UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

WALGREEN CO., THE KROGER CO., SAFEWAY INC., HEB GROCERY COMPANY L.P. and ALBERTSON'S LLC, Plaintiffs, vs. MEDICIS PHARMACEUTICAL CORP., Defendant.	Civil Action No._____ JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Walgreen Co., The Kroger Co., Safeway Inc., HEB Grocery Company L.P. and Albertson's LLC bring this civil action against Defendant Medicis Pharmaceutical Corp. ("Medicis") under the antitrust laws of the United States. For their Complaint, Plaintiffs allege as follows:

I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages and other relief arising out of Defendant's unlawful exclusion of generic competition to the brand-name drug Solodyn, which contains as its active ingredient minocycline hydrochloride, marketed for the treatment of acne. Medicis orchestrated a scheme to delay and suppress generic competition to Solodyn and to maintain and extend its monopoly in the market for minocycline hydrochloride extended release tablets, to the detriment of Plaintiffs and other purchasers of the drug.

2. Solodyn was approved by the FDA in 2006 and quickly became Medicis's best-selling product, generating half of Medicis's revenues by 2007. However, Solodyn was

vulnerable to generic competition because it did not qualify for any regulatory exclusivities and the only patent that purportedly covered Solodyn (for the first three years it was marketed), U.S. Patent no. 5,908,838 ("the '838 Patent"), was likely invalid and/or unenforceable. Accordingly, Medicis sought to prevent generic competition through a variety of anticompetitive and unlawful tactics.

3. First, in December 2007, following notice by Impax Laboratories, Inc. ("Impax") that it had filed an application seeking FDA approval to market a generic version of Solodyn, and Impax's commencement of a declaratory judgment action seeking a ruling that the '838 Patent was invalid and not infringed by Impax's proposed generic product, Medicis filed a petition with the FDA. In that petition, Medicis asked the FDA not to approve any generic version of Solodyn without requiring *in vivo* bioequivalence testing for each of the 45mg, 90 mg and 135 mg Solodyn strengths. Medicis had no scientific basis for this request. Indeed, Medicis had argued that no such tests were needed when it applied for approval of Solodyn. The FDA denied Medicis's petition on February 3, 2009, but the petition served its intended purpose, which was to delay approval of Impax's application. On the same day it denied the petition, the FDA approved Impax's pending application.

4. Second, in November 2008, while Medicis's petition, Impax's generic Solodyn application and Impax's declaratory judgment action were pending, Medicis paid Impax at least $55 million to drop the patent challenge and, in exchange, Impax agreed to delay marketing its generic products until November 2011 (the "Medicis/Impax Reverse Payment Agreement"). This agreement also delayed generic competition.

5. Third, after Congress amended the Food, Drug and Cosmetic Act to apply the Hatch-Waxman 30-month stay (described below) to drugs containing old antibiotics like

Solodyn, Medicis improperly submitted the '838 Patent to the FDA for listing in the Orange Book (described below), and then commenced multiple baseless patent suits against potential generic competitors solely to trigger automatic 30-month stays. The patent listing was improper because the '838 Patent was invalid and/or unenforceable in light of Medicis's misrepresentations and omissions to the patent examiner regarding Medicis's first extended-release minocycline product, Dynacin.

6. Fourth, as part of its improper Orange Book listing and subsequent sham patent suits, Medicis filed a second sham petition with the FDA. This time, Medicis argued that it was entitled to a 30-month stay of FDA approval of any generic application seeking approval to market a generic version of Solodyn even if the application had been filed before Medicis listed the '838 Patent in the Orange Book. Medicis's argument was premised on outdated Hatch-Waxman provisions and lacked any legal basis, but nonetheless served to delay approval of another pending application (from Teva Pharmaceuticals USA, Inc. ("Teva")). On March 17, 2009, the FDA denied Medicis's second petition and simultaneously approved Teva's application.

7. Fifth, in order to prevent any generic version of the 45mg, 90mg or 135mg strengths of Solodyn from coming to market before Impax entered in November 2011, and to give Medicis time to switch the market to other strengths (as described below), Medicis entered into an additional reverse-payment settlement with Sandoz Inc. ("Sandoz"). Medicis paid Sandoz to drop its challenges to the '838 Patent and delay market entry of its generic 45mg, 90mg and 135mg products until November 2011.

8. Sixth, having bought itself time without generic competition, Medicis introduced new strengths of Solodyn in 55mg, 65mg, 80mg, 105mg and 115mg strengths. The new

strengths offered no benefits over the prior "legacy" strengths, but because of generic substitution laws pharmacists could not substitute less expensive generic Solodyn in one of the legacy strengths when presented with a prescription for branded Solodyn in one of the new strengths. Then, Medicis aggressively destroyed demand for the legacy strengths, converted that demand to the new strengths using its army of detailers and stopped shipping branded Solodyn in legacy strengths altogether. As a result, by the time generic Solodyn products became available in November 2011, the prescription base for Solodyn in those strengths was virtually nonexistent.

9. Finally, when potential generic competitors finally neared FDA approval for generic Solodyn in the new strengths, Medicis entered into an agreement with Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin") that had the effect of delaying the launch of generic versions of Solodyn in those new strengths. Pursuant to that agreement, Medicis made payments of at least $20 million, with the potential for $38 million in additional payments, and Lupin agreed to delay entry of generic Solodyn in the 55mg strength, for which Lupin was the first applicant to seek FDA approval.

10. But for Medicis's anticompetitive scheme, including its agreements with generic competitors, robust generic competition to Solodyn would have begun much earlier than it actually did and Plaintiffs would have received the benefit of that competition in the form of lower prices. Plaintiffs' injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Defendant's acts unlawful.

11. Plaintiffs are direct purchasers or assignees of direct purchasers of Solodyn and are included in the proposed class definition in actions currently pending as part of *In re Solodyn (Minocycline Hydrochloride) Antitrust Litigation*, MDL Docket No. 2503, in the MDL transferee

court. The limitations period applicable to Plaintiffs' claims has been tolled since the filing of the first class action on behalf of direct purchasers of Solodyn.

II. THE PARTIES

12. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015. Walgreen owns and operates retail stores in several states at which it dispenses prescription drugs, including Solodyn, to the public. Walgreen brings this action in its own behalf and as the assignee of Cardinal Health, Inc. ("Cardinal"), a pharmaceutical wholesaler, which during the relevant period purchased Solodyn directly from Medicis for resale to Walgreen and which has assigned its claims arising out of those purchases to Walgreen. In addition, Walgreen is contractually entitled to a second assignment from AmerisourceBergen Drug Corporation ("ABDC"), another pharmaceutical wholesaler, which during the relevant period purchased Solodyn directly from Medicis for resale to Walgreen. Walgreen intends to include purchases made through ABDC in its damage claim when it obtains that assignment.

13. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business at 1014 Vine Street, Cincinnati, Ohio 45202. Kroger owns and operates retail stores in several states at which it dispenses prescription drugs, including Solodyn, to the public. Kroger brings this action in its own behalf and as the assignee of Cardinal, which during the relevant period purchased Solodyn directly from Medicis for resale to Kroger and which has assigned its claims arising out of those purchases to Kroger.

14. Plaintiff Safeway Inc. ("Safeway") is a Delaware corporation having its principal place of business at 5918 Stoneridge Mall Road, Pleasanton, California 94588. Safeway owns and operates retail stores in several states at which it dispenses prescription drugs, including Solodyn, to the public. Safeway brings this action in its own behalf and as the assignee of

Cardinal, which during the relevant period purchased Solodyn directly from Medicis for resale to Safeway and which has assigned its claim arising out of those purchases to Safeway.

15. Plaintiff HEB Grocery Company L.P. ("HEB") is a Texas limited partnership having its principal place of business at 646 South Main Avenue, San Antonio, Texas 78204. HEB owns and operates retail stores at which it dispenses prescription drugs, including Solodyn, to the public. HEB brings this action in its own behalf and as the assignee of Cardinal and McKesson Corporation ("McKesson"), another pharmaceutical wholesaler, which during the relevant period purchased Solodyn directly from Medicis for resale to HEB and which have assigned their claims arising out of those purchases to HEB.

16. Plaintiff Albertson's LLC ("Albertson's") is a Delaware limited liability company having its principal place of business at 250 Parkcenter Boulevard, Boise, Idaho 83706. Albertson's owns and operates retail stores in several states at which it dispenses prescription drugs, including Solodyn, to the public. Albertson's brings this action in its own behalf and as the assignee of McKesson, which during the relevant period purchased Solodyn directly from Medicis for resale to Albertson's and which has assigned a portion of its claims arising out of those purchases to Albertson's.

17. Defendant Medicis Pharmaceutical Corp. is a Delaware corporation having its principal place of business at 7720 N. Dobson Road, Scottsdale, Arizona. Medicis develops, manufactures and markets branded pharmaceuticals and other products in the United States.

18. All of Defendant's actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendant's various officers, agents, employees, or other representatives while actively

engaged in the management of Defendant's affairs within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

19. This action arises under 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, to recover threefold damages, injunctive relief, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiffs resulting from Defendant's unlawful foreclosure of the United States market for extended-release minocycline hydrochloride. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

20. Defendants transact business within this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, as well as 28 U.S.C. §1391(b) and (c).

IV. OPERATIVE FACTS

A. Characteristics of the Prescription Pharmaceutical Marketplace

21. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

22. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from

dispensing many pharmaceutical products, including Solodyn, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

23. Brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

24. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand – the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

25. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug

Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

26. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." The manufacturer may list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may subsequently list in the Orange Book within thirty days of issuance any such patents issued after the FDA approves the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

27. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments

28. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, 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 drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug,

and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

29. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having 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. 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. 21 U.S.C. § 355(j)(8)(B).

30. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

31. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historically high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue had soared to $300 billion.

D. Paragraph IV Certifications

32. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

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

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

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

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

33. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

34. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of

the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity. This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. While only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the market. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

35. On October 8, 2008, Congress enacted the QI Program Supplemental Funding Act, codified in relevant part at 21 U.S.C. § 355(v) ("QI Act"), which amended the FDCA to add new § 505(v) and create certain Hatch-Waxman provisions for "old" antibiotics. The QI Act includes three transitional provisions, which: (1) require antibiotic drug NDA sponsors to submit to FDA for Orange Book listing information on applicable patents within 60 days of the date of the enactment of the QI Act; (2) require FDA to list those patents in the Orange Book not later than 90 days after the enactment of the QI Act; and (3) create "first applicant" status (for 180-day exclusivity purposes) for each ANDA applicant that not later than 120 days after enactment of the QI Act amends a pending application to include a Paragraph IV certification to a newly listed antibiotic drug patent.

36. Several provisions of Hatch-Waxman did not apply to Solodyn until enactment of the QI Act. Before enactment, drugs like Solodyn that contained an active moiety like minocycline hydrochloride that had been the subject of a marketing application received by FDA

before November 21, 1997 (an "old antibiotic") were exempt from the market exclusivity, patent listing, patent certification and 30-month stay provisions of Hatch-Waxman. The QI act brought such old antibiotics within those provisions of Hatch-Waxman. Thus, if multiple ANDA applicants each submitted a Paragraph IV certification to a newly listed antibiotic drug within the required time period, they would each be "first applicants" within the meaning of Hatch-Waxman and would share 180-day exclusivity. If any one of the first applicants launched its generic product, that exclusivity would be triggered for all of the first applicants.

37. Brand manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition—as opposed to enforcing a valid patent that is actually infringed by the generic—is demonstrated by the fact that generic firms have prevailed in Paragraph IV litigation, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied.

38. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

39. Brand-name pharmaceutical manufacturers can also game the system by filing citizen petitions. Under FDA regulations, any person or entity can file a citizen petition with the FDA requesting that the FDA take, or refrain from taking, any administrative action. The person or entity submitting such a petition is required to include all information and views on which the petitioner relies, as well as information and data known to the petitioner which is unfavorable to the petition.

40. Although federal regulations provide a 180-day period for the FDA to respond to citizen petitions, the FDA often takes longer in practice. Historically, the FDA's practice has been to refrain from approving an ANDA that is the subject of a pending citizen petition until it rules on the petition. Branded manufacturers have been known to file baseless citizen petitions solely to delay ANDA approval and thereby preserve their monopolies while the petition is pending. The cost of filing a sham citizen petition is trivial compared to the value to the manufacturer of delaying AB-rated generic competition.

41. The tactic of filing sham citizen petitions became such a problem that in 2007 Congress stepped in and revised the FDCA to provide that the FDA could not delay approval of a pending ANDA because of a petition unless it determines that "a delay is necessary to protect the public health." 21 U.S.C. § 355(q)(1). The FDA has frequently invoked this provision, as even baseless petitions require time and resources to evaluate.

42. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic manufacturers to conspire in order to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA

filers to launch their generic products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval from the FDA within 30 months from filing a substantially complete ANDA, unless the failure is caused by a change in or review of the approval requirements. Forfeiture under the MMA most commonly occurs for failure to obtain tentative approval within the requisite 30 months.

43. Under the "failure to market" provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the Orange Book.

44. Brand manufacturers and first-filing generics can structure their settlements in order to intentionally skirt these forfeiture provisions. For example, manufacturers subvert the failure-to-market provision and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing

generic company filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in Paragraph IV litigation.

E. The Benefits of Generic Drugs

45. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that, by one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. In retail pharmacy chains such as Plaintiffs, a generic typically achieves a 90% substitution rate within 90 days. As a result, competition from generic drugs is viewed by brand name drug companies such as Medicis as a grave threat to their bottom lines.

46. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

47. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices that result from generic competition.

48. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the agreement at issue here.

F. The Impact of Authorized Generics

49. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period pursuant to its own approved NDA. Such an "authorized generic" is chemically identical to the brand drug, but is sold as a generic product either by the brand manufacturer or through a third party. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the price of both generic drugs and, in addition, forces the first-filer to share the generic sales made at those lower prices with the brand-name manufacturer. Both of these effects reduce the first-filer's revenues and profits.

50. In its study, Authorized Generic Drugs: Short-term Effects and Long-Term Impact (August 2011) (the "FTC Study"), the Federal Trade Commission found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the

authorized generic takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes prices to decrease.

51. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, drug purchasers such as Plaintiffs benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

52. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their branded drug in response to the entry of an AB-rated generic. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the branded drug at the same intervals and at the same rate at which they raised the price of the drug prior to generic entry.

53. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, and the absence of any other form of price competition from the branded manufacturer, a brand manufacturer's agreement not to launch an authorized generic has tremendous economic value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive drug purchasers such as Plaintiffs of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

V. DEFENDANT'S ANTICOMPETITIVE SCHEME

A. Solodyn accounted for the vast majority of Medicis's revenues and profits.

54. Solodyn accounted for about half of Medicis's entire annual revenue. Medicis unlawfully protected those revenues through an anticompetitive scheme that used many of the tools discussed above.

55. Solodyn's active ingredient is minocycline hydrochloride, a semi-synethetic derivative of tetracycline. Solodyn's once daily, extended-release tablet regimen purports to be more convenient (and potentially more effective) for patients than other tetracycline drugs or isotretinoins, which require multiple doses per day. Extended-release medications like Solodyn have special coatings or ingredients that control how fast the active ingredient is released into the patient's body, allowing the patient to take these drugs only once or twice a day. Medicis touts Solodyn's once daily, extended-release feature to differentiate it from other acne treatments, emphasizing that Solodyn is "the only branded oral minocycline approved for once daily dosage in the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age or older" and "the first and only extended release minocylcine with eight FDA-approved dosage strengths."

56. Solodyn's pharmacological profile, and thus its side effect and efficacy profile, are different from those of other tetracycline and/or antibiotic products that doctors prescribe to treat the same or similar conditions. Those other drugs are not AB-rated to Solodyn, cannot be automatically substituted for Solodyn by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Solodyn at competitive prices, and thus are not economic substitutes for, nor reasonably interchangeable with, Solodyn. Medicis's 2008 10-K confirms: "SOLODYN® is not bioequivalent to any other minocycline products, and is in no way interchangeable with other forms of minocycline."

57. On June 30, 2005, Medicis submitted NDA No. 50-808 seeking FDA approval to market Solodyn extended release tablets in 45mg, 90mg, and 135mg ("legacy") strengths for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age or older. The FDA approved Medicis's Solodyn NDA on May 8, 2006.

58. As discussed below, FDA also subsequently granted approval to Medicis to market Solodyn in five additional strengths: 55mg, 65mg, 80mg, 105mg, and 115mg. FDA approved the 65mg and 115mg strengths on July 23, 2009, and approved the 55mg, 80mg, and 105mg strengths on August 7, 2010.

59. Medicis currently has six patents relating to Solodyn.

60. U.S. Patent No. 5,908,838 (the "'838 Patent") was issued by the United States Patent and Trademark Office on June 1, 1999 to Eugene H. Gans and assigned to Medicis. Medicis asserts that the '838 Patent covers "methods for the treatment of acne" through the "use of oral tetracycline antibiotics." The '838 Patent expires on February 19, 2018.

61. At the time Medicis submitted and FDA approved its NDA for Solodyn in the legacy strengths, Congress had not yet enacted the QI Act and, thus, the '838 Patent was not and could not have been listed in the Orange Book. After the QI Act became effective on October 8, 2008, Medicis submitted, on December 3, 2008, the '838 Patent for listing in the Orange Book in connection with its Solodyn NDA. Under clear and unambiguous law, Medicis was not entitled to any 30-month stay under the Hatch-Waxman Act for any ANDAs submitted by generic manufacturers for the Solodyn legacy strengths before Medicis listed the '838 Patent on December 3, 2008.

62. U.S. Patent No. 7,541,347 (the "'347 Patent") was issued to Medicis on June 2, 2009. Medicis then submitted the '347 Patent for listing in the Orange Book in connection with

its Solodyn NDA. Medicis asserts that the '347 Patent relates to the use of the 90mg controlled-release oral dosage form of minocycline to treat acne. The '347 Patent expires in 2027.

63. U.S. Patent No. 7,544,373 (the "'373 Patent") was issued on June 9, 2009. Medicis then submitted the '373 Patent for listing in the Orange Book in connection with its Solodyn NDA. Medicis asserts that the '373 Patent relates to the composition of the 90mg dosage form. The '373 Patent expires in 2027.

64. U.S. Patent No. 7,790,705 (the "'705 Patent") was issued on September 7, 2010. Medicis subsequently submitted the '705 Patent for listing in the Orange Book. Medicis asserts that the '705 patent relates to all strengths of Solodyn and expires in 2025.

65. U.S. Patent No. 7,919,483 (the "'483 Patent") was issued on April 5, 2011 and was listed in the Orange Book thereafter. Medicis asserts that the '483 Patent "covers methods of using a controlled-release oral dosage form of minocycline to treat acne, including the use of our product SOLODYN in all eight currently available dosage forms." The '483 Patent expires in 2027.

66. U.S. Patent No. 8,268,804 (the "'804 Patent") was issued on September 8, 2012 and was listed in the Orange Book thereafter. Medicis asserts that the '804 Patent covers a method for the treatment of acne and relates to all strengths of Solodyn. The '804 Patent expires in 2025. The '804 Patent had not yet issued at the time of the unlawful conduct alleged herein.

67. The '838, '347, '373, '705, '483, and '804 patents are referred to collectively herein as the "Solodyn Patents." The '347, '373, '705, '483, and '804 patents are referred to collectively herein as the "Later Issued Patents."

68. As discussed more fully below, none of the Solodyn Patents would have prevented generic Solodyn products from entering the market before those patents expired. At

the time Medicis filed its first sham citizen petition, filed sham lawsuits with respect to the '838 Patent, and entered the Exclusion Payment Agreement with Impax, none of the Later Issued Patents had issued. And the invalid and/or unenforceable '838 Patent alone would not have kept generics from entering the market before its expiration in 2018 for the reasons discussed below. Moreover, although the '347 and '373 patents had issued by the time of Medicis's Exclusion Payment Agreement with Sandoz, and the '705 and '483 patents had also issued by the time of Medicis's Exclusion Payment Agreement with Lupin, none of those patents would have prevented earlier generic entry. But for Medicis's anticompetitive conduct, Medicis would not have prosecuted any of the Later Issued Patents to issuance, because Medicis would have lost its profit motive to do so once generics entered and purchasers switched to the less expensive generics.

69. But even if the Later Issued Patents actually issued, they would not have prevented generics from entering the market earlier absent Medicis's unlawful conduct. No automatic 30-month stay of FDA approval applied to any of the Generic Defendant's ANDAs that were submitted before the Orange Book listing of any of the Later Issued Patents. Moreover, each of the Later Issued Patents is weak, and was likely to have been adjudicated invalid, unenforceable, or not infringed.

70. Since obtaining FDA approval in 2006, Solodyn has proven to be very lucrative to Medicis. The annual U.S. sales for Solodyn between 2007 and 2011 are as follows:

YEAR	SALES
2007	$247M
2008	$316M
2009	$479M
2010	$673M
2011	$761M

71. As of 2011, Medicis announced that Solodyn was "[t]he #1 dermatology medication by dollars in the world and the #1 most prescribed branded dermatology product in the U.S. by prescriptions and dollars."

72. Solodyn was Medicis's "flagship" product, representing approximately half of Medicis's sales.

B. Solodyn's Particular Vulnerability to Generics

73. Despite Solodyn's success, Medicis recognized that Solodyn was particularly vulnerable to the drastic loss of sales that would accompany the advent of AB-rated generic competition to Solodyn because: (1) no regulatory exclusivity applied that prevented FDA from approving AB-rated generic Solodyn products; and (2) the '838 patent—for many years, the only patent shielding Solodyn from competition—was likely invalid and/or unenforceable.

74. Solodyn contains as its active ingredient the "old antibiotic" minocycline, which has been marketed since at least the early 1970s. As a result, the various periods of marketing exclusivity granted to certain brand manufacturers with approved NDAs, such as new chemical entity exclusivity or new clinical trial exclusivity, do not apply to Solodyn.

75. Moreover, from the time Medicis obtained FDA approval for Solodyn in 2006 until the passage of the QI Act in 2008, the Paragraph IV and 30-month stay provisions of Hatch Waxman did not apply to Solodyn. Because those provisions did not apply, Medicis could not obtain a 30-month stay of FDA regulatory approval of AB-rated generic versions of Solodyn simply by filing a patent infringement suit within 45 days of receiving notice of an ANDA containing a Paragraph IV certification to an Orange Book-listed patent for Solodyn.

76. In addition, Medicis could not patent the chemical compound in Solodyn; in fact, the claimed invention had been "on sale" prior to Medicis's attempt to patent it, rendering the claimed invention unpatentable. While Medicis's minocycline drug product branded as Solodyn

was itself an "old antibiotic," it was not Medicis's first slow-release minocycline product. That was a product called Dynacin, which Medicis sold as early as 1992.

77. Further, as will be explained more fully below, Medicis used research on its 1992 Dynacin product to generate data for the patent application that eventually issued as the '838 Patent. This is the same patent that Medicis would later claim covered Solodyn and protected it from generic competition.

78. Beginning in November 1992, significantly more than one year before filing the '838 Patent application, Medicis sold minocycline hydrochloride capsules in the United States under the trade name Dynacin. Dynacin was sold by Medicis and was prescribed and used by patients in the United States well before February 18, 1997 for the purpose of treating acne.

79. Sometime before October 1997, the named inventor of the '838 Patent, Eugene H. Gans, performed a study comparing the side effects, including vestibular side effects (vertigo, dizziness or blurred vision), of Dynacin capsules to the side effects of another commercially available minocycline hydrochloride product, Vectrin. The study compared these two minocycline hydrochloride products in order to study the effect of the *in vitro* dissolution rates on the occurrence and magnitude of vestibular side effects *in vivo*. Vectrin released its minocycline almost immediately *in vitro*, and anecdotal reports from dermatologists indicated that Vectrin produced significant vestibular side effects in some patients. Dynacin, on the other hand, had a slow *in-vitro* dissolution and was not known to cause similar vestibular side effects.

80. The results of that study were published in a 1997 article in Clinical Acne Reviews (the "Dynacin Study"). Individuals at Medicis knew about the Dynacin Study because the Dynacin Study was described in Clinical Acne Reviews as a Medicis publication. In

addition, Dr. Gans, who worked as a Medicis consultant at the time, was listed as an author of the Dynacin Study.

81. The results of the Dynacin Study demonstrated, *inter alia*, that patients taking Dynacin had a reduced incidence of vestibular side effects over those taking Vectrin; the study reported a total of 27 incidences of vestibular symptoms in the Vectrin treatment group compared to 5 incidences in the Dynacin treatment group. The Dynacin Study authors, including the only named inventor on the '838 patent—Dr. Gans—hypothesized that the difference in vestibular side effects was due to the difference in dissolution rates between the fast-dissolving dosage form (Vectrin) and the slower-dissolving dosage form (Dynacin).

82. Using the data from the Dynacin Study, Medicis filed the application that eventually issued as the '838 Patent but in doing so did not tell the U.S. Patent and Trade Office ("USPTO") that public use of Dynacin occurred before February 18, 1997, that Dynacin had been sold before February 18, 1997, or that the data that formed the basis for the '838 Patent was entirely based on Dynacin and the prior Dynacin Study.

83. Entities filing a patent application have a duty of candor to the USTPO. "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned." 37 C.F.R. § 1.56(a) (July 1, 1999); Manual of Patent Examining Procedure § 2001 (7th ed. July 1998). Applicants before the USPTO have a duty to disclose "all information known to that individual to be material to patentability" promptly, generally before the first office action by the USPTO.

37 C.F.R. §1.59 (July 1, 1999). Medicis's filing of the patent application that led to the '838 Patent triggered the legal duty of candor to the USPTO, including the duty to disclose information material to patentability.

84. The '838 Patent claims a method for the treatment of acne that results in the reduction of vestibular side effects, following administration of oral tetracycline antibiotics in a slowly dissolving dosage form. Until June 2009, the '838 Patent was the only patent that purportedly covered Solodyn.

85. Claim 1 of the '838 Patent as it originally issued describes Dr. Gans' alleged invention:

> 1. A method of reducing the incidence or severity of vestibular side effects resulting from the treatment of acne by the use of oral tetracycline antibiotics, comprising administering the oral tetracycline antibiotic in a slowly dissolving dosage form.

Not surprisingly, the Dynacin product that Medicis had sold since before February 18, 1997 was encompassed by this claim, because it was based on research on the very same Dynacin product. Given the breadth of this and other similar claims in the '838 Patent, Medicis, Dr. Gans, and/or the prosecuting attorneys knew this to be the case but misrepresented and/or withheld this information from the USPTO with deceptive intent.

86. Some of the data in the Dynacin Study and the '838 Patent are identical. For example, table 2 of the '838 Patent describes the exact same results that were reported in the Dynacin Study. Despite this, all reference to the prior art Dynacin was removed when the data was presented in the application for the '838 Patent. In fact, the only data included within the specification of the '838 Patent was data that came from the Dynacin Study but without any attribution or explanation that the 1992 Dynacin product was available and on sale before February 18, 1997. In essence, the '838 Patent and the Dynacin Study both report a study

conducted with the identical methodology, results, and data for the symptoms, severity, number of time intervals, and severity category for each of the identified instances of vestibular side effects. The slower dissolving dosage form used in the study of vestibular effects reported in the '838 Patent was Medicis's Dynacin capsules. Yet Dr. Gans, Medicis, and/or the prosecuting attorneys intentionally and deceptively omitted from the '838 Patent application and supporting materials any and all references to Dynacin. Medicis, Dr. Gans, and/or the prosecuting attorneys intentionally omitted this critical information because they knew that the prior public use and sale of Dynacin since at least 1992 would have been a bar to patentability.

87. Dr. Gans, Medicis, and/or the prosecuting attorneys chose to deliberately misrepresent or omit this potential on-sale bar to the USPTO during prosecution of the '838 Patent. Specifically, the facts that Dynacin was publicly used, sold, and/or offered for sale in the United States prior to one year before the filing of the '838 Patent application were misrepresented or improperly withheld with deceptive intent. In addition, the only data submitted with the '838 Patent was data derived from experiments conducted using Dynacin, but the specification of the '838 Patent had all reference to the 1992 Dynacin product carefully extricated from the data submitted to the USPTO and no one associated with Medicis took any steps to make the examiner aware of these and other material facts.

88. In addition, the Dynacin Study itself was never disclosed to the USPTO. The fact that Medicis and Dr. Gans knew in 1997 that a controlled extended release composition of minocycline hydrochloride (such as Dynacin) was on sale and would reduce vestibular side effects as later claimed in the '838 Patent would have been relevant to a reasonable examiner under 37 C.F.R. §1.56, but Medicis, Dr. Gans, and/or the prosecuting attorneys deliberately withheld this information from the USPTO during the prosecution of the '838 Patent.

89. Dr. Gans, Medicis, and/or the prosecuting attorneys chose to deliberately misrepresent or omit with deceptive intent that Dynacin capsules were a controlled and extended release form of minocycline hydrochloride that was available prior to February 18, 1997 and that Dynacin itself was actually used in the study of vestibular side effects reported in the '838 Patent.

90. Further, Dr. Gans, Medicis, and/or the prosecuting attorneys made the decision to misrepresent or deliberately omit the Dynacin Study with deceptive intent during prosecution of the '838 Patent. The portion of the Dyancin Study that was included in the specification of the '838 Patent had all reference to the prior art Dynacin and the Dyancin Study carefully extricated. As a result, the '838 Patent was obtained by knowingly and willfully misrepresenting facts to the USPTO.

91. A reasonable examiner would have considered each of these misrepresentations and deliberate omissions material to the patentability of one or more of the claims of the '838 Patent.

92. Moreover, Medicis, Dr. Gans, and/or the prosecuting attorneys—all of whom had a duty to disclose under 37 C.F.R. §1.56—deliberately omitted certain material information contained in the Dynacin Study from the '838 Patent. A reasonable examiner would have considered the study data omitted from the '838 Patent material to the patentability of one or more claims of the '838 Patent because, *inter alia*, the omitted data cast doubt on the utility of the claims of the invention. The materiality of the information omitted from the '838 Patent suggests that data was cherry-picked from the Dynacin Study as published and that certain unhelpful data was intentionally and fraudulently withheld from the USPTO.

93. In addition to being unenforceable due to inequitable conduct, the specter of invalidity hung over the '838 Patent after it was issued on June 1, 1999. In June 2008, an undisclosed party submitted to the USPTO a Request for Reexamination of the '838 Patent. Patent reexamination is the procedure by which a granted patent is reexamined by a primary examiner in the USPTO to determine whether the prior art raises a substantial question of patentability. During the August 2008 Reexamination Proceedings before USPTO, Medicis canceled claims 1-2, 5-11, and 15-18; amended claims 3, 4, 12, and 13 to be independent; and provided new claims 19-34. Although the USPTO ultimately reissued the '838 Patent on June 1, 2010—after Medicis entered its Exclusion Payment Agreements with Impax and Sandoz—none of the original '838 Patent claims survived without amendment, demonstrating that Medicis recognized that the '838 Patent was likely invalid as originally issued. Moreover, as discussed above, the '838 Patent (both as originally issued and reissued) was likely invalid due to the public use and sale of Dynacin prior to February 18, 1997.

94. Accordingly, the '838 Patent was invalid and/or unenforceable and thus unlikely to prevent a generic Solodyn product from coming to market in advance of patent expiration. This fact was not lost on Medicis, which cautioned investors in 2007 that its "failure to obtain additional patent protection could adversely affect our ability to deter generic competition, which would adversely affect Solodyn revenue."

95. With respect to the '838 Patent, Dr. Gans, Medicis, and/or the prosecuting attorney made false representations or deliberate omissions of highly material information to the USPTO examiner with the intent to deceive the USPTO. The examiner was justified in relying on the statements made by Dr. Gans, Medicis, and/or the prosecuting attorney and was justified in believing that if there were material information known to those involved in the prosecution

this information would have been brought to the attention of the examiner under the applicant's duty to disclose information material to the patentability of the '838 Patent. Had the examiner known of the misrepresented and omitted information the examiner would not have issued the '838 Patent because such information was material to whether the invention was "in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States," and therefore could be anticipatory prior art to the application that led to the '838 Patent. 35 U.S.C. § 102(b).

96. To make matters worse, with full knowledge of the infirmity of the '838 Patent, as more fully described below, Medicis continued in litigation with Impax from January to November of 2008 until Medicis ultimately negotiated an Exclusion Payment Agreement, and then later engaged in additional litigation that involved the '838 Patent with several other generic drug manufacturers. Medicis continued to assert the patent against generic competitors despite knowledge that the '838 Patent was procured by fraud and was invalid and/or unenforceable.

C. Medicis's Multi-Part Strategy to Thwart Generics

97. Because Solodyn was critical to Medicis's overall financial performance and was particularly susceptible to the threat of competition from generics, Medicis developed multiple unlawful tactics to prevent, delay, or impair competition from generic Solodyn products. As Medicis explained to its investors: "[Y]ou can be sure that in every conceivable respect, we are attempting to protect Solodyn," (Medicis at Credit Suisse Healthcare Conference (Nov. 14, 2007)), "keeping it alive as long as we can," (Medicis at Merrill Lynch 19th Global Pharmaceutical, Biotechnology & Medical Device Conference (Feb. 7, 2008)). Medicis's Chief Executive Officer, Jonah Shacknai, even boasted that it had "hired a couple of [law] firms that I

think are vicious" to go after generics and prop up the Solodyn brand. (Medicis Earnings Conference Call (Feb. 28, 2007)).

98. Then, during an earnings call on February 27, 2008, Medicis CEO Shacknai specifically identified some of the steps Medicis planned to take in order to impair generic competition. Shacknai outlined Medicis's "three-part strategy" to protect Solodyn from generic competition, which included "intellectual property," "regulatory" and "commercial" components. First, Medicis would seek to enforce the '838 Patent, and any other patents it could convince the USPTO to grant, against any potential generic competitors. Second, Medicis would file citizen petitions with the FDA with respect to the bioequivalence requirements for generic versions of Solodyn, as well as other potential regulatory matters, which would delay FDA approval of generic Solodyn products. Third, Medicis would develop "other generations of Solodyn" in order to prevent the automatic substitution of AB-rated generics for Solodyn in the event that its other tactics failed to prevent FDA approval of generic Solodyn products. Mr. Shacknai characterized each of the "three elements . . . as part of an interrelated and fairly complex strategy to defend the brand to the utmost of our ability."

99. Once potential generic competitors to Solodyn became a real and imminent threat, Medicis systematically employed each of these strategies—as well as the unlawful Exclusion Payment Agreements discussed herein—to delay and impair competition from generic versions of Solodyn.

D. Impax's Attempt to Enter the Market

100. On or about October 5, 2007, Impax submitted to the FDA its ANDA 90-024 seeking to market generic versions of Solodyn in 45mg, 90mg, and 135mg strengths. Because there were no Orange Book-listed patents for Solodyn at the time Impax submitted its ANDA,

Impax was not required by Hatch-Waxman to notify Medicis of its application to market generic Solodyn.

101. On December 20, 2007, however, Impax notified Medicis of the generic Solodyn ANDA filing and requested that Medicis provide Impax with a covenant not to sue under the '838 Patent in connection with Impax's ANDA 90-024. Impax informed Medicis that any attempt by Medicis to enforce the '838 Patent against generic versions of Solodyn would be "clearly improper, since the claims of the '838 patent issued only because the patent examiner was not aware of highly relevant prior art during prosecution of the '838 patent." Impax further notified Medicis that "[i]f Medicis were to attempt to enforce the '838 patent against Impax . . . such an effort would be objectively and subjectively baseless, and would give rise to potential antitrust liability." In order to assist Medicis's consideration of a covenant not to sue, and to support Impax's position that its generic Solodyn products were not covered by any valid claim of the '838 Patent, Impax offered to give Medicis access to the relevant portions of ANDA 90-024.

102. Medicis failed to grant Impax's requested covenant not to sue or to respond to Impax's offer of confidential access. Consequently, on January 15, 2008, Impax filed a complaint for declaratory judgment in the United States District Court for the Northern District of California seeking a declaration that the claims of the '838 Patent were invalid and not infringed by Impax.

103. The price of Medicis's shares on the New York Stock Exchange plunged dramatically—a 12% percent drop, its biggest decline in seven years of U.S. trading—after Medicis disclosed the Impax ANDA filing in an 8-K filed January 15, 2008, the same day that Impax brought suit.

104. On March 5, 2008, Medicis moved to dismiss Impax's declaratory judgment complaint, arguing that no justiciable Article III controversy existed because (a) Impax had not begun the commercial marketing of its generic Solodyn products and was thus not at risk of incurring patent infringement damages; (b) there could be no automatic 30-month stay of FDA approval of Impax's generic Solodyn products and thus Impax could not suffer any injury that might arise from such a stay; and (c) no conduct of Medicis was preventing Impax from marketing its generic Solodyn products.

105. Opposing Medicis's motion to dismiss, Impax emphasized, *inter alia*: (a) Medicis's repeated threats to preserve its monopoly position with respect to Solodyn by aggressively enforcing the '838 Patent against potential generic competitors through the use of "vicious" patent litigation; and (b) the public's interest in increasing competition in the drug industry and obtaining generic drugs at lower prices.

106. Before the court could decide whether Impax had standing to challenge the '838 Patent, however, Medicis implemented the next in a series of unlawful tactics which were designed to, and did, delay and impair the entry and market penetration of less expensive generics.

E. Medicis's Implementation of Its Multi-Part Anticompetitive Scheme

107. On March 18, 2008, while Medicis's motion to dismiss Impax's declaratory judgment complaint was still pending, Medicis filed a sham citizen petition with the FDA solely to delay approval of Impax's ANDA. The Medicis citizen petition, Number FDA-2008-P-0185, asked FDA not to approve any generic versions of Solodyn without requiring *in vivo* bioequivalence testing for each strength of Solodyn ("Medicis's Proportionality Petition"). Under FDA's draft bioequivalence guidelines for Solodyn (minocycline hydrochloride) extended-

release tablets, posted on FDA's website in December 2007, *in vivo* bioequivalence testing was required for the 135mg tablets of Solodyn, but not for the 45mg and 90mg tablets as long as those strengths were "proportionally similar" to the 135mg tablets.

108. In its petition, Medicis asked the FDA not to approve 45mg and 90mg strengths of any generic Solodyn products on the basis of bioequivalence testing on the 135mg strength. In support, Medicis argued that the 45mg and 90mg strengths of Solodyn are not dose-proportional to the 135mg strength and therefore requested that FDA designate 90mg Solodyn as a separate reference-listed-drug from the 135mg strength, and that the 90mg be the focus of bioequivalence testing for all strengths other than the 135mg.

109. Medicis's argument was directly contrary to the argument Medicis itself had successfully made to the FDA in order to get approval of its own Solodyn products. Medicis convinced the FDA to approve Medicis's own 45mg and 90mg products on the ground that they are dose-proportional to the 135mg strength. Medicis's *in vivo* pharmacokinetic studies demonstrated that the different strengths of Solodyn result in dose-proportional exposure. FDA therefore approved Solodyn's label, which states: "A single-dose, four-way crossover study demonstrated that all strengths of Solodyn tablets (45 mg, 90 mg, 135 mg) exhibited dose-proportional pharmacokinetics." Also based on this finding of dose-proportional exposure, FDA designated the highest approved strength of Solodyn tablets, 135 mg, as the reference standard against which generic versions of Solodyn must establish *in vivo* bioequivalence.

110. On February 3, 2009, FDA denied Medicis's Proportionality Petition. The FDA refused to require ANDA applicants for minocycline hydrochloride extended-release tablets to conduct *in vivo* bioequivalence testing on 45mg or 90mg strengths if bioequivalence was

demonstrated *in vivo* for the 135mg strength and the generic product demonstrated appropriate grounds for testing the lower strengths using *in vitro* methods.

111. In denying Medicis's Proportionality Petition, FDA found that "none of the[] facts" Medicis asserted were "directly relevant to whether ANDA applicants must separately demonstrate *in vivo* bioequivalence to Solodyn for multiple strengths." Indeed, the FDA noted that Medicis itself had submitted data to the FDA showing that the drug's pharmokinetics were proportional to the amount of the active ingredient, the proportions of inactive ingredients notwithstanding. FDA also noted that Solodyn's own labeling states that "[a] single-dose, fourway crossover study demonstrated that all strengths of Solodyn tablets (45 mg, 90 mg, 135 mg) exhibited dose-proportional pharmacokinetics." As a result of Medicis's own studies and labeling, the FDA concluded there was in fact "dose proportional exposure *in vivo*," and reaffirmed its prior finding that "135 mg [Solodyn is] the reference standard against which generic versions of Solodyn must establish *in vivo* bioequivalence."

112. Medicis's petition was objectively baseless and a sham, made and timed as an improper attempt to slow down the FDA approval process for Impax's ANDA. As noted above, Medicis's CEO had stated publicly that Medicis would file citizen petitions as part of a campaign to delay entry by generic rivals. Merely filing a citizen petition, regardless of its merits, delays the FDA's approval process for an ANDA. As a matter of pattern and practice, the FDA does not approve an ANDA if a pertinent petition—even a baseless one—is pending. Adjudicating even a meritless citizen petition requires FDA to expend its time and resources, and the FDA will frequently cite public health concerns to take more time to evaluate such petitions, even ones which are ultimately meritless. Absent Medicis's petition, FDA would have processed Impax's ANDA more rapidly and approved it earlier.

113. On February 3, 2009, the same day that FDA denied Medicis's Proportionality Petition, FDA gave final approval to Impax's ANDA Number 90-024 for generic 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets.

114. But for Medicis's conduct, including the Proportionality Petition, FDA would have given final approval to Impax's ANDA before February 3, 2009.

115. Impax, however, did not launch its generic Solodyn products on February 3, 2009 despite receiving FDA approval to do so. Rather than launch its products—which Impax had represented would be in the public's interest in increasing competition in the drug industry and obtaining generic drugs at lower prices—Impax reached an anticompetitive agreement with Medicis to delay Impax's entry into the market for three years.

116. On April 16, 2008, the district court granted Medicis's motion to dismiss Impax's declaratory judgment complaint for lack of jurisdiction. The court did not address Impax's contentions concerning the validity or infringement of the '838 Patent. Impax filed its notice of appeal of the motion to dismiss ruling with the United States Court of Appeals for the Federal Circuit on May 12, 2008.

117. In November 2008, while Impax's appeal and Medicis's baseless Proportionality Petition were still pending, Medicis and Impax entered into the Medicis/Impax Exclusion Payment Agreement. Pursuant to that Agreement, on or about November 26, 2008, Impax agreed to: (a) drop the appeal of its declaratory judgment action against Medicis; (b) admit that the '838 Patent, plus 297 unissued claims from twelve pending patent applications, are valid and enforceable; and (c) admit that its activities in connection with its ANDA 90-024 infringed the '838 Patent. At the time of the unlawful Agreement, neither the parties nor the court had addressed any of the substantive merits of the patent dispute.

118. Under the Medicis/Impax Exclusion Payment Agreement, Impax agreed to delay launching its generic Solodyn products in 45mg, 90mg, and 135mg strengths until the earlier of: (a) November 26, 2011; or (b) the date on which another generic version of Solodyn entered the market. In other words, Impax agreed to delay the launch of its generic Solodyn products until November 26, 2011 unless another generic Solodyn product entered earlier.

119. As the *quid pro quo* for Impax's agreement to drop its challenge to the '838 Patent, Medicis agreed to pay Impax tens of millions of dollars or more. Medicis's payments to Impax under the Agreement took a variety of forms.

120. First, in December 2008, Medicis paid Impax an "upfront fee" of $40 million under the guise of a Joint Development Agreement providing for the collaboration and development of four generic dermatology products and an advanced form of Solodyn.

121. Second, the Agreement obligated Medicis to pay Impax up to $23 million in milestone payments, of which Medicis has already paid Impax $15 million.

122. Third, to the extent any products were commercialized under the Agreement, Medicis was to pay Impax royalties on sales of the "new" form of Solodyn, and Impax would receive 50% of all profits on the generic dermatology products.

123. Fourth, the Agreement granted to Impax the right to distribute an authorized generic version of the subsequent form of Solodyn for a split of the gross profits related to the sales of such authorized generic product.

124. Although Medicis and Impax characterize the payments under the Agreement as consideration for the collaboration and development of additional dermatology products, and/or for the distribution of an authorized generic version of a subsequent branded Solodyn product, that characterization is pretextual. In fact, the payments from Medicis to Impax were for

Impax's agreement to delay generic competition to Solodyn for three years. Absent Impax's agreement to delay entry into the market with generic Solodyn, Medicis would not have entered the Joint Development Agreement with Impax and/or would not have agreed to the price and/or other terms that it did under those provisions of the Agreement. Medicis paid Impax for delayed market entry of generic Solodyn.

125. Impax did, in fact, delay continued marketing of its generic 45mg, 90mg, and 135mg Solodyn products until November 26, 2011 (although, as discussed below, entry at that late date was practically worthless to purchasers because Medicis destroyed demand for Solodyn in 45mg, 90mg, and 135mg strengths as part of its multi-part, anti-generic strategy). Other generic manufacturers, however, were still threatening to enter the market with competing generic Solodyn products. So Medicis swiftly mitigated the threat from other potential generic competitors with additional tactics that were designed to, and did in fact, delay generic Solodyn products from entering the market.

126. On December 3, 2008, Medicis wrongfully submitted the '838 Patent for listing in the FDA Orange Book. Although the QI Act made the Orange Book listing provisions of Hatch-Waxman generally applicable to old antibiotics like Solodyn, any patents covering an antibiotic or method of using an antibiotic still had to meet all of the other requirements for Orange Book listing. Method-of-use patents are eligible for Orange Book listing only if a claim for patent infringement could reasonably be asserted against a generic manufacturer not licensed by Medicis. As Medicis knew, no reasonable claim for infringing the '838 Patent could have been asserted because, as discussed above, the '838 Patent was invalid and/or unenforceable. Yet Medicis submitted the '838 Patent for listing in the Orange Book anyway, solely as part of its plan to delay generic competition.

127. After improperly listing the '838 Patent in the Orange Book, Medicis received multiple Paragraph IV notifications in connection with multiple generic manufacturers' previously-filed ANDAs to market generic Solodyn products.

128. On or about December 5, 2008, Medicis received a notice letter from Mylan Inc. ("Mylan") stating that its subsidiary Matrix Laboratories Ltd. ("Matrix") had filed ANDA 09-0911 seeking to market generic versions of Solodyn in 45mg, 90mg, and 135mg strengths and including a Paragraph IV certification that the '838 Patent is invalid, unenforceable, and/or would not be infringed by Mylan's generic product. Mylan's subsidiary Matrix had filed its ANDA 09-0911 on September 30, 2008.

129. On or about December 8, 2008, Medicis received a notice letter from Sandoz stating that it had filed ANDA 09-0422 seeking to market generic versions of Solodyn in 45mg, 90mg, and 135mg strengths and including a Paragraph IV certification that the '838 Patent is invalid, unenforceable, and/or would not be infringed by Sandoz's generic product. Sandoz had filed its ANDA 09-0422 before December 5, 2008.

130. On or about December 23, 2008, Medicis received a notice letter from Barr Laboratories, Inc. ("Barr") stating that it had filed ANDA 65-485 seeking to market generic versions of Solodyn in 45mg, 90mg, and 135mg strengths and including a Paragraph IV certification that the '838 Patent is invalid, unenforceable, and/or would not be infringed by Barr's generic product. Barr had filed its ANDA 65-485 in April 2007.

131. On December 12, 2008, Medicis also received a notice letter from Impax stating that it had filed its ANDA with a Paragraph IV certification that the '838 Patent is invalid, unenforceable, and/or would not be infringed by Impax's generic product. Impax and Medicis, however, had already entered the Medicis/Impax Exclusion Payment Agreement. Because

Impax, Teva, Sandoz, and Mylan had each submitted a Paragraph IV certification to the newly-listed '838 Patent within the requisite time under the transitional provisions of the QI Act, the four generic manufacturers were each entitled to share 180-day exclusivity regarding the 45mg, 90mg, and 135mg strengths of generic Solodyn.

132. On January 13, 2009, Medicis filed suit against Mylan, Barr (subsequently acquired by Teva Pharmaceuticals USA, Inc. ("Teva")) and Sandoz in the United States District Court for the District of Delaware seeking an adjudication that the generic manufacturers infringed one or more claims of Medicis's '838 Patent by submitting to FDA their respective ANDAs for 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets with Paragraph IV certifications. No reasonable litigant could have realistically expected to succeed on claims that Mylan, Barr/Teva, Sandoz—or any generic manufacturer— infringed the invalid and unenforceable '838 Patent. Medicis filed and prosecuted the '838 Patent infringement suits discussed herein for the sole purpose of delaying generic competition.

133. Next, as part and parcel of its scheme to improperly list and assert the '838 Patent, on February 13, 2009, Medicis submitted a second baseless citizen petition to FDA, Number FDA-2009-P-0081-0004, requesting that FDA not approve for thirty (30) months, measured from the date Medicis received notice of the Paragraph IV Certification: (a) the ANDAs submitted by Mylan, Barr/Teva, and Sandoz; and (b) any other then-pending ANDA referencing Solodyn for which the applicant made a Paragraph IV certification and for which Medicis sued for patent infringement within the requisite 45-day period ("Medicis's 30-Month Stay Petition").

134. On March 17, 2009, FDA denied Medicis's 30-Month Stay Petition, ruling that no 30-month stay of FDA approval applied because the '838 Patent was not Orange Book-listed until after the ANDAs were pending before FDA. According to FDA, Medicis's positions were

"not supported by either the plain language of the QI Act or by the regulatory framework for innovator and generic drug products of which the QI Act is a part." Medicis had no objectively reasonable basis for its requests that a 30-month stay should apply to ANDAs submitted before the '838 Patent was listed in the Orange Book, and no reasonable petitioner could have expected to succeed on the merits of Medicis's 30-Month Stay Petition. The 30-Month Stay Petition was filed solely to delay generic competition.

135. Conceding that nothing in the QI Act actually states that an ANDA applicant that amends its ANDA to include a Paragraph IV certification pursuant to the QI Act would be subject to a 30-month stay, Medicis's 30-Month Stay Petition raised three objectively baseless grounds as to why a 30-month stay should nonetheless be read into the Act (where it does not appear): (1) the QI Act requires application of the 30-month stay provisions of the original Hatch-Waxman Amendments as enacted in 1984, rather than the version of the statute as amended by the MMA in 2003, which limits 30-month stays to only those ANDAs that are filed after a patent is Orange Book-listed; (2) ANDAs amended to contain a Paragraph IV certification to a patent that was submitted for Orange Book listing pursuant to the QI Act should be deemed submitted to FDA on the date when the first possible application containing a Paragraph IV Certification could have been submitted (even though they were not); and (3) the patent at issue should be treated as having been submitted to FDA with the original NDA (even though it was not).

136. Regarding the first of Medicis's baseless grounds, its sole argument was based on a reference in the QI Act that "the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply" to old antibiotics. According to Medicis, because the QI Act referred once to the Hatch Waxman Act "of 1984," the 2003 amendments to the Hatch-Waxman

Act should not apply and therefore 30-month stays based on patents filed after ANDA submission purportedly did not govern Medicis's 2008 patent listing or the generic Solodyn ANDAs submitted in 2007 and 2008.

137. FDA flatly rejected Medicis's argument, concluding that Congress "did not require FDA to turn back the clock to 1984," and that such an "outcome is inconsistent with the purpose of the QI Act." FDA further explained that the bare statutory reference to the Hatch Waxman Act "of 1984" did not permit the FDA to ignore the 2003 amendments, and nothing in the statutory text, legislative history, or regulatory considerations supported any different conclusion. The reference to the "Drug Price Competition and Patent Term Restoration Act of 1984" was simply "a more formal shorthand than the more common reference to 'the Hatch-Waxman Amendments.'" Moreover, the text of the QI Act itself, which refers to other statutory provisions as amended in 2003 by the MMA, was "fatal" to the argument that the original 1984 Act, rather than the law as it existed at the time, should have applied.

138. As the second of Medicis's baseless grounds, Medicis argued that the QI Act recalculates the actual ANDA submission dates to be after the patent listing date. Medicis's tortured argument went like this: a transitional provision of the QI Act deems all ANDA applicants who timely file a Paragraph IV certification to a patent listed pursuant to the QI Act to be "first applicants" for the purpose of 180-day exclusivity; "first applicants" are defined as "an applicant that, on the first day on which a substantially complete application containing [a Paragraph IV Certification] is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [Paragraph IV Certification] for the drug"; thus, the ANDAs at issue must be treated as having been submitted on the first day on which the

first possible ANDA containing a Paragraph IV Certification could have been submitted (which, by necessity, must have been after the patent was Orange Book-listed).

139. Once again, FDA dismissed Medicis's argument. Under the MMA, 180-day exclusivity is not limited to the situation in which an ANDA contains a Paragraph IV certification to a listed patent on the date the ANDA is originally submitted to FDA. To the contrary, an ANDA that is originally submitted without a Paragraph IV certification to a listed patent, but is then amended to contain a Paragraph IV certification to a listed patent, is also eligible for 180-day exclusivity. Although the QI Act effectively treats the applicants' amendments containing Paragraph IV certifications as having been submitted on the first day on which any ANDA applicant submitted a substantially complete application that contains a Paragraph IV certification to a patent for the listed drug, the QI Act in no way recalculates the date on which the applicant originally submitted its ANDA.

140. For its third baseless argument, Medicis asserted that the patent at issue should be treated as having been submitted to FDA with the original NDA—i.e., before the generic Solodyn ANDAs. Medicis relied on QI Act transitional provision 4(b)(1) which states that patent information "required to be filed with [FDA] under subsection (b)(1) or (c)(2)" of section 505 of the FDCA must be filed within 60 days after enactment of the QI Act. Medicis argued that because those subsections of FDCA Section 505 require the patent information to be filed at the time of NDA filing, the date of its patent information submission must necessarily be moved back to the date of NDA filing, even though its NDA had been submitted years before. FDA rejected Medicis's "tortured" and "strained" reading. The QI Act's reference to Section 505 was merely to the type of information that needed to be submitted. Medicis clearly understood the reasonable (i.e., the FDA's, not Medicis's) interpretation of this language since Medicis itself

submitted the type of patent information specified within the time frame specified by this section of the QI Act.

141. Medicis's 30-Month Stay Petition was baseless and a sham, made and timed solely as an improper attempt to delay FDA approval of the generic Solodyn ANDAs. As noted above, Medicis's CEO had stated publicly that Medicis would file citizen petitions as part of a campaign to delay entry by generic rivals. And even though Medicis was ultimately unsuccessful in having the FDA stay approval of the generic Solodyn ANDAs for 30 months, Medicis's mere filing of the petition, regardless of its merits, delayed the FDA's ANDA approval process. As a matter of pattern and practice, the FDA does not approve an ANDA if a pertinent petition—even a baseless one—is pending.

142. Medicis's 30-Month Stay Petition did, in fact, delay at least Teva's generic Solodyn ANDA. FDA approved Teva's generic Solodyn ANDA on March 17, 2009, the same day it denied Medicis's 30-Month Stay Petition. But for Medicis's second sham citizen petition, Teva would have received final approval to launch its generic Solodyn products in 45mg, 90mg, and 135mg strengths before March 17, 2009.

143. It was essential to Medicis to stave off generic competition until November 2011, to give it time to switch the market to new versions of Solodyn for which there were no approved generic equivalents (this aspect of Medicis's scheme is discussed further below). But as of January 2009, Teva, Sandoz, and Mylan had filed ANDAs for the 45mg, 90mg, and 135mg strengths of Solodyn, and Medicis expected that FDA would grant approval of those ANDAs as early as spring 2009. Medicis knew that FDA was likely to reject Medicis's 30-Month Stay Petition that spring. So Medicis implemented another tactic to delay and limit generic competition from those manufacturers until November 2011.

144. Medicis's plan was straightforward. Under Hatch-Waxman, Teva, Sandoz, and Mylan were entitled to shared 180-day exclusivity. But if all three generic manufacturers entered the market at once, competition among them would quickly drive the price of generic Solodyn far below the price of branded Solodyn—likely to a discount of 85% or more off the price of branded Solodyn. Moreover, if such generic entry occurred, Medicis would be likely to launch its own authorized generic product, eroding generic prices even further. Entry of multiple generics, and the consequent low prices, would of course be a boon for consumers, but it would significantly reduce the generics' profits below those available if there were only one generic on the market. In light of these competitive dynamics, which are well known in the pharmaceutical industry, Medicis devised a plan that would give the generic manufacturers more profit than they could have achieved had they competed against each other, and at the same time secure higher profits for itself by robbing purchasers of competition to which they are entitled.

145. Under the guise of a litigation settlement with Teva, Medicis arranged for Teva to sell an approximate 6-month supply (for the entire market) of generic Solodyn free from competition from Sandoz or Mylan, and free from competition from a Medicis authorized generic. After almost all the 6-month supply of the Teva product had been sold through to consumers, Medicis then arranged for Sandoz to sell a similarly limited supply of generic Solodyn free from competition from Teva or Mylan, and again free from competition from a Medicis authorized generic. Then after all the Sandoz product had been sold through to consumers, Medicis arranged for Mylan to sell an approximate 6-month supply of generic Solodyn free from competition from Teva or Sandoz, and again free from competition from a Medicis authorized generic. Organizing these *seriatim* periods of *de facto* exclusivity for each of the would-be generic competitors— periods in which the generic manufacturers did not compete

against each other or against a Medicis authorized generic—was Medicis's way of paying the generics to delay unrestrained generic competition until November 2011. The *seriatim* periods of generic exclusivity delivered more profits to each of the generic manufacturers than if two or more of them were in the market at the same time. Medicis preserved most of its monopoly profits, and the generics made far more profits than competition would have allowed them. The only losers were consumers.

146. Below are the details of how Medicis acted as the ringleader of the elimination of competition among the generic manufacturers in exchange for their agreement to defer unrestrained competition until November 2011.

147. As noted above, on January 13, 2009, Medicis filed suit against Teva, along with Mylan and Sandoz, in the United States District Court for the District of Delaware, No. 1:09-CV-00033-LPS, alleging that Teva infringed the '838 Patent by submitting to FDA the ANDA for 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets.

148. On February 9, 2009, Teva answered the complaint, asserting that the '838 Patent is invalid and would not be infringed by its generic Solodyn products, and that Medicis improperly obtained the '838 Patent through inequitable conduct. Teva asserted that Medicis had deliberately omitted all mention of its product, Dynacin, and its own Dynacin Study, during prosecution of the '838 Patent before the PTO.

149. On March 17, 2009, FDA granted Teva final approval to market its generic 45mg, 90mg, and 135mg Solodyn products. Teva commenced shipment of its product immediately after the FDA's approval of the ANDA.

150. On or before March 17, 2009, Medicis and Teva entered an agreement, which they subsequently memorialized in part in a written agreement dated March 18, 2009. At the

time of the agreement, neither the parties nor the court had addressed the substantive merits of the suit beyond the initial complaint and answer.

151. Pursuant to the Medicis/Teva Agreement, Teva agreed to: (a) admit that the '838 Patent, plus the non-issued claims of twelve pending patent applications, are valid and enforceable; (b) admit that the '838 Patent is infringed by Teva's generic Solodyn products; (b) initially sell only a 6-month supply of its generic Solodyn products; and (d) thereafter delay unrestrained entry of its generic Solodyn products until November 2011, or earlier under certain circumstances.

152. As the *quid pro quo* for Teva's agreement to drop its challenge to the '838 Patent and thereafter delay unrestrained entry of its generic Solodyn products until November 2011, Medicis agreed to: (a) grant a license to Teva to sell a 6-month supply of its generic Solodyn products beginning on March 17, 2009; (b) agree not to grant a similar license to any other generic manufacturer during the period that Teva was negotiating with its buyers regarding the price and quantity terms for the sale of the limited quantity of its generic Solodyn products; and (c) agree not to compete against Teva during this period with Medicis's own authorized generic Solodyn. The intended result of the Agreement was that Teva would have the only generic Solodyn product on the market, and that buyers would know, when negotiating with Teva, that it would have the only generic Solodyn on the market during that time. The Agreement worked as planned, with Teva selling all of the 6-month supply at a price only slightly less than the branded price.

153. Teva has acknowledged in SEC filings that its "revenues and profits are closely tied to our ability to obtain U.S. market exclusivity for generic versions of significant products." 2009 20-F. To the extent that Teva succeeds "in being the first to market a generic version of a

significant product . . . [its] sales, profits and profitability can be substantially increased in the period following the introduction of such product and prior to a competitor's introduction of an equivalent product." Teva reported that its launch of generic Solodyn was one of those "products launched with U.S. market exclusivity, or with otherwise limited competition" which contributed to Teva's 2009 operating results.

154. The purpose and effect of Medicis's payment to Teva was to delay unrestrained generic competition to Solodyn until November 2011 (or earlier under certain circumstances). Absent Teva's agreement to delay unrestrained entry into the market with generic Solodyn, Medicis would not have (a) agreed to refrain from granting a similar license to any other generic manufacturer during the period that Teva was negotiating price and quantity terms for the sale of the limited quantity of its generic Solodyn products; (b) agreed not to compete against Teva during this period with Medicis's own authorized generic; and/or (c) agreed to the terms that it did. Medicis paid Teva to delay unrestrained market entry of generic Solodyn.

155. Medicis then repeated this same ploy with Sandoz.

156. As mentioned above, Medicis had sued Sandoz on January 13, 2009, along with Teva and Mylan, in the United States District Court for the District of Delaware, No. 1:09-CV-00033-LPS, alleging that Sandoz infringed the '838 Patent by submitting to FDA the ANDA for 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets.

157. On February 27, 2009, Sandoz answered the complaint and asserted a counterclaim seeking a declaratory judgment that the '838 Patent is invalid and would not be infringed by its generic Solodyn products.

158. On August 13, 2009, FDA granted Sandoz final approval to market its generic 45mg, 90mg, and 135mg Solodyn products. Sandoz could have received final FDA approval earlier if it had wanted such earlier approval.

159. On or before August 17, 2009, Medicis and Sandoz entered into the Medicis/Sandoz Exclusion Payment Agreement, which they subsequently memorialized in part in a written agreement dated August 18, 2009. At the time of the Medicis/Sandoz Exclusion Payment Agreement, the parties had not briefed and the court had not adjudicated the substantive merits of the suit.

160. Pursuant to that Agreement, Sandoz agreed to: (a) admit that the '838 Patent is valid and enforceable; (b) admit that the '838 Patent was infringed by Sandoz; (b) initially sell only a limited supply of its generic Solodyn products; and (d) thereafter delay unrestrained entry of its generic Solodyn products until November 2011, or earlier under certain circumstances.

161. As the *quid pro quo* for Sandoz's agreement to drop its challenge to the '838 Patent and thereafter delay entry of its generic Solodyn products until November 2011, Medicis agreed to make substantial payments to Sandoz. The payments took the form of Medicis: (a) granting a license to Sandoz to sell a limited supply of its generic Solodyn products beginning on August 17, 2009; (b) agreeing not to grant a similar license to any other generic manufacturer during the period that Sandoz was negotiating with its buyers regarding the price and quantity terms for the sale of the limited quantity of its generic Solodyn products; (c) agreeing not to compete against Sandoz during this period with Medicis's own authorized generic Solodyn; and (d) agreeing to make substantial payments to Sandoz pursuant to a "business partnership agreement" and "APA Agreement." The intended result of the Agreement was that Sandoz would have the only generic Solodyn product on the market, and that buyers would know, when

negotiating with Sandoz, that it would have the only generic Solodyn on the market during that time. The Agreement worked as planned, with Sandoz selling all of the limited supply at a price only slightly less than the branded price.

162. The purpose and effect of Medicis's payment to Sandoz was to delay unrestrained generic competition to Solodyn until November 2011 (or earlier under certain circumstances). Absent Sandoz's agreement to delay unrestrained entry into the market with generic Solodyn, Medicis would not have: (a) agreed to refrain from granting a similar license to any other generic manufacturer during the period that Sandoz was negotiating price and quantity terms for the sale of the limited quantity of its generic Solodyn products; (b) agreed not to compete against Sandoz during this period with Medicis's own authorized generic; (c) agreed to make substantial payments to Sandoz pursuant to a "business partnership agreement" and "APA Agreement;" and/or (d) agreed to the terms that it did. Medicis paid Sandoz to delay unrestrained market entry of generic Solodyn.

163. Medicis then repeated this same ploy yet again with Mylan.

164. As mentioned above, Medicis had sued Mylan on January 13, 2009, along with Teva and Sandoz, in the United States District Court for the District of Delaware, No. 1:09-CV-00033-LPS, alleging that Mylan infringed the '838 Patent by submitting to FDA the ANDA for 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets.

165. On February 3, 2009, Mylan answered the complaint and asserted a counterclaim seeking a declaratory judgment that the '838 Patent is invalid and would not be infringed by its generic Solodyn products.

166. On March 11, 2010, the USPTO issued a Notice of Intent to Issue a Reexamination Certificate stating that the USPTO had closed the reexamination proceedings and

intended to issue a Reexamination Certificate as to claims 3, 4, 12 and 13 (which had been amended by Medicis during the reexamination proceedings), and new claims 19-34.

167. On May 7, 2010, Medicis received a Paragraph IV certification from Mylan stating that its subsidiary Matrix Laboratories Limited had filed an ANDA, Number 20-1467, for generic Solodyn in 65mg and 115mg strengths. In this Paragraph IV certification, Mylan alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Mylan's generic product.

168. The USPTO issued the Ex Parte Reexamination Certificate on June 1, 2010.

169. On June 14, 2010, Medicis filed suit against Mylan and Matrix in the United States District Court for the District of Delaware, No. 1:10-cv-00524-JJF-LPS, alleging that Defendants infringed the '838 Patent by submitting their ANDAs for 45mg, 90mg, and 135mg, and for 65mg and 115mg generic minocycline hydrochloride extended release tablets, respectively.

170. On July 7, 2010, Medicis and Mylan submitted a stipulated motion to extend time for Mylan to answer Medicis's second complaint against it, in case 1:10-cv-00534-LPS, and to answer an amended complaint in the first case against it, case 1:09-cv-00033, until August 16, 2010.

171. On July 8, 2010, Medicis filed an amended complaint for patent infringement in case 1:09-cv-00033-LPS against Mylan, alleging that through the filing of its ANDA 90-911 Mylan infringed certain claims of the '838 Patent as set forth in the June 1, 2010 Reexamination Certificate.

172. On July 20, 2010, FDA granted Mylan final approval to market its generic 45mg, 90mg, and 135mg Solodyn products.

173. On or before July 21, 2010, Medicis and Mylan entered into an agreement, which they subsequently memorialized in part in a written agreement dated July 22, 2010. At the time of the Medicis/Mylan agreement, the court had not issued any substantive decisions regarding the merits of Medicis's claims or Mylan's counterclaims.

174. Pursuant to that agreement, Mylan agreed to: (a) admit that the '838 Patent is valid and enforceable; (b) admit that the '838 Patent is infringed by the products described in Mylan's ANDA 90-911 and ANDA 20-1467; (c) initially sell only a limited supply of its 45mg, 90mg, and 135mg generic Solodyn products; (d) thereafter delay unrestrained entry of those generic Solodyn products until November 2011, or earlier under certain circumstances; and (d) delay launching its generic Solodyn products in 65mg and 115mg strengths until certain undisclosed circumstances occurred at some point in the future.

175. As the *quid pro quo* for Mylan's agreement to drop its challenge to the '838 Patent and thereafter delay entry of its generic Solodyn products until November 2011, Medicis agreed to: (a) grant a license to Mylan to sell a 6-month supply of its generic Solodyn products beginning on July 22, 2010; (b) agree not to grant a similar license to any other generic manufacturer during the period that Mylan was negotiating with its buyers regarding the price and quantity terms for the sale of the limited quantity of its generic Solodyn products; and (c) agree not to compete against Mylan during this period with Medicis's own authorized generic. The intended result of the Agreement was that Mylan would have the only generic Solodyn product on the market, and that buyers would know, when negotiating with Mylan, that it would have the only generic Solodyn on the market during that time. The Agreement worked as planned, with Mylan selling all of the 6-month supply at a price only slightly less than the branded price.

176. The purpose and effect of Medicis's payment to Mylan was to delay unrestrained generic competition to Solodyn in 45mg, 90mg, and 135mg strengths until November 2011 (or earlier under certain circumstances) and to delay generic competition to Solodyn in 65mg and 115mg strengths. Absent Mylan's agreement to delay entry into the market with generic Solodyn, Medicis would not have: (a) agreed to refrain from granting a similar license to any other generic manufacturer during the period that Mylan was negotiating price and quantity terms for the sale of the limited quantity of its generic Solodyn products; (b) agreed not to compete against Mylan during this period with Medicis's own authorized generic Solodyn; and/or (c) agreed to the terms that it did. Medicis paid Mylan to delay unrestrained market entry of generic Solodyn.

177. Under the Medicis/Impax Exclusion Payment Agreement, Medicis agreed not to grant a license to any other generic pharmaceutical manufacturer to sell generic Solodyn product in 45mg, 90mg, and/or 135mg strengths before Impax. If Medicis authorized another generic manufacturer to sell such generic Solodyn products before Impax's licensed entry date of November 2011, Impax had the right to be notified and immediately launch its product.

178. Shortly after Teva launched its generic Solodyn products, Impax filed suit on May 19, 2009 against Medicis in the Superior Court of the State of Arizona in and for the County of Maricopa alleging that Medicis authorized Teva's launch of its generic Solodyn products and that such launch triggered Impax's right to enter the market before November 2011 under the Medicis/Impax Exclusion Payment Agreement. Medicis settled the case by paying Impax substantial consideration, and on June 24, 2009, Impax and Medicis submitted a stipulation for dismissal of Impax's suit with prejudice, which was entered by the court on July 1, 2009.

179. On July 27, 2010, just days after Medicis authorized the third generic manufacturer (Mylan) to sell a limited supply of its generic Solodyn products, Impax again filed

suit against Medicis in the Superior Court of the State of Arizona in and for the County of Maricopa alleging that Medicis's authorization of these additional generic Solodyn products had triggered Impax's right to enter the market before November 2011 under the Medicis/Impax Exclusion Payment Agreement. After Medicis asserted counterclaims against Impax and each party moved to dismiss the other's claims—but before the court reached any substantive decision on the merits—Medicis and Impax entered a January 21, 2011 settlement of the second Arizona state court action. As in the prior settlement, Medicis again paid substantial consideration to Impax in order to end the litigation.

180. Through the various anticompetitive tactics described above, which successfully delayed the onset of unrestrained generic competition to the 45mg, 90mg, and 135mg Solodyn tablets until November 2011, Medicis literally bought itself time to execute another part of its "three-part strategy" to defeat generic competition. Medicis bought time to eliminate the market for Solodyn in 45mg, 90mg, and 135mg (i.e., "legacy" strengths) and shift that demand to Solodyn in 55mg, 65mg, 80mg, 105mg, and 115mg strengths (i.e., "new" strengths) that did not face imminent generic competition.

181. Delaying generic competition to the original 45mg, 90mg and 135mg strengths was critical to Medicis's "product hopping" scheme. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the follow-on product will make very few sales unless it offers substantial, demonstrable medical benefits to consumers because consumers are unlikely to switch from a generic to a brand.

182. It was also known in the pharmaceutical industry that Medicis in particular needed to switch the market to the new strengths sufficiently in advance of anticipated generic

competition in November 2011–and that Medicis's Exclusion Payment Agreements had bought Medicis the time it needed to do just that. An October 8, 2010 Morningstar report, for example, stated:

> Medicis has managed to fend off generic Solodyn competition until late 2011, thanks to several deals with Teva, Sandoz (a unit of Novartis), Mylan, and Impax. By paying the generic companies to delay competition, Medicis has lengthened the runway for Solodyn. The firm may have bought enough time to get its follow-on product to Solodyn approved and launched. If Medicis can transition current Solodyn users to the next-generation product, then the picture could be more optimistic for Solodyn than we had assumed earlier.

183. Thus, knowing that the 45mg, 90mg, and 135mg strengths would soon face generic competition, Medicis worked to switch the market to new strengths—starting with the 65mg and 115mg strengths, then followed by the 55mg, 80mg, and 105mg strengths. To this end, on February 29, 2008, Medicis submitted a supplemental NDA No. 50-808/S-007 to the FDA seeking approval to market Solodyn in the 65 mg and 115 mg strengths. On July 23, 2009, the FDA approved Medicis's application. In August 2010, the FDA also approved a supplemental NDA No. 50-808/S-013 revising the Solodyn label to include the 55mg, 80mg, and 105mg strengths.

184. The only benefit of the new strengths was to Medicis. Because the expected generic Solodyn products in legacy strengths would not be AB-rated to branded Solodyn in the new strengths, pharmacists could not substitute less-expensive generic Solodyn in one of the legacy strengths when presented with a prescription for Solodyn in one of the new strengths. Such automatic substitution of less-expensive AB-rated generics at the pharmacy counter is the means by which generic competition reduces drug prices. Disrupting this competitive mechanism was Medicis's sole reason for introducing the new Solodyn strengths.

185. But merely introducing the new dose strengths was not enough to ensure Medicis's stranglehold on the market for minocycline hydrochloride extended release tablets. In addition, Medicis aggressively destroyed demand for Solodyn legacy strengths and then converted that demand to the new Solodyn strengths using its army of detailers. By August 2010, the new 65 mg and 115 mg strengths accounted for 61.5% of new Solodyn prescriptions and 58.5% of total prescriptions. By May 2011, Medicis announced that "92% of the total prescriptions in SOLODYN, moved over to the five new strengths, and 95% of new prescriptions are being written in the new strengths."

186. And then, in July 2011, shortly before legacy generics were scheduled to enter the market, Medicis stopped shipping branded Solodyn in legacy strengths altogether. In an August 8, 2011 earnings call, Medicis's CEO Shacknai explained the "new SOLODYN strategy, which [Medicis] believe[d] [would] be advantageous for the SOLODYN franchise in 2011 and beyond." Medicis's purpose in withdrawing the legacy strengths from the market was to "deplete channel inventory of branded and generic versions of the legacy strengths months ahead of the November 26 date upon which five generic companies could launch generic competitors only to these legacy strengths of SOLODYN." Shacknai continued to describe how the launch of the new strengths and market withdrawal of the legacy strengths would "have the effect of reducing the impact significantly of generic launches at the end of November 2011."

187. Medicis's conduct in draining the legacy strengths of Solodyn from the distribution channel before generic entry had an anticompetitive purpose and effect. As a result of Medicis's draining, there was little or no legacy strength Solodyn available in the marketplace from May 2011 through November 2011, when Impax, Teva, Sandoz, and Mylan entered. As explained above, Medicis took steps to make sure that physicians stopped writing prescriptions

for Solodyn in legacy strengths and started writing prescriptions for Solodyn in the new strengths instead. To the extent a physician nevertheless wrote a prescription for legacy strength Solodyn, Medicis's draining of the distribution channel ensured that there would be no legacy strength Solodyn available at the pharmacy to fill such a prescription. As a matter of good pharmacy practice and continuity of patient care, a pharmacist receiving a prescription for legacy strength Solodyn during this time would call the prescribing physician to switch the prescription to the next closest available product, namely Solodyn in one of the new strengths.

188. In shifting demand to the new Solodyn strengths, Medicis knew that these strengths offered no medical, convenience, or other benefits to consumers as compared to the legacy strengths. The recommended dosage of Solodyn is approximately 1mg/kg (that is, 1 mg per 1 kg of body mass) taken once daily for twelve weeks. Dosing is thus approximately weight-based; clinical studies demonstrated that higher doses are no more effective, and may result in more adverse effects. When Medicis originally obtained approval for Solodyn, it did so by demonstrating the safety and effectiveness of the 45mg, 90mg, and 135mg strengths based on an approximate dose of 1mg/kg.

189. The new Solodyn strengths are no more effective and no safer than Solodyn in legacy strengths. The only benefit that Medicis ascribes to the new strengths is "complement[ing] the current SOLODYN lineup to offer physicians greater weight-based dosing precision of SOLODYN, mak[ing] SOLODYN the first and only extended release minocycline with eight FDA-approved dosing strengths." This purported "benefit," however, is pure pretext, belied by Medicis's own representations and actions.

190. Particularly telling is Medicis's opposition to a May 9, 2011 Suitability Petition filed by Lachman Consultant Services, Inc. on behalf of a generic manufacturer that wanted to

file an ANDA referencing Medicis's Solodyn NDA for different strengths (70mg and 95mg) than those the FDA had previously approved for the drug. The generic manufacturer proposed to recommend the 70mg and 95mg tablets for patients in two new weight classes, which would arguably create even greater weight-based dosing precision.

191. The FDA-approved labeling for Solodyn, which reflected all eight approved Solodyn dose strengths, contained the following dosing chart:

Patient's Weight (lbs.)	Patient's Weight (kg)	Tablet Strength (mg)	Actual mg/kg Dose
99 – 109	45 – 49	45	1 – 0.92
110 – 131	50 – 59	55	1.10 – 0.93
132 – 157	60 – 71	65	1.08 – 0.92
158 – 186	72 – 84	80	1.11 – 0.95
187 – 212	85 – 96	90	1.06 – 0.94
213 – 243	97 – 110	105	1.08 – 0.95
244 – 276	111 – 125	115	1.04 – 0.92
277 – 300	126 – 136	135	1.07 – 0.99

192. The Lachman petition recommended the following dosing guidelines to account for the two new weight classes associated with the 70mg and 95mg doses:

Patient's Weight (lbs.)	Patient's Weight (kg)	Tablet Strength (mg)	Actual mg/kg Dose
99 – 109	45 – 49	45	1 – 0.92
110 – 131	50 – 59	55	1.10 – 0.93
132 – 142	60 – 64	65	1.08 – 1.02
143 – 157	65 – 71	70	1.08 – 0.99
158 – 186	72 – 84	80	1.11 – 0.95
187 – 199	85 – 90	90	1.06 – 1
200 – 212	91 – 96	95	1.04 – 0.99
213 – 243	97 – 110	105	1.08 – 0.95
244 – 276	111 – 125	115	1.04 – 0.92
277 – 300	126 – 136	135	1.07 – 0.99

193. Medicis opposed the Lachman petition, arguing to the FDA that the new strengths were no safer or more effective than the currently available strengths – even though the creation of two new weight classes around the 70mg and 95mg doses arguably created even more precise

dosing around the recommended approximate 1mg/kg dose. Specifically, Medicis argued that recommending a 70mg dose for patients who were previously recommended to take the 65mg dose, an "otherwise equivalent" product, improperly risked doctor confusion as to safety and effectiveness, notwithstanding the arguable creation of more precise dosing, stating:

> The agency may find, for example, that singling out for higher doses patients weighing 143-157 and 200-212 lbs. – when an otherwise equivalent product (Solodyn) is currently available in lower doses – may confuse healthcare providers and patients. For example, if a patient weighing 143 lbs., who has consistently taken a 65 mg Solodyn tablet, is now guided by a generic product's labeling to take a 70 mg tablet, healthcare providers and patients may incorrectly believe that the change is based on postmarketing studies or other clinical evidence. They may also incorrectly conclude that FDA's approved 65 mg Solodyn tablet is somehow less safe or effective for a patient weighing 143 lbs. The risk of such potential confusion is unwarranted.

(Medicis's Aug. 24, 2011 Suitability Petition Response at 5). In other words, it was of no importance to Medicis that a patient weighing 157 pounds, for example, would be getting 0.99 mg/kg if given a 70mg tablet—almost exactly the approximate 1mg/kg recommended dose—compared to the 0.92 mg/kg he or she would receive if given a 65mg; the doses were "equivalent." After the FDA granted the suitability petition, Medicis sought reconsideration and a stay of that action, characterizing the enhanced dosing precision created by the two new doses as providing "marginal benefit, if any" (Medicis March 7, 2013 Petition for Reconsideration and Stay of Action at 5).

194. Moreover, if Medicis were truly concerned with offering physicians greater weight-based dosing precision, it would not have stopped selling Solodyn in three of the eight approved strengths (a fact Medicis omitted from its Suitability Petition response). Without the 45mg, 90mg, and 135mg dose strengths on the market, the FDA-approved Solodyn labeling offers no guidance to doctors as to which dose strength should be prescribed for patients

weighing 99-109 pounds (recommended 45mg dose), 187-212 pounds (recommended 90mg dose) or 277-300 pounds (recommended 135mg dose).

195. Medicis publicly derided such lack of guidance in the product's labeling in its opposition to Lachman's suitability petition. Medicis argued, inter alia, that the "safe and effective use of the 70 and 95 mg strengths cannot be ensured" because the FDA-approved Sololdyn label instructed patients to take different tablet strengths than those proposed by the Lachman petition. Thus, under Medicis's own reasoning, the safe and effective use of Solodyn can no longer be ensured for patients in the 99-109, 187-212, or 277-300 pound ranges, who are recommended in the approved Solodyn label to take the discontinued 45mg, 90mg, and 135mg doses, respectively.

196. If the new Solodyn strengths were truly superior in that they provided physicians with greater weight-based dosing options, Medicis would have developed and marketed the new strengths sooner than it did and it would not have withdrawn the legacy strengths. Medicis's delay in developing and marketing the new Solodyn strengths, and its decision to stop shipping the legacy strengths and to shift the market to the new strengths before the onset of generic competition, confirm that Medicis developed and marketed the new Solodyn strengths not because they were superior to legacy strengths, but because they advanced Medicis's overall strategy to impair generic competition and thereby protect and expand its monopoly profits.

197. Medicis's predatory product change was intended to harm, and had the effect of harming, generic competition. Medicis did not expect the new dose strengths to garner any additional sales or revenues (except by impairing generic competition), lower its costs, or increase its efficiency. Indeed, Medicis recognized publicly that the new strengths would not result in any "incremental revenue" associated with increased sales over and above sales of the

legacy strengths (Medicis Q4 2007 Earnings Call). In fact, Medicis fully expected that, but for the effect of impairing generic competition, launching Solodyn in the new strengths would cause Medicis to lose sales and revenues, increase its costs, and decrease its efficiency. And that is indeed what happened. Medicis filed an 8-K on August 8, 2011 reflecting a revised 2011 guidance that was adjusted to reflect the "decrease in sales and profitability associated with the Legacy Strengths. The average selling price for the Legacy Strengths is approximately $200 higher than that of the current strengths." Similarly, a Medicis press release dated February 27, 2012 stated that its revenues for the three months ended December 31, 2011 decreased by approximately $17.0 million, or approximately 14.3%, compared to the same three-month period for the previous year. For the twelve months ended December 31, 2011, Medicis's revenues decreased by approximately $34.8 million, or approximately 7.2%, compared to 2010. Medicis attributed these decreases to, *inter alia*, "the Company's decision to stop shipment of the Legacy Strengths of SOLODYN to wholesalers."

198. Medicis cannot justify its scheme by pointing to any offsetting consumer benefit. The higher prices and corresponding anticompetitive harm caused by suppressing generic competition to Solodyn far outweigh any cognizable, non-pretextual procompetitive justifications Medicis could possibly offer. And, whatever justifications Medicis may offer, it did not need to engage in the conduct challenged in this lawsuit to achieve them.

199. As a result of Defendant's unlawful conduct, by the time generic Solodyn became available in November 2011, the prescription base for the legacy strengths was virtually non-existent. But for this predatory product change, together with Medicis's unlawful exclusion payment agreements and other anticompetitive conduct, generic Solodyn would have been

available in the market long before November 2011 and Medicis would not have launched the new Solodyn strengths or, if it had, it would have made far fewer sales of them.

200. Having bought time until November 2011 to switch the market to the new dosage strengths, Medicis next took steps to delay and suppress competition to those strengths.

201. After Medicis's predatory product change and switch strategy, the 65mg and 115mg dose strengths comprised approximately three quarters of Solodyn sales. Medicis needed to protect these Solodyn sales from generic competitors in order to retain the bulk of its supracompetitive Solodyn profits.

202. Knowing that Medicis's Solodyn Patents were weak, generic manufacturers lined up to get FDA approval to market generic versions of the new strengths. To continue to reap the benefits of anticompetitive scheme, Medicis needed to delay and impair this new competitive threat.

203. Medicis impaired that competition through a two-part strategy: (1) Medicis paid Teva, the first-filer with respect to the 65mg and 115mg strengths, to drop its challenge to the patents, delay entry, and "park" its 180-day exclusivity; and (2) Medicis paid the later-filing generic manufacturers, Ranbaxy, Mylan, and Lupin, not to unplug the bottleneck that Medicis and Teva created.

204. On November 20, 2009, Medicis received a Paragraph IV certification indicating that Teva had filed a supplement to its ANDA No. 65-485, seeking permission to market generic Solodyn in 65mg and 115mg strengths. In its Paragraph IV certification, Teva alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Teva's generic product.

205. Teva was the first generic manufacturer to file a substantially complete ANDA with respect to the 65mg and 115mg strengths. As the first filer, Teva was potentially entitled to

180-day exclusivity on the generic 65mg and 115mg strengths, provided it met the other statutory criteria and a forfeiture event did not occur.

206. On December 28, 2009, Medicis filed another sham suit against Teva in the United States District Court for the District of Maryland, No. 1:09-cv-03464, alleging that Teva infringed one or more claims of Medicis's invalid and/or unenforceable '838 Patent by submitting the ANDA.

207. On March 5, 2010, Teva answered the complaint, asserting defenses of noninfringement, invalidity, and unenforceability due to inequitable conduct before the USPTO and unclean hands.

208. On July 9, 2010, Medicis filed an amended complaint, alleging that Teva infringed the '838 Patent as amended pursuant to the June 1, 2010 Ex parte Reexamation Certificate.

209. On August 9, 2010, Teva answered the amended complaint, asserting defenses of non-infringement, invalidity, and unenforceability due to inequitable conduct before the PTO and unclean hands.

210. On September 7, 2010, the PTO issued the '705 Patent, which was later assigned to Medicis. The FDA listed the '705 Patent in the Orange Book for Solodyn in 45mg, 65mg, 90mg 115mg, and 135mg strengths.

211. On October 18, 2010, Medicis filed a second amended complaint, alleging that Teva infringed one or more claims of the '838 Patent and '705 Patent by its ANDA supplement for 65mg and 115mg generic Solodyn.

212. On November 28, 2010, Teva answered the second amended complaint, asserting defenses of non-infringement, invalidity, and unenforceability due to inequitable conduct before

the USPTO and unclean hands with respect to the '838 Patent and defenses of non-infringement and invalidity with respect to the '705 Patent.

213. On or about February 25, 2011, Medicis and Teva entered into a second Medicis/Teva agreement. At the time of the agreement, neither the parties nor the court had addressed the substantive merits of the suit beyond the complaints and answers.

214. Pursuant to that agreement, Teva agreed to: (a) admit that the '838 Patent and '705 Patent are valid and enforceable; (b) admit that the '838 Patent and '705 Patent are infringed by Teva's generic Solodyn 65mg and 115mg products; and (c) delay entry of generic 65mg and 115mg Solodyn products until February 2018, or earlier under certain circumstances.

215. As the *quid pro quo* for Teva's agreement to drop its challenge to the '838 Patent and '705 Patent and thereafter delay entry of its generic 65mg and 115mg Solodyn products until February 2018, Medicis agreed: (a) to block other generic manufacturers from entering the market with 65mg or 115mg Solodyn products until 180 days after Teva's scheduled entry in February 2018; and (b) not to compete against Teva with Medicis's own authorized generic 65mg or 115mg Solodyn products. The intended result of the agreement was that Teva would have *de facto* 180-day exclusivity for the generic 65mg and 115mg products regardless of whether it was statutorily entitled to such exclusivity (unless later-filing generics won their patent litigations against Medicis), and that there would be no competition between Teva's products and Medicis's own authorized generic 65mg and 115mg products during the 180 days of exclusivity and beyond.

216. The purpose and effect of Medicis's agreement with Teva was to delay generic competition to Solodyn 65mg and 115mg until February 2018 (or earlier under certain circumstances). Absent Teva's agreement to delay entry into the market with generic 65mg and

115mg Solodyn, Medicis would not have: (a) agreed to refrain from granting a license to any other generic manufacturer to enter the market before Teva's scheduled entry in February 2018; (b) agreed not to compete against Teva with Medicis's own authorized generic 65mg and 115 Solodyn; and/or (c) agreed to the terms that it did. Medicis paid Teva to delay market entry of generic 65mg and 115mg Solodyn.

217. The second Medicis/Teva agreement created a bottleneck that impaired later-filing generics' ability to get their 65mg and 115mg products onto the market. Medicis also ensured that none of those later filers would dislodge the bottleneck.

218. Medicis filed a sham suit against Ranbaxy, Inc. and related entities ("Ranbaxy") on June 11, 2009 in the United States District Court for the District of Delaware, No. 1:09-CV-00435-JJF, alleging that Ranbaxy infringed one or more claims of Medicis's invalid and/or unenforceable '838 Patent by submitting to FDA its ANDA for 135mg Solodyn.

219. On July 1, 2009, Ranbaxy answered the complaint, asserting that the '838 Patent was invalid and would not be infringed by Ranbaxy's generic Solodyn product, and that Medicis's claims were barred by the doctrine of unclean hands and patent misuse. Ranbaxy asserted that Medicis had deliberately omitted all mention of its product, Dynacin, and its own Dynacin Study, during prosecution of the '838 Patent before USPTO. Further, Ranbaxy asserted a counterclaim against Medicis seeking a declaratory judgment that the '838 Patent was invalid and unenforceable.

220. On September 24, 2009, Medicis's suit against Ranbaxy was joined with Medicis's suit against Teva, Sandoz, and Mylan in the same court, No. 1:09-vc-00033-JJF.

221. On January 5, 2010, Medicis received Ranbaxy's Paragraph IV certification stating that Ranbaxy had supplemented its ANDA to include the 45mg and 90mg strengths of Solodyn.

222. On February 16, 2010 Medicis sued Ranbaxy in the United States District Court for the District of Delaware, No. 1:10-CV-00120-JJF, alleging that Ranbaxy infringed one or more claims of Medicis's '838 Patent by submitting to FDA its supplemented ANDA for 45mg and 90mg Solodyn.

223. Ranbaxy answered Medicis's complaint on April 16, 2010.

224. On April 15, 2010, Medicis received Ranbaxy's Paragraph IV certification stating that Ranbaxy had supplemented its ANDA to include the 65mg and 115mg strengths of Solodyn.

225. On May 4, 2010, Medicis and Ranbaxy formally entered an agreement.

226. Pursuant to the agreement, Ranbaxy agreed to: (a) admit that the '838 Patent was valid and enforceable and covered Ranbaxy's products under ANDA 91-118; (b) be permanently enjoined from any distribution of generic versions of Solodyn except pursuant to the Agreement; (c) delay launching its generic Solodyn products in the 45mg, 90mg, and 135mg strengths until November 2011, or earlier under certain circumstances; and (d) delay launching its generic Solodyn products in the 65mg and 115mg strengths until after Teva launched its generic versions of those products.

227. As the *quid pro quo* for Ranbaxy's agreement to drop its challenge to the '838 Patent and delay entry of its 45mg, 90mg, and 135mg generic Solodyn products until November 2011 and its 65mg and 115mg products until after Teva launched its generic versions of those strengths, Medicis granted a license to Ranbaxy to make and sell a "branded proprietary

dermatology product currently under development by Ranbaxy . . . commencing on the later of August 2011 or upon the sale of such product by Ranbaxy following approval by the FDA."

228. The purpose and effect of the Medicis/Ranbaxy agreement was to: (a) delay generic competition to the 45mg, 90mg, and 135mg Solodyn strengths until November 2011 (or earlier under certain circumstances); (b) delay generic competition to the 65mg and 115mg Solodyn strengths; (c) ensure that Ranbaxy would not obtain a court decision that would trigger the start of Teva's 180-day exclusivity. Absent Ranbaxy's agreement to delay entry into the market with generic Solodyn, Medicis would not have granted Ranbaxy a license to make and sell Medicis's "branded proprietary dermatology product" that was under development by Ranbaxy, or would not have granted that license on the terms that it did. Medicis paid Ranbaxy for delayed market entry of generic Solodyn.

229. On October 8, 2009, Medicis received a Paragraph IV certification from Lupin giving notice that it had filed ANDA No. 19-424 with FDA for generic Solodyn in 45mg, 90mg, and 135mg strengths. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product.

230. On November 17, 2009, Medicis filed a sham suit against Lupin in the United States District Court for the District of Maryland, No. 1:09-cv-03062, alleging that Lupin infringed one or more claims of Medicis's invalid and/or unenforceable '838 Patent by submitting to FDA the ANDA for 45mg, 90mg, and 135mg Solodyn.

231. On March 4, 2010, Lupin answered the complaint, asserting defenses of noninfringement, invalidity, and unenforceability and alleging a counterclaim seeking a declaratory judgment that the '838 Patent would not be infringed by its generic Solodyn

products, the claims of the '838 Patent are invalid, and the '838 Patent is unenforceable due to inequitable conduct before the PTO.

232. On November 24, 2009, Medicis received a Paragraph IV certification from Lupin giving notice that it had filed an amendment and/or supplement to its ANDA Number 19-424, for 65mg generic Solodyn. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product.

233. On December 23, 2009, Medicis received a Paragraph IV certification from Lupin giving notice that it had filed an amendment and/or supplement to its ANDA Number 19-424, for 115mg generic Solodyn. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product.

234. Medicis amended its complaint to allege that Lupin's 65mg and 115mg generic products would also infringe Medicis's '838 Patent.

235. On March 4, 2010, Lupin answered the complaint, asserting defenses of noninfringement, invalidity, and unenforceability and asserting a counterclaim seeking a declaratory judgment that the '838 Patent is invalid, not infringed, and unenforceable due to inequitable conduct before the USPTO.

236. On July 1, 2010, Medicis filed its third amended complaint, alleging that Lupin infringed the '838 Patent as amended pursuant to the June 1, 2010 Ex parte Reexamination Certificate.

237. On September 7, 2010, the PTO issued the '705 Patent, which was later assigned to Medicis. The FDA listed the '705 Patent in the Orange Book for Solodyn after Medicis submitted information regarding the '705 Patent to the FDA on September 9, 2010 for Solodyn in 45mg, 65mg, 90mg 115mg, and 135mg strengths.

238. On or about September 17, 2010, Medicis received notice from Lupin stating that its ANDA and supplements were submitted with a Paragraph IV certification that the '705 Patent is not infringed.

239. On October 18, 2010, Medicis filed its fourth amended complaint, alleging that Lupin's proposed generic Solodyn products in 45mg, 65mg, 90mg, 115mg, and 135mg strengths would infringe the '838 and '705 Patents.

240. On December 3, 2010, Medicis received a Paragraph IV certification informing it that Lupin had filed an amendment and/or supplement to ANDA Number 19-424, for 55mg and 80mg generic Solodyn. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product and that the '705 Patent is not infringed.

241. On January 10, 2011, Medicis filed its fifth amended complaint, alleging that Lupin's 55mg and 80mg generic product would infringe the '838 and '705 Patents. Medicis further alleged that Lupin was the first to file an ANDA with respect to the 55 mg strength.

242. On January 24, 2011, Medicis received a Paragraph IV certification informing it that Lupin had filed an amendment and/or supplement to ANDA Number 19-424, for 105mg generic Solodyn. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product and that the '705 Patent was not infringed.

243. On March 2, 2011, Medicis filed its sixth amended complaint, alleging that Lupin's 105mg generic Solodyn product would infringe the '838 and '705 Patents.

244. On July 21, 2011, Medicis and Lupin entered into the Medicis/Lupin Exclusion Payment Agreement. At the time of the Agreement, neither the parties nor the court had addressed the substantive merits of the suit.

245. Pursuant to the Agreement, Lupin agreed to: (a) admit that the '838 and '705 patents (and certain other "patent rights" including other patents and patent applications) are valid, enforceable, and infringed by Lupin's proposed generic Solodyn products; (b) delay launching its generic Solodyn products in 45mg, 90mg, and 135mg strengths until November 26, 2011, or earlier under certain circumstances; (c) delay launching its generic Solodyn products in 65mg and 115mg strengths until February 2018, or earlier under certain circumstances; (d) delay launching its generic Solodyn products in 55mg, 80mg, and 105mg strengths until February 2019, or earlier under certain circumstances. Notwithstanding the foregoing admissions with respect to Medicis's patent rights, Lupin explicitly retained its right to maintain its Paragraph IV certification, thereby creating an FDA approval bottleneck on the 55mg strength of generic Solodyn.

246. As the *quid pro quo* for Lupin's agreement to drop its challenge to the '838 and '705 Patents and delay marketing its generic Solodyn products, Medicis agreed to pay Lupin tens of millions of dollars or more. Medicis's payments to Lupin under the Agreement took a variety of forms.

247. First, Medicis paid Lupin an "upfront fee" of $20 million under the guise of a Joint Development Agreement providing for the collaboration and development of "multiple novel therapeutic products."

248. Second, in April 2012, Medicis paid Lupin $2.5 million in connection with the parties' entering into the March 30, 2012 Amended and Restated Joint Development Agreement.

249. Third, Medicis agreed to pay Lupin up to $35.5 million in milestone payments.

250. Fourth, to the extent any products are commercialized under the Agreement, Medicis agreed to pay Lupin royalties on sales of such products.

251. Although Medicis's payments to Lupin under the Exclusion Payment Agreement are characterized as payments for the collaboration on and development of additional products, that characterization is pretextual. In fact, the payments from Medicis to Lupin were for Lupin's agreement to delay generic competition. Absent Lupin's agreement to delay entry into the market with generic Solodyn, Medicis would not have entered the Joint Development Agreement with Lupin and/or would not have agreed to the price and/or other terms that it did under those provisions of the Agreement. Medicis paid Lupin for delayed market entry of generic Solodyn.

VI. ANTICOMPETITIVE EFFECTS OF DEFENDANT'S SCHEME

252. Medicis's overarching anticompetitive scheme delayed and substantially diminished competition between branded Solodyn and generic versions of Solodyn in the United States, and unlawfully enabled Medicis to sell Solodyn at artificially inflated prices without losing substantial sales. But for Defendant's illegal conduct, generic manufacturers would have been able to enter the market unimpeded (either by entering while the patent litigation was pending, or prevailing in the patent litigation and then entering) and compete on the merits against Solodyn. Generic competitors would also have been able to compete far earlier than they did, and additional generic competitors would have entered the market earlier thereafter. Moreover, if Medicis had continued to pursue the sham litigations against the Generic Defendants, Medicis would have lost those litigations.

253. Teva, Lupin, and Mylan have all introduced generic products at risk while patent litigation was ongoing, and it was well-known within the drug industry that generic manufacturers are willing to do so. For example, Defendant Teva, has launched at-risk over

twenty times, including a September 2005 launch of a generic version of Allegra prior to resolution of the patent litigation. Defendant Lupin launched generic Fortamet at-risk on September 30, 2011. Defendant Mylan launched generic Amrix at-risk in May 2011.

254. Medicis would not have prevailed against its generic competitors in the patent litigation. In Hatch-Waxman patent litigation, generic firms have prevailed, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied. Medicis was no doubt aware that both as a general matter, and because of the particular and severe problems it faced in its patent litigation relating to Solodyn, it most likely would not be able to keep generic competitors off the market solely by using its patents (by, for example, obtaining an injunction from a court).

255. Alternatively, but for the substantial payments Medicis made to its competitors in exchange for their agreements to delay marketing generic Solodyn products, Medicis and one or more of those competitors would have agreed to an unrestrained licensed entry date significantly earlier than November 2011 for Solodyn in the legacy strengths (and, to the extent Medicis would have even marketed the new dose strengths but for Defendant's unlawful conduct, significantly earlier than February 2018 for the 65mg and 115mg strengths and February 2019 for the 55mg, 80mg, and 105mg strengths). Without the payments, which were the *quid pro quo* for the delay, and absent an at-risk launch, one or more of those competitors would have insisted on, and received, earlier, unrestrained licensed entry. According to the FTC, "the vast majority of patent settlements (greater than 70%)" are resolved "without compensation to the generic manufacturer." FTC analyses also show that in 2004 and 2005, twenty-seven out of thirty, or 90% of agreements between brand and generic manufactures settling patent disputes contained no anticompetitive payment from the brand to the generic manufacturer. Many of those twenty-

seven agreements allowed for sustained entry of a generic drug well before the date of patent expiration. Those agreements took various forms, but many agreements resulted in either: (a) split patent life whereby the generic would enter the market before the expiry of the challenged patent on a date not influenced by a payment to the generic; or (b) unrestricted generic entry immediately upon or very soon after the settlement, sometimes accompanied by a royalty payment from the generic manufacturer to the brand manufacturer. Medicis and its competitors could and likely would have entered into agreements containing such procompetitive provisions but for their entry into the exclusion agreements.

256. Defendant's conduct unlawfully prevented purchasers of Solodyn from obtaining the benefits of unimpaired generic competition. By delaying the onset of unrestrained generic competition and reducing the prescription base, Defendant deprived would-be generic versions of the most efficient means of distribution under the governing statutory and regulatory regime. But for other aspects of Medicis's anticompetitive scheme, which bought Medicis the time necessary to effectuate its unlawful switch strategy, Medicis would not have developed or marketed Solodyn in the new strengths and switched a substantial portion of sales to that product, and/or generic Solodyn in legacy strengths would have entered the market before Solodyn in the new strengths, and Medicis would have been able to switch few if any prescriptions to the new strengths.

257. Defendant's scheme and unlawful payments harmed Plaintiffs by depriving them of the benefits of generic competition. Contrary to the purpose of the Hatch-Waxman Act, the anticompetitive scheme and payments have enabled Medicis to: (a) delay the entry of less expensive generic versions of Solodyn in the United States; (b) fix, raise, maintain, or stabilize

the price of Solodyn; and (c) maintain a near-monopoly in the U.S. market for minocycline hydrochloride extended release tablets.

258. Defendant's scheme and payments to suppress generic competition to Solodyn significantly delayed the sale of generic Solodyn.

259. The generic manufacturers seeking to sell generic Solodyn have extensive experience in the pharmaceutical industry, including in obtaining approvals for ANDAs, marketing generic pharmaceutical products, manufacturing commercial quantities adequate to meet market demand, and, where appropriate, entering into arrangements with other generic manufacturers to waive or relinquish 180-day exclusivity in order to bring generic drugs to market in a timely manner.

260. As a consequence of the unlawful conduct alleged above, Plaintiffs and/or their assignors have sustained substantial losses and damage to their business and property in the form of overcharges.

VII. INTERSTATE COMMERCE

261. The drugs at issue in this case are sold in interstate commerce. Defendant's unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

VIII. MARKET POWER AND MARKET DEFINITION

262. At all relevant times, Medicis had market power with respect to extended-release minocycline hydrochloride because it had the power to raise and/or maintain the price of the drug at supracompetitive levels without losing substantial sales.

263. A small but significant, non-transitory price increase above the competitive level for Solodyn by Medicis would not have caused a significant loss of sales sufficient to make the price increase unprofitable.

264. At competitive price levels, Solodyn does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Solodyn.

265. For clinical reasons, among others, physicians and patients prefer Solodyn to other products designed to treat non-nodular severe to moderate acne.

266. The existence of other products designed to treat similar disorders has not significantly constrained Medicis's pricing of Solodyn. At all relevant times, Medicis's price for Solodyn has been substantially above its marginal cost of production, and substantially above its marginal cost including marketing costs. Medicis has never lowered the price of Solodyn in response to the pricing of other medications (or the launch of generic versions of those other medications).

267. Medicis needed to control only Solodyn and its AB-rated generic equivalents, and no other products, in order to maintain the price of Solodyn profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Solodyn would render Medicis unable to profitably maintain supracompetitive prices for Solodyn.

268. Medicis knew that entry of a generic version of Solodyn would be a uniquely significant market event. The entry of other branded drugs in the same therapeutic class (or generic versions of those other brands) did not take substantial sales from Solodyn or cause Medicis to lower its price. But Medicis was aware that entry of generic Solodyn would immediately cause branded Solodyn to lose 80 to 90% of its unit sales.

269. At all relevant times, Medicis has sold Solodyn at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

270. Medicis had, and exercised, the power to exclude and restrict competition in the market for Solodyn and its AB-rated generic equivalents.

271. Medicis, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

272. To the extent that Plaintiffs are legally required to prove market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is Solodyn and its AB-rated generic equivalents.

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

274. At all relevant times, Medicis's market share in the relevant market has been at or close to 100%, implying a substantial amount of market power.

IX. EFFECT ON COMPETITION AND INJURY TO PLAINTIFFS

275. But for the anticompetitive conduct alleged above, Solodyn would have been subject to unrestrained AB-rated generic competition earlier than November 2011(when Solodyn in actuality became subject to ineffective, non-AB-rated generic competition). Medicis would have launched an authorized generic version of Solodyn at that same time. Other generic manufacturers would have entered the market with additional generic version of Solodyn thereafter.

276. Defendant's anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Solodyn from generic competition.

277. Defendant's anticompetitive conduct, which delayed and suppressed the introduction into the United States marketplace of generic versions of Solodyn, has caused

Plaintiffs and/or their assignors to pay more than they would have paid for extended-release minocycline hydrochloride absent Defendant's illegal conduct.

278. But for Defendant's anticompetitive conduct, Plaintiffs and/or their assignors would have paid less for extended-release minocylcine by: (a) substituting purchases of less-expensive AB-rated generic Solodyn for their purchases of more-expensive branded Solodyn; and (b) purchasing generic Solodyn at lower prices sooner.

279. Plaintiffs and/or their assignors purchased substantial amounts of Solodyn. As a result of Defendant's illegal conduct as alleged herein, Plaintiffs and/or their assignors were compelled to pay, and did pay, artificially inflated prices for extended-release minocycline hydrochloride. Plaintiffs and/or their assignors paid prices for extended-release minocycline hydrochloride that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein.

280. As a consequence, Plaintiffs and/or their assignors have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial. Plaintiffs' injuries are injuries of the type the antitrust laws were designed to prevent and flow from that which makes Defendant's acts unlawful.

281. Defendant's anticompetitive scheme threatens continuing loss and injury to Plaintiffs unless enjoined by this Court.

X. CLAIMS FOR RELIEF

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

282. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 281 above as though fully set forth herein.

283. At all relevant times, Medicis possessed substantial market power (i.e., monopoly power) in the relevant market. Medicis possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

284. Through its overarching anticompetitive scheme, as alleged above, Medicis willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and thereby injured Plaintiffs. Such conduct includes filing sham litigation, filing sham citizen petitions, entering into unlawful Exclusion Payment Agreements with its generic competitors and switching the market from Solodyn's legacy strengths to new strengths. Medicis's conduct was designed to delay the introduction of generic formulations of Solodyn into the market.

285. It was Medicis's conscious object to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

286. Medicis's scheme substantially harmed competition in the relevant market.

287. There is and was no cognizable, non-pretextual procompetitive justification for Medicis'ss actions that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Medicis were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

288. As a direct and proximate result of Medicis's illegal and monopolistic conduct, as alleged herein, Plaintiffs and/or their assignors have suffered injury to their business and property.

Claim II: Violation of 15 U.S.C. § 2
Attempt to Monopolize

289. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 281 above as though fully set forth herein.

290. Medicis, through its overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Medicis's conscious objective to control prices and/or to exclude competition in the relevant market.

291. The natural and probable consequence of Medicis's overarching anticompetitive scheme, which was intended by it and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

292. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Medicis would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

293. As a direct and proximate result of Medicis's illegal and monopolistic conduct, Plaintiffs and/or their assignors have suffered injury to their business and property.

Claim III: Violation of 15 U.S.C. § 1
Conspiracy in Restraint of Trade (Medicis/Impax)

294. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 281 above as though fully set forth herein.

295. In or about November 2008, Medicis and Impax entered into the Medicis/Impax Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Medicis agreed to make large and unjustified payments to Impax in exchange for Impax's agreement to delay bringing its generic version of Solodyn to market. The purpose and effect of this Agreement was to: (a) allocate to Medicis 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay and impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiffs purchased Solodyn and its generic equivalents at supracompetitive levels.

296. The purpose and effect of the payments flowing from Medicis to Impax was to delay and impair generic competition to Solodyn, and there is no legitimate, non-pretextual, precompetitive justification for the payments that outweighs their harmful effects.

297. At all relevant times, Medicis possessed market power in the relevant market. Medicis possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

298. The goal, purpose and/or effect of the Exclusion Payment Agreements was to prevent and/or delay generic competition to Solodyn and enable Medicis to continue charging supracompetitive prices for Solodyn without a substantial loss of sales. By means of those Agreements, Defendants shared the supracompetitive profits that their unlawful conspiracy made possible.

299. As a direct and proximate result of Defendant's unlawful conspiracy in restraint of trade, Plaintiffs and/or their assignors have suffered injury to their business and property.

Claim IV: Violation of 15 U.S.C. § 1
Conspiracy in Restraint of Trade (Medicis/Sandoz)

300. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 281 above as though fully set forth herein.

301. In or about August 2009, Medicis and Sandoz entered into the Medicis/Sandoz Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Medicis agreed to make large and unjustified payments to Sandoz in exchange for Sandoz's agreement to delay bringing its generic version of Solodyn to market. The purpose and effect of this Agreement was to: (a) allocate to Medicis 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay and impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic

competition; and (c) fix the price at which Plaintiffs purchased Solodyn and its generic equivalents at supracompetitive levels.

302. The purpose and effect of the payments flowing from Medicis to Sandoz was to delay and impair generic competition to Solodyn, and there is no legitimate, non-pretextual, precompetitive justification for the payments that outweighs their harmful effects.

303. At all relevant times, Medicis possessed market power in the relevant market. Medicis possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

304. The goal, purpose and/or effect of the Exclusion Payment Agreement was to prevent and/or delay generic competition to Solodyn and enable Medicis to continue charging supracompetitive prices for Solodyn without a substantial loss of sales. By means of that Agreement, Defendants shared the supracompetitive profits that their unlawful conspiracy made possible.

305. As a direct and proximate result of Defendant's unlawful conspiracy in restraint of trade, Plaintiffs and/or their assignors have suffered injury to their business and property.

Claim V: Violation of 15 U.S.C. § 1
Conspiracy in Restraint of Trade (Medicis/Lupin)

306. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 281 above as though fully set forth herein.

307. In or about July 2011, Medicis and Lupin entered into the Medicis/Lupin Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Medicis agreed to make large and unjustified payments to Lupin in exchange for Lupin's agreement to delay bringing its generic version of Solodyn to market. The purpose and effect of this Agreement was to: (a) allocate to Medicis 100% of the market for

Solodyn and its generic equivalents in the United States; (b) delay and impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiffs purchased Solodyn and its generic equivalents at supracompetitive levels.

308. The purpose and effect of the payments flowing from Medicis to Lupin was to delay and impair generic competition to Solodyn, and there is no legitimate, non-pretextual, precompetitive justification for the payments that outweighs their harmful effects.

309. At all relevant times, Medicis possessed market power in the relevant market. Medicis possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

310. The goal, purpose and/or effect of the Exclusion Payment Agreement was to prevent and/or delay generic competition to Solodyn and enable Medicis to continue charging supracompetitive prices for Solodyn without a substantial loss of sales. By means of that Agreement, Defendants shared the supracompetitive profits that their unlawful conspiracy made possible.

311. As a direct and proximate result of Defendant's unlawful conspiracy in restraint of trade, Plaintiffs and/or their assignors have suffered injury to their business and property.

XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

B. A permanent injunction enjoining Defendants from continuing their illegal conduct and requiring them to take affirmative steps to dissipate the continuing effects of their prior conduct;

C. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled;

D. An award of Plaintiffs' costs of suit, including reasonable attorneys' fees as provided by law; and

E. Such other and further relief as the Court deems just and proper.

XII. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: March 26, 2015

Respectfully submitted,

/s/ Matthew A. Thomsen, Esq.

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