored version of Doryx 150 mg tablets to a dual-scored version of Doryx 150 mg tablets as Defendants expected Mylan to launch its generic Doryx 150 mg product at the end of September 2011, upon expiration of its 30-month stay. Soon after approval of the dual-scored Doryx 150 mg tablets, Defendants discontinued sale of the single-scored 150 mg tablet and filed a citizen petition with the FDA requesting that the agency not approve Mylan's (or any other ANDA applicant's) 150 mg generic Doryx tablet until the generic product is modified from single-scoring to dual-scoring. Defendants claimed that marketing different scoring configurations at the same time would cause customer confusion and suboptimal dosing despite the fact that Defendants *themselves* had introduced dual-scored tablets while still marketing single-scored tablets. The FDA rejected Defendants' citizen petition on February 8, 2012, discussing the inconsistency between the relief Defendants requested and Defendants' own practice, 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 noted the suspect timing of Defendants' scoring changes made "on the eve of expected generic approval." (*Id.* at 8).

6. In addition, on information and belief, Defendants are (or were) plotting a fourth switch whereby they planned to convert the market from Doryx 150 mg tablets to yet another

version of Doryx in furtherance of their scheme to deny consumers a lower-priced generic alternative to Defendants' branded Doryx products.

7. As Defendants know, because a generic drug must be the same dosage strength and form as the reference listed branded drug to be substitutable at the pharmacy level, many of these minor product modifications—which have provided consumers little or no therapeutic benefit—have had the effect of preventing and/or delaying generic competition to Doryx.

8. Rather than deny this overarching strategy to impede and delay generic competition to their Doryx franchise, Defendants brag about their “anti-generic strategy.” In a 2007 earnings call, the President and Chief Executive Officer of Warner Chilcott, Roger Boissonneault, 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 at 10) (emphasis added). Four years later, in a 2011 earnings conference call Mr. Boissonneault 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 at 6-7). Defendant Mayne, Warner Chilcott's supplier, likewise noted in 2011 that “one of the challenges . . . with . . . Doryx is that competition is keenly seeking ways to access the market.” Mayne further acknowledged that it has 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 150 mg tablet in July 2008.” (Mayne 2011 Annual Report at 11).

9. As these strategies have netted Defendants hundreds of millions of dollars, it is not surprising that Defendants would brag to their investors about the steps they have taken to “preserve the franchise” and prevent generic competition to Doryx. However, such conduct has

been devastating to consumers and federal, state, and private payors as well as competition in the market for delayed-release doxycycline hyclate products. As a result of Defendants' anticompetitive conduct, consumers and federal, state, and private payors have been forced to overspend on prescriptions for delayed-release doxycycline hyclate products and have been denied the substantial benefits of lower-priced generic competition to Doryx. Indeed, but for Defendants' anticompetitive conduct, consumers and federal, state, and private payors would have enjoyed a lower-priced generic alternative to Doryx years earlier. At the same time, Mylan has been prevented and/or delayed from competing in the delayed-release doxycycline hyclate market and has been forced to spend millions of dollars on research and development to make modifications to its generic delayed-release doxycycline hyclate formulations for which there is little or no therapeutic benefit to consumers.

II. The Parties

10. Plaintiff Mylan is a corporation organized and existing under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

11. On information and belief, 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.

12. On information and belief, 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.

13. On information and belief, 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.

14. On information and belief, 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.

15. On information and belief, 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.

III. Jurisdiction and Venue

16. This action arises under the antitrust laws of the United States, including Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, and under state tort law.

17. The actions complained of have occurred in and substantially affected interstate commerce in the Eastern District of Pennsylvania.

18. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), and 1367.

19. Defendants may be found, transact business, and are subject to personal jurisdiction in the Eastern District of Pennsylvania.

20. The violations of law alleged in this Complaint took place, in part, and have injured Mylan in this judicial district. Venue is therefore proper in the Eastern District of Pennsylvania pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391.

IV. Hatch-Waxman Statutory and Regulatory Background

21. The Federal Food, Drug and Cosmetic Act (the “Act”), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Restoration Act of 1984, codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), commonly known as the “Hatch-Waxman Act,” requires FDA approval before a company may market or sell a branded or generic pharmaceutical product in the United States. One purpose of the Hatch-Waxman Act is to balance the public’s interest in access to low-cost generic drugs with patentees’ interest in maintaining their patent rights.

22. The Hatch-Waxman Act permits generic drug manufacturers to file an Abbreviated New Drug Application (“ANDA”) that appropriately expedites the drug approval process. Rather than conduct full clinical trials, as is required for a New Drug Application (“NDA”), the statute only requires an ANDA filer to show that its drug is bioequivalent (within a defined range) to the reference listed drug, typically the branded drug, to demonstrate that the generic product has the same or comparable safety and efficacy as the reference listed drug. Two drugs are considered bioequivalent if they contain the same active pharmaceutical ingredient and if there is no significant difference in the rate and extent to which the products are absorbed in the human body under similar experimental conditions, when administered in the same dose. *See* 21 U.S.C. § 355(j)(8)(B). If the generic drug is bioequivalent and is the same dosage strength and form as the reference listed branded drug, it is deemed to be an “AB-rated equivalent” to the reference listed branded drug. Many states have “automatic substitution” laws that require pharmacists to substitute AB-rated generic versions for prescriptions written for reference listed branded drugs unless the prescribing physician specifically requests otherwise. Conversely, generic drugs that are not “AB-rated” to the reference listed branded drug cannot be automatically substituted for the reference listed branded drug at the pharmacy level.

23. The NDA-holder of a branded drug is required to identify all patents that it asserts cover the branded drug and the expiration dates of the patents in an FDA publication referred to as the “Orange Book.” *See* 21 U.S.C. § 355(b)(1) and (c)(2).

24. If an ANDA applicant seeks approval to sell a drug before the expiration of one or more patents listed in the Orange Book as covering that drug, the ANDA must contain a certification as to each, “that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Such a certification is known as a “Paragraph IV Certification.”

25. The filing of a Paragraph IV Certification permits the NDA holder as well as the holder of any patent identified in the Orange Book, as purportedly covering the listed drug, to assert a cause of action for patent infringement against the ANDA applicant. If such an action is brought within 45 days from receipt of notification of any Paragraph IV Certification, the FDA cannot grant final approval of the ANDA until the earlier of (i) 30 months from the patent-holder’s receipt of notification of the Paragraph IV Certification; or (ii) the date on which a final judgment is entered in the patent infringement case holding that such patent is invalid, not infringed, or unenforceable.

26. If an ANDA has satisfied all FDA regulatory requirements and the 30-month stay period has not expired, the FDA will grant tentative approval of the ANDA. The ANDA applicant can sell the generic product in the United States only upon receipt of final approval from the FDA, not upon receipt of tentative approval.

27. The Hatch Waxman Act originally excluded products using so-called “old” antibiotics (i.e., antibiotic active ingredients included in an application submitted to the FDA for review prior to November 27, 1997) from its patent market exclusivity provisions. Doxycycline

hyclate, the active ingredient in Doryx, qualifies as an “old” antibiotic. Doryx was not subject to the Hatch Waxman Act 30-month stay provisions until the law was amended by the QI Program Supplemental Funding Act of 2008 (Pub. L. No. 110-379) (“QI Act”). The QI Act eliminated some of the Hatch Waxman Act exemptions to products containing “old” antibiotics, which has allowed certain “new” products (e.g., Doryx 150 mg Tablet Product) containing “old” antibiotics to utilize the patent listing and certification provisions, including the 30-month stay provision.

V. Benefits of Generic Competition

28. Generic drugs are typically sold at substantial discounts from the price of 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 may fall to as low as 5% of the referenced listed branded drug’s price.

29. Generic drug competition generates large savings for consumers and federal, state, and private payors. A 1998 Congressional Budget Office Report estimates that, in 1994 alone, consumers saved \$8-10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the corresponding brand name products. A 2004 FDA study found that consumers whose needs can be fully satisfied with generic drugs could enjoy reductions of 52% in their daily medication costs. 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 2001-2010, and that the savings for 2010 alone were over \$158 billion. The study also cites data from the federal Centers for Medicare and Medicaid Services establishing that, for every 2% increase in generic utilization, Medicaid saves an additional \$1.3

billion annually. As a result of Defendants' unlawful tactics, consumers have been unable to enjoy similar savings with respect to purchases of delayed-release doxycycline hyclate products.

VI. Relevant Market and Market Power

30. Doxycycline hyclate is a tetracycline-class oral 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.

31. 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 product ("Doryx 75 mg Capsule Product"); (2) a 100 mg delayed-release doxycycline hyclate capsule product ("Doryx 100 mg Capsule Product"); (3) a 75 mg delayed-release doxycycline hyclate tablet product ("Doryx 75 mg Tablet Product"); (4) a 100 mg delayed-release doxycycline hyclate tablet product ("Doryx 100 mg Tablet Product"); and (5) a 150 mg delayed-release doxycycline hyclate tablet product ("Doryx 150 mg Tablet Product").

32. Mylan manufactures and sells a generic 75 mg delayed-release doxycycline hyclate tablet product that is an AB-rated equivalent to the Doryx 75 mg Tablet Product ("Generic Doryx 75 mg Tablet Product") and a 100 mg delayed-release doxycycline hyclate tablet product that is an AB-rated equivalent to the Doryx 100 mg Tablet Product ("Generic Doryx 100 mg Tablet Product"). 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 Product ("Generic Doryx 150 mg Tablet Product").

33. Mylan's approved generic delayed-release doxycycline hyclate products are AB-rated to their Doryx branded equivalents only, which means, under most state substitution laws, they are automatically substitutable for their Doryx branded equivalents only. For example, the Generic Doryx 75 mg Tablet Product is AB-rated to the Doryx 75 mg Tablet Product and is, thus, automatically substitutable for the Doryx 75 mg Tablet Product under most state substitution laws. However, because it is not the same strength or dosage form, the Generic Doryx 75 mg Tablet Product is not AB-rated to—and, therefore, not automatically substitutable for—the Doryx 100 mg Tablet Product, the Doryx 75 mg and 100 mg Capsule Products, or the Doryx 150 mg Tablet Product.

34. Delayed-release doxycycline hyclate products are not reasonably interchangeable with other products due to, for example, price, use, qualities, characteristics, and/or distinct customers or end uses. Moreover, the presence of other products, if any, indicated for the treatment of similar conditions—but not AB-rated to delayed-release doxycycline hyclate products—is not sufficient to prevent the anticompetitive effects of Defendants' conduct relating to delayed-release doxycycline hyclate. As discussed above, unless a generic product is AB-rated to an equivalent referenced listed branded drug product, it cannot be automatically substituted for the referenced listed branded drug product at the pharmacy level.

35. Generic delayed-release doxycycline hyclate products are priced substantially below the price Defendants charge for their branded Doryx products. Upon entry of AB-rated generic delayed-release doxycycline hyclate products, these lower-priced but interchangeable products divert substantial sales from branded Doryx products, which benefits consumers, patients, government programs (such as Medicare and Medicaid), and private payors.

36. Because of this competitive relationship between branded drugs and their generic competitors, such products comprise a distinct relevant product market for antitrust purposes. Thus, the relevant product market in which to assess the anticompetitive effects of Defendants' conduct is the market for Doryx products and their AB-rated equivalents ("the Doxycycline Hyclate Market").

37. Moreover, because a generic drug is AB-rated to and automatically substitutable for its reference listed branded drug equivalent only, each separate version of Doryx and its AB-rated equivalents constitute a separate relevant market for antitrust purposes. Thus, there are also separate relevant markets for (1) Doryx 75 mg Capsule Product and any bioequivalent generic equivalents ("Doxycycline Hyclate 75 mg Capsule Product Market"); (2) Doryx 100 mg Capsule Product and any bioequivalent generic equivalents ("Doxycycline Hyclate 100 mg Capsule Product Market"); (3) Doryx 75 mg Tablet Product and any bioequivalent generic equivalents ("Doxycycline Hyclate 75 mg Tablet Product Market"); (4) Doryx 100 mg Tablet Product and any bioequivalent generic equivalents ("Doxycycline Hyclate 100 mg Tablet Product Market"); and (5) Doryx 150 mg Tablet Product and any bioequivalent generic equivalents ("Doxycycline Hyclate 150 mg Tablet Product Market"), in which to assess the anticompetitive effects of Defendants' conduct (collectively, along with the Doxycycline Hyclate Market, the "Relevant Markets").

38. The relevant geographic market in which to assess the anticompetitive 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.

39. There are substantial barriers to entry in the Relevant Markets, including the FDA's regulatory requirements. Moreover, through their anticompetitive, exclusionary conduct, Defendants have erected additional, artificial barriers to entry in the Relevant Markets.

40. At all times relevant to this Complaint, Defendants have possessed monopoly power in each of the Relevant Markets with market shares ranging from approximately 90% to 100%.

VII. Defendants' Unlawful Conduct

Background on Delayed-release Doxycycline Hyclate

41. Mayne received FDA approval for the Doryx 100 mg Capsule Product 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 Product (and later all other Doryx product lines) in the United States. Mayne continues to manufacture Doryx for Warner Chilcott to sell in the United States.

42. Mayne received FDA approval for the Doryx 75 mg Capsule Product on August 13, 2001 and Defendants introduced the Doryx 75 mg Capsule Product for sale in the United States in January 2002.

43. Defendants received FDA approval for the Doryx 75 mg and 100 mg Tablet Products on May 6, 2005 and began commercialization of these products soon thereafter. By June 2006, Warner Chilcott had discontinued the marketing of the Doryx 75 mg and 100 mg Capsule Products.

44. Defendants received FDA approval for the Doryx 150 mg Tablet Product on June 20, 2008, and soon thereafter stopped promoting the Doryx 75 mg and 100 mg Tablet Products.

45. Sales for the Doryx franchise for the twelve months ending December 31, 2011 were approximately \$271 million.

Defendants' Relentless Efforts to Conspire to Suppress Generic Competition in the Relevant Markets

46. Defendants have made no secret of their desire to manipulate the regulatory and competitive processes to avoid generic competition in the Relevant Markets. 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: “[W]e’ve been successful in moving the product along and creating the next generation Doryx and rest assured it’s a better product. If we look at the history of Doryx no, *there has never been a generic.*” (Q4 2007 Warner Chilcott Earnings Conference Call Q&A Transcript at 10) (emphasis added).

47. In another earnings conference call last year, Defendants openly and brazenly 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. Boissonneault 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. Boissonneault 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 can 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).

48. Defendant Mayne, Warner Chilcott’s supplier, even admits to relentlessly working with the Warner Chilcott Defendants 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 life-cycle management programme to stay ahead of potential competition.” (Mayne (at the time named Halcygen Pharmaceuticals Limited) 2010 Annual Report at 16) (emphasis added). 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).

49. Moreover, Defendants’ internal documents further confirm their scheme to monopolize the Relevant Markets through their product hopping strategy. For example, in discussing the switch from capsules to tablets, internal Faulding (now Mayne) documents explain that “[t]he tablet is to be used as an anti-generic strategy” and that “[i]t is [Warner Chilcott’s] intention to discontinue the Doryx capsule as soon as the tablet is available to eliminate generic competition.” (Doryx Trial Tr. at 84, 86). Similarly, internal Warner Chilcott documents describe the switch from capsules to tablets as a “Swap-out Strategy” designed “to preserve the [Doryx] franchise.” (Doryx Trial Tr. at 78, 81).

50. Defendants have deliberately worked in tandem to prevent competition and to achieve and maintain their monopoly in the Relevant Markets. As referenced in Defendants' September 2011 citizen petition—designed to further delay Mylan's ability to enter the Relevant Markets—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.

51. As described in more detail below, Defendants have relentlessly conspired to prevent competition and to maintain and extend their monopoly power in the Relevant Markets. As a result of this anticompetitive 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 Markets at every turn, at the expense of manufacturers of generic Doryx and consumers (including federal, state, and private payors) of Doryx alike.

Defendants' First Market Switch: Capsules to Tablets

52. Defendants first faced the possibility of generic competition to their Doryx franchise as early as 2005. Several generic companies, including Mylan, were developing generic formulations of the Doryx 75 mg and 100 mg Capsule Products and were forging ahead to seek FDA approval to sell their lower-priced generic versions of Doryx Capsules. Mylan had expended substantial efforts and expense in developing Generic Doryx 75 mg and 100 mg Capsules, including but not limited to the development and analytical testing of these products.

53. Given the threat posed by impending generic competition, Defendants acted to prevent competition to their Doryx franchise. Specifically, Defendants (1) sought and obtained

FDA approval to market the Doryx 75 mg and 100 mg Tablet Products on May 6, 2005 and launched the Doryx 75 mg and 100 mg Tablet Products shortly after approval; (2) converted greater than 90 percent of the delayed-release doxycycline hyclate market from Doryx Capsules to Doryx Tablets within approximately six months; and (3) by June 14, 2006, had discontinued marketing Doryx Capsules.

54. 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 Capsule Products, including Mylan, were forced to forego their efforts to develop and/or effectively commercialize this product and, instead, switch their development efforts to focus on the Doryx 75 mg and 100 mg Tablet Products. Since Doryx Capsules would not be AB-rated to Doryx Tablets, generic Doryx Capsules could not be automatically substituted for Doryx Tablets at the pharmacy level. Simply put, as a result of the switch from Doryx Capsules to Doryx Tablets, the opportunity to effectively commercialize a generic version of Doryx Capsules no longer existed and, therefore, continued development of such a product was pointless.

55. Defendants incurred significant expenses to switch from Doryx 75 mg and 100 mg Capsules to Doryx 75 mg and 100 mg Tablets, a switch that provided little or no benefit other than to exclude generic competition from the market.

56. While Mylan and other firms pursuing generic Doryx were forced to forego their efforts to commercialize generic versions of the Doryx 75 mg and 100 mg Capsule Products, they continued their efforts to attempt to bring a lower-priced generic alternative to consumers in the Doxycycline Hyclate Market by developing generic versions of the Doryx 75 mg and 100 mg Tablet Products. Mylan put forth a substantial amount of time and money into the development, testing, manufacture, and launch of a delayed-release tablet form of Doryx. In response,

Defendants again erected obstacles to prevent or delay Mylan's generic approval, which allowed Defendants additional time to effectuate their next unlawful switch strategy.

Defendants' Applesauce Study

57. In 2006, Defendants released studies and sought a labeling change regarding the use of their Doryx 75 mg and 100 mg Tablet Products when broken into pieces and sprinkled over applesauce for patient consumption (the "Tablet Applesauce Study"). Again, because a generic product needs to be the same as its reference listed branded drug equivalent—including any changes in labeling—Defendants' conduct required Mylan to undertake studies similar to the Tablet Applesauce Study. Moreover, Defendants' conduct forced Mylan to undertake significant additional development efforts and testing. Indeed, the Tablet Applesauce Study forced Mylan to go back to the drawing board and reformulate a product that could achieve the necessary delayed-release properties when broken into pieces and sprinkled over applesauce.

58. Moreover, Defendants' timing on the release of the Tablet Applesauce Study and subsequent change in labeling is telling. Notably, Defendants completed a similar applesauce study for the Doryx 75 mg and 100 mg Capsule Products (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. Notwithstanding this fact, Defendants waited until February 2006—*over three years later and after Mylan 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 for the Doryx 75 mg and 100 mg Tablet Product, obtaining approval for the labeling change in December 2006. Defendants' strategically timed change in labeling to include the Tablet Applesauce Study was designed to, and had the effect of, delaying Mylan's ANDAs for its Generic Doryx 75 mg and 100 mg Tablet Products anywhere

from 6 to 12 months, providing Defendants with additional time to effectuate their second market switch from the 75 mg and 100 mg tablets to 150 mg tablets.

59. Despite the fact that the Tablet Applesauce Study significantly delayed Mylan's development and approval of its Generic Doryx 75 mg and 100 mg Tablet Products, Mylan was able to successfully formulate products bioequivalent to Defendants' Doryx 75 mg and 100 mg Tablet Products and filed an ANDA for 75 mg and 100 mg doxycycline hyclate delayed-release tablets on March 31, 2008.

Defendants' Scoring Change

60. Not satisfied with that delay, Defendants then sought to tie-up Mylan's ANDA for Generic Doryx 75 mg and 100 mg Tablets in the FDA review and approval process by filing citizen petitions before the FDA and/or tweaking their Doryx 75 mg and 100 mg Tablets slightly to force Mylan to jump through additional regulatory hoops in the ANDA approval process. For example, in February 2009, Defendants obtained approval for a "scored" version of the Doryx 100 mg Tablet Product and, in March 2009, obtained approval for a "scored" version of the Doryx 75 mg Tablet Product. The scored versions of these products, which allow patients to break the tablets into halves, were designed to force Mylan to modify its product again to create "scored" versions of its Generic Doryx 75 mg and 100 mg Tablet Products in order to obtain FDA approval. This tactic resulted in further delay and additional testing and development costs as well as the destruction of several batches of product manufactured in preparation to launch the non-scored product after receipt of FDA approval.

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

61. Again in response to the threat of potential generic competition and having bought time through the erection of anticompetitive obstacles to Mylan's ANDA approval for the 75 mg

and 100 mg tablet strengths, Defendants wasted no time in implementing their next switch strategy to move the market from the Doryx 75 mg and 100 mg Tablet Products to the Doryx 150 mg Tablet Product.

62. After seeking and obtaining FDA approval for 150 mg single-scored delayed-release tablet version of Doryx (“Doryx 150 mg Tablet Product”) in June 2008, Defendants again converted the Doxycycline Hyclate Market—this time from the Doryx 75 mg and 100 mg Tablet Products to the Doryx 150 mg Tablet Product—by shifting approximately 90 percent of the prescriptions to the Doryx 150 mg Tablet Product before Mylan was able to receive FDA approval for its ANDA covering the 75 mg and 100 mg tablet strengths in December 2010. Defendants accomplished this goal by quickly phasing out the Doryx 75 mg and 100 mg Tablet Products through (1) the elimination of all promotional activities regarding the Doryx 75 mg and 100 mg Tablet Products, and, subsequently, (2) the discontinuance of the sale of the Doryx 75 mg and 100 mg Tablet Products.

63. Similar to Defendants’ first market switch, Defendants’ second market switch had the intended anticompetitive effect, furthering their scheme to maintain and enhance their monopoly power in the Relevant Markets. By the time that Mylan received final FDA approval for its generic versions of the Doryx 75 mg and 100 mg Tablet Products on December 28, 2010—and subsequently launched and sought to commercialize these products—once again there was little to no market left in which to compete. Indeed, just as customers were set to enjoy the benefits of generic competition, Defendants pulled the rug out from underneath consumers, Mylan, and other potential manufacturers of generic delayed-release doxycycline hyclate, by cannibalizing the markets for the Doryx 75 mg and 100 mg Tablet Products (in which Defendants would face generic competition) and shifting approximately 90 percent of

prescriptions to the Doxycycline Hyclate 150 mg Tablet Product Market (in which Defendants would not face generic competition).

64. Defendants incurred significant expenses to switch from Doryx 75 mg and 100 mg Tablets to Doryx 150 mg Tablets, a switch that provided little or no benefit other than to exclude generic competition from the market. Defendants' own current prescribing information for Doryx 150 mg Tablets does not provide for a dosage administration in an amount equal to 150 mg.

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

65. In response to Defendants' switch from the Doryx 75 mg and 100 mg Tablet Products to the Doryx 150 mg Tablet Product, Mylan filed an ANDA for a generic Doryx 150 mg Tablet Product 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 engaged in yet another transparent attempt to delay generic competition to their Doryx franchise by changing the scoring configuration on their Doryx 150 mg Tablet Product from a "single score" to a "dual score."

66. This, of course, was an additional attempt by Defendants to further impede generic entry into the Relevant Markets. 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.

67. 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 Product, 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-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). Indeed, Defendants attempted to time the manipulation of the FDA regulatory processes perfectly 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 Product 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"—rather than a change concerning the safety and effectiveness of the drug. Indeed, the "new tablet design" is designed to "replace" the current tablet design. (Warner Chilcott Letter to Pharmacists Regarding Doryx 150 mg (Sept. 2011) at 1).

68. Notably, contrary to Defendants' arguments, the FDA indicated that there were no safety or dosing related issues resulting from the change in scoring by Defendants and that Mylan did not have to implement the new scoring configuration prior to receipt of final FDA approval. However, the FDA informed Mylan that—going forward—it could no longer manufacture single-scored 150 mg tablets and needed to make changes to its manufacturing process to be consistent with the new dual-scoring configuration with a post-approval

commitment, though the FDA would allow Mylan to commercially distribute the single-scored tablets that Mylan had already manufactured.

69. Despite this finding (which Defendants were well aware of), on September 23, 2011, Defendants filed *yet another* citizen petition with the FDA contending that Mylan's Doryx 150 mg Tablet Product should not be approved unless and until modified from a "single-scored" to a "dual-scored" tablet. In other words, as soon as Defendants learned that their change in scoring would not hold up Mylan's expected FDA approval, they quickly sought to achieve the same anticompetitive effect through the citizen petition process.

70. 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 Product 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. Thus, the relief sought by Defendants, with respect to the introduction of generic single-scored Doryx 150 mg Tablets, was inconsistent with Defendants' own practice. Moreover, in considering the facts and circumstances of the case in determining the legitimacy of Defendants' citizen petition, the FDA found relevant the suspect timing of Defendants' scoring changes, which were made "on the eve of expected generic approval." (*Id.* at 8).

71. On the same day as the FDA rejected Defendants' citizen petition, they approved Mylan's generic version of Defendants' single-scored Doryx 150 mg Tablet Product, with a postapproval requirement to comply with the new dual scoring configuration of the product when Mylan conducts its next manufacturing run. Thus, once again as a result of Defendants' anticompetitive, exclusionary conduct, Mylan was forced to reconfigure its generic Doryx product to keep pace with Defendants' ever-changing product hopping strategy.

72. Defendants incurred significant expenses to switch from its single-scored Doryx 150 mg Tablet Product to its dual-scored Doryx 150 mg Tablet Product, a switch that provided little or no benefit other than to exclude generic competition from the market.

Defendants Plans for a Fourth Market Switch

73. Never ones to pass up another delay opportunity, on information and belief, Defendants are (or were) plotting their next switch from dual-scored 150 mg Doryx Tablets to the next formulation of Doryx.

74. On information and belief, Defendants are (or were) developing and undertaking clinical trials related to a new formulation of Doryx in addition to pursuing other "multiple strategies" to ensure that the Doryx franchise remains (or remained) insulated from lower-priced generic competition.

75. Defendants' relentless efforts to convert the Doxycycline Hyclate Market, on the eve of generic entry, in order to delay and/or prevent generic competition to Doryx have delayed meaningful generic competition in the Doxycycline Hyclate Market for several years. Moreover, Defendants' product modifications have provided little or no benefit to consumers that they could not already receive from the previous formulations of Doryx. While these changes have

provided little or no benefit to customers, Defendants' modifications have imposed immense costs on consumers and federal, state, and private payors as well as Mylan and other potential manufacturers of generic delayed-release doxycycline hyclate products.

* * *

76. But for Defendants' anticompetitive conduct—which spans three separate product switches, plans for a future product switch, and several acts to manipulate the FDA regulatory process—consumers and federal, state, and private payors would have enjoyed the benefits of lower-priced generic competition years earlier. Instead, as a result of Defendants' “multiple strategies” to thwart generic entry, for the past several years, consumers and federal, state, and private payors have been forced to pay monopoly rents for Defendants' various iterations of branded Doryx without the ability to select a lower-priced generic alternative.

77. Notably, while Defendants have switched the U.S. market (1) from capsules to 75 mg and 100 mg 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, and (4) are (or were) planning to switch from dual-scored 150 mg tablets to the next iteration of Doryx, 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.

VIII. The Anticompetitive Effects of Defendants' Conduct

78. As a result of the Defendants' conspiracy to maintain monopoly control over the Relevant Markets and delay and/or prevent generic competition to their Doryx franchise through anticompetitive, exclusionary conduct, Mylan has been foreclosed from competing in (1) the Doxycycline Hyclate Market; (2) the Doxycycline Hyclate 75 mg Capsule Product Market; (3) the Doxycycline Hyclate 100 mg Capsule Product Market (4) the Doxycycline Hyclate 75 mg

Tablet Product Market; (5) the Doxycycline Hyclate 100 mg Tablet Product Market; and (6) the Doxycycline Hyclate 150 mg Tablet Product Market (collectively, “Relevant Markets”). This foreclosure has already harmed consumers and federal, state, and private payors of delayed-release doxycycline hyclate to the tune of hundreds of millions of dollars.

79. Because Mylan’s competing delayed-release doxycycline hyclate products are and/or would be priced below Defendants’ branded Doryx products and are and/or would be AB-rated equivalents to Defendants’ branded Doryx products (and therefore eligible for automatic substitution), Mylan will capture and retain significant sales immediately upon entry into the Relevant Markets.

80. Defendants’ anticompetitive conduct has delayed, prevented, and/or impeded Mylan’s sale of generic delayed-release doxycycline hyclate in the Relevant Markets, and thus has enabled Defendants to maintain and extend their monopoly power in the Relevant Markets. Defendants have sold Doryx at artificially inflated monopoly prices.

81. This conduct has harmed the competitive process and allowed Defendants to obtain and perpetuate supracompetitive prices from wholesalers, retailers, consumers and federal, state, and private payors.

82. There are no procompetitive justifications, countervailing efficiencies, increases in consumer welfare, or legitimate business reasons for Defendants’ conduct. Without fail, Defendants’ conduct has precluded and/or reduced, rather than expanded, consumer choice.

83. Mylan has extensive experience in the pharmaceutical industry, including successfully obtaining approval for ANDAs and selling generic pharmaceutical products.

84. Mylan has sufficient financial capacity to enter the Relevant Markets and has done so.

85. Mylan has obtained final FDA regulatory approval for its Generic Doryx 75 mg and 100 mg Tablet Products as well as its Generic Doryx 150 mg Tablet Product.

86. Mylan has expended substantial labor and sums of money in developing its generic delayed-release doxycycline hyclate products, and in otherwise preparing to enter the Relevant Markets. Indeed, in addition to the damages Mylan has suffered as a result of Defendants' unlawful exclusion of Mylan from the Relevant Markets, Mylan has also suffered considerable damages due to the lost investment of time and money spent on developing previous formulations of generic delayed-release doxycycline hyclate, which resulted from Defendants' "product hopping" strategy.

Count I (Plaintiff vs. All Defendants)
Agreement in Restraint of Trade (Sherman Act § 1)

87. Mylan repeats and re-alleges the allegations of paragraphs 1-___ as if fully set forth herein.

88. During the relevant period, Defendants Warner Chilcott and Mayne entered into a contract, conspiracy, and/or combination to restrain trade, and have taken affirmative acts in furtherance of their contract, conspiracy, and/or combination to restrain trade, by suppressing competition in the Relevant Markets through their continued efforts (1) to convert the Relevant Markets to new versions of Doryx, on the eve of generic entry, in order to delay and/or prevent generic competition to Doryx, thereby foreclosing Mylan from the Relevant Markets; and (2) to manipulate the FDA regulatory processes to delay and/or prevent generic competition to Doryx, thereby foreclosing Mylan from the Relevant Markets.

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

90. Defendants' conduct has caused anticompetitive effects in the Relevant Markets by impeding the sale of generic delayed-release doxycycline hyclate in the Relevant Markets, and thus has allowed Defendants to sell their branded Doryx products at artificially inflated monopoly prices.

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

92. As a direct and proximate cause of Defendants' unlawful, anticompetitive conduct, Mylan has been injured and has sustained damages.

93. Mylan's injury is the type the antitrust laws were designed to prevent and flows from Defendants' unlawful conduct.

**Count II (Plaintiff vs. All Defendants)
Monopolization (Sherman Act § 2)**

94. Mylan repeats and re-alleges the allegations of paragraphs 1-91 as if fully set forth herein.

95. At all relevant times, Defendants have possessed monopoly power in the Relevant Markets.

96. During the relevant period, Defendants have willfully and unlawfully maintained and extended their monopoly power through their continued efforts (1) to convert the Relevant Markets to new versions of Doryx, on the eve of generic entry, in order to delay and/or prevent generic competition to Doryx, thereby foreclosing Mylan from the Relevant Markets; and (2) to manipulate the FDA regulatory processes to delay and/or prevent generic competition to Doryx, thereby foreclosing Mylan, from the Relevant Markets. Defendants' conduct was intended to suppress rather than promote competition on the merits, and it has had precisely the intended effect.

97. Defendants' conduct has caused anticompetitive effects in the Relevant Markets by impeding the sale of generic delayed-release doxycycline hyclate in the Relevant Markets, and thus has allowed Defendants to sell their branded Doryx products at artificially inflated monopoly prices.

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

99. As a direct and proximate cause of Defendants' unlawful, anticompetitive conduct, Mylan has been injured and has sustained damages.

100. Mylan's injury is the type the antitrust laws were designed to prevent and flows from Defendants' unlawful conduct.

**Count III (Plaintiff vs. All Defendants)
Attempted Monopolization (Sherman Act § 2)**

101. Mylan repeats and re-alleges the allegations of paragraphs 1-91 as if fully set forth herein.

102. At all relevant times, there has been a dangerous probability that Defendants will obtain, maintain, and extend its monopoly power in the Relevant Markets.

103. During the relevant period, Defendants have willfully and unlawfully maintained and extended their monopoly power through their continued efforts (1) to convert the Relevant Markets to new versions of Doryx, on the eve of generic entry, in order to delay and/or prevent generic competition to Doryx, thereby foreclosing Mylan from the Relevant Markets; and (2) to manipulate the FDA regulatory processes to delay and/or prevent generic competition to Doryx, thereby foreclosing Mylan from the Relevant Markets.

104. Defendants' conduct was intended to suppress rather than promote competition on the merits, and has had precisely the intended effect. Defendants have a specific intent to

monopolize, and have taken affirmative exclusionary steps in furtherance of their attempt to monopolize the Relevant Markets.

105. Defendants' conduct has caused anticompetitive effects in the Relevant Markets by impeding the sale of generic delayed-release doxycycline hyclate in the Relevant Markets, which has enabled them to sell their branded Doryx products at artificially inflated monopoly prices.

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

107. As a direct and proximate cause of Defendants' unlawful, anticompetitive conduct, Mylan has been injured and has sustained damages.

108. Mylan's injury is the type the antitrust laws were designed to prevent and flows from Defendants' unlawful conduct.

Count IV (Plaintiff vs. All Defendants)
Tortious Interference with Prospective Economic Relationships

109. Mylan repeats and re-alleges the allegations of paragraphs 1-91 as if fully set forth herein.

110. Mylan had valid business expectancies concerning the approval and sale of Generic Doryx 75 mg and 100 mg Capsules Products to various prospective customers.

111. Mylan has and/or had valid business expectancies concerning the sale of Generic Doryx 75 mg and 100 mg Tablet Products to various prospective customers.

112. Mylan has valid business expectancies concerning the sale of the Generic Doryx 150 mg Tablet Product to various prospective customers.

113. Defendants have or had knowledge of Mylan's prospective business relationships with its various prospective customers of Generic Doryx 75 mg and 100 mg Capsule Products and Generic Doryx 75 mg, 100 mg, and 150 mg Tablet Products.

114. Defendants have intentionally interfered with Mylan's business relationships for the purpose of harming Mylan's relationships with its prospective customers by eliminating and/or attempting to eliminate the markets for Generic Doryx 75 mg and 100 mg Capsule Products and Generic Doryx 75 mg, 100 mg, and 150 mg Tablet Products through their continued efforts (1) to convert the Relevant Markets to new versions of Doryx, on the eve of generic entry, in order to delay and/or prevent generic competition to Doryx, thereby foreclosing Mylan from the Relevant Markets; and (2) to manipulate the FDA regulatory processes to delay and/or prevent generic competition to Doryx, thereby foreclosing Mylan from the Relevant Markets.

115. Defendants' conduct was wrongful, improper, and without privilege or justification.

116. Defendants' motives were to gain an unfair marketplace advantage over Mylan in connection with the Relevant Markets.

117. As a direct and proximate cause of Defendants' conduct, Mylan has been injured and has sustained damages.

118. There was a reasonable likelihood that Mylan's prospective business relationships would have occurred but for Defendants' interference.

119. Mylan is entitled to actual and punitive damages as a result of Defendants' intentional and improper acts of interference with Mylan's prospective business and economic relationships with its prospective customers.

Prayer for Relief

WHEREFORE, Mylan requests that the Court enter a judgment in its favor and against Defendants and grant the following relief:

- A. Entering a judgment that Defendants have violated Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2 as well as the common law of the Commonwealth of Pennsylvania for the tort of interference with prospective economic relationships;
- B. Entering an Order, pursuant to the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2, *et seq.*, the Clayton Act, 15 U.S.C. § 15, awarding damages, costs of suit, interest and attorneys fees to Mylan, and that Mylan's damages be trebled;
- C. Entering an Order, pursuant to the common law of the Commonwealth of Pennsylvania, awarding actual and punitive damages and costs of suit;
- D. Awarding Mylan such further relief as this Court deems just and proper.

Dated: July 6, 2012

Respectfully submitted,

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DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Mylan Pharmaceuticals Inc. demands a trial by jury as to all issues of right to a jury.

Dated: July 6, 2012