

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE SOLODYN ANTITRUST  
LITIGATION

THIS DOCUMENT RELATES TO:

ALL END-PAYOR ACTIONS

MDL No. 2503

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JURY TRIAL DEMANDED

**CONSOLIDATED AMENDED CLASS ACTION COMPLAINT**

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Plaintiffs United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund, City of Providence, Fraternal Order of Police, Fort Lauderdale Lodge 31 Insurance Trust Fund, International Union of Operating Engineers Local 132 Health and Welfare Fund, International Union of Operating Engineers Stationary Engineers Local 39 Health & Welfare Trust Fund, Painters District Council No. 30 Health and Welfare Fund, Plumbers & Pipefitters Local 178 Health & Welfare Trust Fund, Heather Morgan, Man-U Service Contract Trust Fund, Sheet Metal Workers Local No. 25 Health & Welfare Fund, and Local 274 Health & Welfare Fund, and Allied Services Welfare Fund (together, “Plaintiffs”) on behalf of themselves and all others similarly situated, file this Consolidated Amended Class Action Complaint against Defendants Medicis Pharmaceutical Corp., Valeant Pharmaceuticals International, Inc., Impax Laboratories, Inc., Lupin Limited, Lupin Pharmaceuticals Inc., and Sandoz Inc. (together, “Defendants”) and allege as follows based on: (a) personal knowledge; (b) the investigation of its counsel; and (c) information and belief.

## **I. NATURE OF THE ACTION**

1. Medicis Pharmaceutical Corp. (“Medicis”) faced a major dilemma in 2006. The Food and Drug Administration (“FDA”) had just approved its acne medication Solodyn, an extended release minocycline hydrochloride tablet, for sale in the United States in three dosage strengths: 45mg, 90mg, and 135mg (the “Legacy Strengths” or “Legacy Strength Solodyn”). But because it contained minocycline, an old antibiotic ingredient, Solodyn had none of the usual protections for a newly approved brand drug and therefore it did not enjoy any regulatory periods of marketing exclusivity that would prevent the FDA from approving generic extended release minocycline hydrochloride products. Furthermore, the only patent that purportedly covered Solodyn—U.S. Patent No. 5,908,838 (the “838 Patent”)—was invalid and/or unenforceable and

could not protect Solodyn from generic competition either. Solodyn, which would shortly exceed annual sales of more than \$500 million and become the “#1 dermatology medication by dollars in the world,” was likely to face generic competition and soon.

2. Faced with the imminent threat of competition, Medicis hatched and orchestrated a multi-faceted scheme to illegally delay generic competition for Solodyn, undertaking some pieces alone and effectuating others through conspiracy with potential rivals, the generic defendants. Medicis’s Chief Executive Officer even boasted about this strategy to delay generic competition in calls with investors.

3. When potential generic competitors began to emerge, starting with defendant Impax Laboratories, Inc. (“Impax”), Medicis went to work using its invalid and unenforceable ‘838 Patent and other tactics—including illegal exclusion payment agreements—to delay generic competition.

4. Specifically, Medicis and its potential generic competitors—first Impax and later Sandoz Inc. (“Sandoz”) and Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”)<sup>1</sup>—entered into unlawful exclusion payment agreements, whereby Medicis paid the Generic Defendants to stay out of the market for Legacy Strength extended release minocycline hydrochloride until November 2011.

5. The scheme further involved Medicis listing the ‘838 Patent, which it knew was invalid and unenforceable, in the FDA’s Orange Book and using the invalid and unenforceable ‘838 Patent to file sham patent infringement suits against its potential generic competitors as a means to delay generic entry.

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<sup>1</sup> Impax, Sandoz and Lupin are collectively referred to as the “Generic Defendants” or “generic defendants.”

6. Medicis used the time it bought free of generic competition for its Legacy Strength Solodyn to switch the Solodyn market from the Legacy Strengths of Solodyn—which were set to belatedly face generic competition in November 2011—to different strengths (65mg, 55mg, 80mg, 105mg, and 115mg, the “Add-On Strengths” or “Add-On Strength Solodyn”) which did not face imminent generic competition because pharmacists could not automatically substitute less expensive generic Legacy Strength Solodyn when presented with a prescription for Solodyn in one of the Add-On Strengths.

7. When potential generic competitors then tried to gain approval for generic Add-On Strength Solodyn, Medicis continued its scheme using the same tactics—sham patent litigation and an unlawful exclusion payment agreement with Lupin—to delay generic competition to the Add-On Strengths, which now dominate the market, to February 2018 (for 65mg and 115mg) or February 2019 (for 55mg, 80mg and 105mg).

8. In essence, Medicis bribed the Generic Defendants to stay out of the market. The deals unlawfully protected Medicis’s stream of monopoly profits and paid Impax, Sandoz, and Lupin handsomely to do so. Absent Defendants’ unlawful conduct, Impax, Sandoz, Lupin, and other generic manufacturers would have begun and would have sustained their marketing of generic Legacy Strength Solodyn earlier than they finally did and before the market for Legacy Strength Solodyn had been impaired by the scheme. Defendants’ unlawful conduct delayed and substantially diminished the sale of generic Solodyn products in the United States, and unlawfully enabled Medicis to sell Solodyn at artificially inflated prices, including after July 2009 and continuing to this date and beyond.

9. Plaintiffs and members of the Class have been compelled to pay artificially inflated prices for minocycline hydrochloride extended release tablets, including after July 2009

and continuing to this date. Plaintiffs and members of the Class will continue to pay artificially inflated prices for minocycline hydrochloride extended release tablets until some future date when the anticompetitive effects of Defendants' conduct cease.

10. Plaintiffs bring this action on their own behalf and on behalf of a proposed End-Payor Class comprised of consumers and third-party payors who indirectly purchased, paid and/or provided reimbursement for Solodyn or its generic equivalents, other than for resale, since July 23, 2009. End-Payor Plaintiffs seek a judgment declaring that Defendants' conduct is unlawful under Sections 1 and 2 of the Sherman Act, 15 U.S.C. § 1, 2. Plaintiffs also seek an injunction pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, because, unless enjoined, the Defendants' unlawful conduct will continue unchecked and Plaintiffs will continue to suffer financial harm as a result of Defendants' antitrust violations. Plaintiffs also assert claims for compensatory and treble damages and equitable relief for continuing violations of state antitrust, consumer protection and unjust enrichment laws.

## **II. PARTIES**

### **A. Plaintiffs**

11. Plaintiffs United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund ("UFCW") maintains its principal place of business at 3031-A Walton Road, Plymouth Meeting, Pennsylvania 19462. UFCW indirectly purchased, paid and/or provided reimbursement for Solodyn and/or generic Solodyn once it became available, other than for resale, in California, Florida, Maryland, New Jersey and Pennsylvania at supracompetitive prices during the Class Period, and was thereby injured.

12. Plaintiff City of Providence, Rhode Island ("Providence") is a municipal corporation with a principal address of 25 Donance Street, Providence, Rhode Island. Providence is a self-insured health and welfare plan, and provides reimbursement for some or all

of the purchase price of prescription drugs including Solodyn. Providence indirectly purchased, paid and/or provided reimbursement for Solodyn and/or generic Solodyn once it became available, other than for resale, in Colorado, Connecticut, Florida, Illinois, Maryland, Massachusetts, New Mexico, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, and Texas at supracompetitive prices during the Class Period, and was thereby injured.

13. Plaintiff Fraternal Order of Police, Fort Lauderdale Lodge 31 Insurance Trust Fund (“FOP”) is a health and benefit fund operated for the benefit of present and retired workers of the union and their families. The Fund was established pursuant to a duly executed Trust Agreement for the purpose of providing health benefits, including prescription benefits, to its defined beneficiaries. The Fund maintains its principal place of business in Fort Lauderdale, Florida. FOP indirectly purchased, paid and/or provided reimbursement for Solodyn and/or generic Solodyn once it became available, other than for resale, in Florida at supracompetitive prices during the Class Period, and was thereby injured.

14. Plaintiff International Union of Operating Engineers Local 132 Health and Welfare Fund (“IUOE Local 132”) maintains its principal place of business at 636 Fourth Avenue in Huntington, West Virginia. IUOE Local 132 indirectly purchased, paid and/or provided reimbursement for Solodyn and/or generic Solodyn once it became available, other than for resale, at supracompetitive prices during the Class Period, and was thereby injured.

15. Plaintiff International Union of Operating Engineers Stationary Engineers Local 39 Health & Welfare Trust Fund (“IUOE Local 39”) is a self-insured health and welfare benefit plan with its principal place of business in 337 Valencia Street, San Francisco, California 94103. IUOE Local 39 provides reimbursement to its members for some or all of the purchase price of

prescription drugs including Solodyn. IUOE Local 39 indirectly purchased, paid and/or provided reimbursement for Solodyn and/or generic Solodyn once it became available, other than for resale, in California, Nevada, Pennsylvania and Texas at supracompetitive prices during the Class Period, and was thereby injured.

16. Plaintiff Painters District Council No. 30 Health and Welfare Fund (“Painters Fund”) maintains its principal place of business in Aurora, Illinois. Painters Fund is an “employee welfare benefit plan” and an “employee benefit plan” within the Employee Retirement Income Security Act (“ERISA”), 29 U.S.C. §§ 1002(1), 1002(3) and 1003(a). Painters Fund is a legal entity entitled to sue in its own name under 29 U.S.C. §1132(d). Painters Fund is a not-for-profit trust, sponsored by and administered by a Board of Trustees, established and maintained to provide comprehensive health coverage for its participants and beneficiaries. Painters Fund indirectly purchased, paid and/or provided reimbursement for Solodyn and/or generic Solodyn once it became available, other than for resale, in Florida, Illinois, Ohio and Wisconsin at supracompetitive prices during the Class Period, and was thereby injured.

17. Plaintiff Plumbers & Pipefitters Local 178 Health & Welfare Trust Fund (“Plumbers and Pipefitters Local 178”) is located in Springfield, Missouri. Plumbers and Pipefitters Local 178 indirectly purchased, paid and/or provided reimbursement for Solodyn and/or generic Solodyn once it became available, other than for resale, in Missouri at supracompetitive prices during the Class Period, and was thereby injured.

18. Plaintiff Heather Morgan is an individual who resides in South Carolina. Ms. Morgan indirectly purchased, paid and/or provided reimbursement for Solodyn and/or generic Solodyn once it became available, other than for resale, in South Carolina at supracompetitive prices during the Class Period, and was thereby injured.

19. Plaintiff Man-U Service Contract Trust Fund (“Man-U”) is a trust that maintains its principal place of business at 7130 Columbia Gateway Drive, Suite A, Columbia, Maryland 21046. Man-U indirectly purchased, paid and/or provided reimbursement for Solodyn and/or generic Solodyn once it became available, other than for resale, in Maryland and the District of Columbia at supracompetitive prices during the Class Period, and was thereby injured.

20. Plaintiff Sheet Metal Workers Local No. 25 Health & Welfare Fund (“Sheet Metal Workers Local No. 25”) is a New Jersey trust that maintains its principal place of business at 440 Barrel Avenue, Carlstadt, New Jersey 07072. Sheet Metal Workers Local No. 25 indirectly purchased, paid and/or provided reimbursement for Solodyn and/or generic Solodyn once it became available, other than for resale, at supracompetitive prices during the Class Period, and was thereby injured.

21. Plaintiff Local 274 Health & Welfare Fund (“Local 274”) is a Pennsylvania Trust that maintains its principal place of business at 22 South 22<sup>nd</sup> Street, Philadelphia, Pennsylvania 19103. Local 274 indirectly purchased, paid and/or provided reimbursement for Solodyn and/or generic Solodyn once it became available, other than for resale, at supracompetitive prices during the Class Period, and was thereby injured.

22. Plaintiff Allied Services Welfare Fund (“Allied Services”) is a health and welfare benefit fund with its principal place of business at 53 West Seegers Road, Arlington Heights, Illinois 60005, and is involved in the business of providing health benefits for covered lives. Allied Services is a multi-employer employee welfare benefit plan, within the meaning of the Employee Retirement Income Security Act, 29 U.S.C. § 1001(2) and § 1002(37). Allied Services indirectly purchased, paid and/or provided reimbursement for Solodyn and/or generic

Solodyn once it became available, other than for resale, in New Jersey and North Carolina at supracompetitive prices during the Class Period, and was thereby injured.

**B. Defendants**

23. Defendant Medicis Pharmaceutical Corp. is a division of Valeant Pharmaceuticals International, Inc. (“Valeant”). Valeant acquired Medicis in December 2012. Prior to that time, Medicis was incorporated under the laws of the State of Delaware and its common stock was traded on the New York Stock Exchange under the symbol MRX. Until July 2013, Medicis’s corporate headquarters were located at 7720 N. Dobson Road in Scottsdale, Arizona. Since July 2013, Medicis’s corporate headquarters have been located at 400 Somerset Corporate Blvd. in Bridgewater, New Jersey. Medicis develops, manufactures, and markets Solodyn, as well as other pharmaceuticals and related products, in the United States.

24. Defendant Valeant Pharmaceuticals International, Inc. is a Canadian corporation with its principal place of business at 2150 St. Elzéar Blvd. West, Laval, Quebec Canada H7L 4A8. Valeant’s United States headquarters are located at 700 Route 202/206 Bridgewater, New Jersey 08807. Valeant acquired Medicis in an all-cash transaction in December 2012. The combined company’s commercial dermatology operations are located in Bridgewater, New Jersey. Valeant develops, manufactures, and markets Solodyn, as well as other pharmaceuticals and related products, in the United States.

25. Upon the completion of its acquisition of Medicis, Valeant joined the unlawful course of conduct challenged herein—including the unlawful exclusion payment agreements, collusion and conspiracy—with respect to the suppression of generic competition for Solodyn. Valeant also directly and independently participated in the conduct alleged herein by continuing to adhere to the unlawful agreements, including by making payments pursuant to the agreements.

26. Defendant Impax Laboratories, Inc. is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue in Hayward, California. Impax develops, manufactures, and markets pharmaceutical products, primarily generic products, in the United States.

27. Defendant Lupin Limited is a company organized under the laws of India with its principal place of business at B/4 Laxami Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Defendant Lupin Pharmaceuticals, Inc. is a Virginia corporation with its principal place of business at 111 South Calvert Street, 21st Floor in Baltimore, Maryland. Lupin Pharmaceuticals, Inc. develops, manufactures, and markets pharmaceutical products, primarily generic products, in the United States. Defendants Lupin Limited and Lupin Pharmaceuticals Inc. are referred to collectively as “Lupin.”

28. Defendant Sandoz Inc. is a Colorado corporation with its principal place of business at 506 Carnegie Center in Princeton, New Jersey. Sandoz develops, manufactures, and markets pharmaceutical products, primarily generic products, in the United States.

29. All of the Defendants’ actions described in this Complaint are part of, and in furtherance of, the unlawful anticompetitive scheme and illegal restraints of trade alleged herein, and were authorized, ordered, and/or performed by the Defendants’ various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants’ affairs, within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the Defendants.

### **III. JURISDICTION AND VENUE**

30. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds \$5,000,000

and at least one member of the putative class is a citizen of a state different from that of one or more of the Defendants.

31. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiffs bring claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy the Defendants' violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1, 2. The Court has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. § 1367.

32. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. §1391(b) and (c), because Defendants transact business within this district, and/or have an agent and/or can be found in this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district and this action has been transferred to this district by the Judicial Panel on Multidistrict Litigation.

#### **IV. REGULATORY BACKGROUND**

##### **A. The prescription pharmaceutical marketplace suffers a unique imperfection whereby those who choose the product do not pay.**

33. 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 who pays 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 product choice and, consequently, manufacturers have an appropriate incentive to lower prices.

34. 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.

35. 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 typically do not advise doctors of the cost of the brand 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.

36. 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 market power: the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The market imperfections and marketing practices described above allow brand manufacturers to gain and maintain market power for many brand prescription pharmaceuticals.

**B. Generic drugs cost significantly less and take substantial sales directly from the corresponding brand drugs.**

37. Manufacturers of generic drugs typically price their versions of brand drugs significantly below the brand price. These price differentials prompt pharmacists to liberally and substantially substitute generic versions for the brand counterparts whenever generics are

available and the law permits substitution. Generic drugs that are pharmaceutically equivalent (same dosage form and strength) and bioequivalent (exhibiting the same drug absorption characteristics) (together, “therapeutically equivalent”) to their brand counterparts are given an “AB” rating by FDA and are typically priced much less than their brand counterpart. Pharmacists substitute a less-expensive AB-rated generic product for the corresponding brand product unless the doctor has indicated that the prescription for the brand product must be “dispensed as written” or the patient objects. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand drug to the corresponding generics accelerates.

38. All states permit (and some states require) pharmacists to automatically substitute an AB-rated generic drug for the corresponding brand drug unless the doctor has stated that the prescription for the brand name product must be dispensed as written (or the patient objects).

39. Many third party payors (such as health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their brand counterparts. In addition, many consumers routinely switch from a brand drug to an AB-rated generic drug once the generic becomes available. Consequently, AB-rated generic drugs typically capture a significant share of their brand counterparts’ sales, causing a rapid and significant reduction of the brand drug’s unit and dollar sales.

40. Once a generic equivalent enters the market, the generic quickly captures sales of the brand drug, often capturing 80% or more of unit sales within the first six months. According to a 2010 study by the Federal Trade Commission (“FTC”), one year after market entry, generics

on average have taken 90% of the brand's unit sales and generic prices are on average 15% of the brand price.

41. Generic competition enables purchasers at all levels of the pharmaceutical supply chain, including all members of the proposed Class, to: (a) purchase generic versions of a drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price. Until a generic manufacturer enters the market, however, there is no bioequivalent generic drug to compete with the brand drug, and therefore the brand manufacturer can continue to profit from supracompetitive pricing, without losing its brand sales. Brand manufacturers have a strong incentive to use various tactics, including those alleged herein, to delay the introduction of generic competition into the market.

42. Brand manufacturers are well aware of generics' rapid erosion of their previously monopolized market. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to illegal means.

**C. The regulatory structure incentivizes drug innovation and encourages approval and use of generic drugs.**

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

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

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

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

47. As a counter-balance to this abbreviated process for bioequivalent generic drugs, Hatch-Waxman provided a number of benefits to brand manufacturers. For example, Hatch-Waxman grants a five-year period of exclusivity (regardless of any patent protection) to NDAs for products containing chemical entities never previously approved by FDA either alone or in combination. Hatch-Waxman also grants a three-year period of exclusivity (regardless of any patent protection) for a drug product that contains an active ingredient that has been previously approved, when the application contains reports of new clinical investigations (other than bioavailability studies) conducted by the sponsor that were essential to approval of the application. Neither of these exclusivities were available to Medicis for Solodyn.

48. Hatch-Waxman also streamlined the process for a brand manufacturer to enforce its patents against infringement by generic manufacturers, and provided that, under certain conditions, FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand drug for up to 30 months.

49. When it approves a brand manufacturer’s NDA, the FDA lists any compound patents which (according to the brand manufacturer) claim the approved drug in a publication

entitled the “Approved Drug Products with Therapeutic Equivalence Evaluations,” known as the “Orange Book.” 21 U.S.C. §355(j)(7)(A)(iii). In the case of method-of-use patents, FDA lists in the Orange Book any patents that (according to the brand manufacturer) claim the drug for its approved method of use. Method-of-use patents are properly submitted to the FDA for Orange Book listing only if the manufacturer could reasonably assert a claim of patent infringement against a person who was not licensed by the owner to manufacture, use, or sell the drug. 21 U.S.C.A. § 355 (b)(1). In listing patents in the Orange Book, the FDA performs purely a ministerial act. The FDA does not check the facts supplied to it by the brand manufacturer, but trusts that the manufacturer will be truthful. After the NDA is approved, the brand manufacturer may list other new patents in the Orange Book as related to the NDA if the brand manufacturer similarly certifies, *inter alia*, that the new patents claim either the approved drug (for compound patents) or approved methods of use (for method-of-use patents).

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

- a. that no patent for the brand drug has been filed with FDA (a “Paragraph I certification”);
- b. that the patent for the brand drug has expired (a “Paragraph II certification”);
- c. that the patent for the brand drug will expire on a particular date and the generic manufacturer does not seek to market its generic product before that date (a “Paragraph III certification”); or
- d. 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”).

21 U.S.C. § 355(j)(2)(A)(vii).

51. If a generic manufacturer files only Paragraph I, II, or III certifications, then it can take advantage of the expedited Hatch-Waxman approval process, and FDA must act on the application within 180 days of receipt, unless both FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5)(A).

52. If a generic manufacturer files a Paragraph IV certification asserting that a patent listed in the Orange Book is invalid or will not be infringed, a brand manufacturer often has an opportunity to delay final FDA approval of the ANDA and the sale of the competing generic drug. When a generic drug manufacturer files a Paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of the patent(s) at issue. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the Paragraph IV certification, then in certain circumstances FDA may not grant final approval to the ANDA until the earlier of either: (a) 30 months; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii). Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification, a brand manufacturer often may delay FDA's approval of the generic drug and its entry into the market.<sup>2</sup> During the pendency of an applicable 30-month stay, FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval but for the stay. The FDA does not grant tentative approvals when 30-month stays are inapplicable, however.

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<sup>2</sup> Brand companies can wait and sue after the 45-day period, but then cannot take advantage of the automatic 30-month stay.

53. Congress also created incentives for generic manufacturers to seek approval of generic alternatives to branded drugs and challenge weak patents. Hatch-Waxman grants to the first generic manufacturer to file a substantially complete ANDA containing a Paragraph IV certification to at least one Orange Book-listed patent (a “first filer”) a 180-day period of market exclusivity (“180-day exclusivity”), during which the first filer enjoys temporary freedom from competition from other generic versions of the drug approved via ANDA.<sup>3</sup>

54. This 180-day exclusivity period (or any period during which there is only one generic version of a brand name drug on the market) 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. The entry of a second generic (or additional generics) can cut the original generic price by half or more. Selling six months’ worth of a generic drug for a product such as Solodyn, as the only generic on the market, can be worth hundreds of millions of dollars in profit. As the Supreme Court explained in *FTC v. Actavis*, the period during which a generic is exclusive in the market is exceedingly valuable, indeed, the “vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period.”<sup>4</sup>

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

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<sup>3</sup> The exclusivity does not apply to a brand company selling its own “authorized generic” version (basically, the brand with a general label, priced like a generic). Brand companies often start selling an authorized generic when the first ANDA-based generic launches to recapture some of the sales the brand would otherwise lose.

<sup>4</sup> See *FTC v. Actavis, Inc.*, 570 U.S. \_\_\_, 133 S. Ct. 2223, 2229 (2013) (citation omitted).

marketing application received by FDA before November 21, 1997 (and thus known as an “old antibiotic”) were exempted 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.

56. The QI Act included three transitional provisions. Those provisions: (1) require antibiotic drug NDA sponsors to submit to FDA for Orange Book listing information on applicable patents within 60 days of enactment of the QI Act; (2) require FDA to list those patents in the Orange Book no 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 contain a Paragraph IV certification to a newly listed antibiotic drug patent. Thus, if multiple ANDA applicants each submitted a Paragraph IV certification to a newly listed antibiotic drug patent within the requisite time period, they would each be “first applicants” within the meaning of Hatch-Waxman and share 180-day exclusivity. If any one of the first applicants launched its generic product, the start of 180-day exclusivity would be triggered for all of the first applicants.

**D. Manufacturers can and do unlawfully “game” the regulatory structure.**

**1. Manufacturers abuse the 30-month stay provision to delay generic competition.**

57. Brand manufacturers can “game the system” by listing patents in the Orange Book (even patents that are not eligible for listing) and then suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the patent is clearly invalid, or the generic’s product non-infringing) in order to obtain the automatic 30-month stay and delay final FDA approval of the ANDA for up to two and a half years. Brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition, rather than to enforce valid

patents against infringing products. 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 73% of the cases studied.

**2. Manufacturers conspire to pay for potential generic competitors to stay off of the market.**

58. In order to delay the drastic loss of monopoly profits from their branded drugs, some unscrupulous brand manufacturers design schemes to enter exclusion payment agreements to buy their way out of competition from generics and the chance that the brand patents might be invalidated or found not to be infringed. Brand manufacturers sometimes compensate generic manufacturers to defer entering the market and to drop their challenges to the patents. Brand and generic manufacturers often try to disguise these payments as a way to try to escape liability under the antitrust laws.

59. Although these exclusion payment agreements purport to settle patent infringement suits, in making a payment to the accused infringer, the patentee uses the strength of its wallet, as opposed to the strength of its patents, to obtain the agreement of the generic manufacturers to delay entry into the market and to avoid a court decision as to whether the patent is invalid or not infringed. The brand manufacturer effectively shares its monopoly profits with the generic manufacturers as a quid pro quo for their agreement to delay competition. The brand and generic manufacturers split between themselves the savings that earlier generic entry would have brought to consumers. As the Supreme Court stated: "The patentee and the challenger gain; the consumer loses."<sup>5</sup>

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<sup>5</sup> *Actavis, Inc.*, 570 U.S. \_\_\_, 133 S. Ct. at 2235.

60. In many circumstances 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 any relevant 180-day period of generic market exclusivity, a tactic called exclusivity “parking.” This tactic creates a “bottleneck” because later generic applicants cannot launch their generic versions of the product until the first generic applicant’s 180-day exclusivity has elapsed or is forfeited.

61. 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 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. 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, 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 FDA Orange Book.

62. The brand manufacturer and first filer frequently take various steps to fortify the bottleneck by making it less economically viable for subsequent filers to trigger the first filer’s exclusivity. For instance, exclusion payment agreements often include provisions, which allow

the first filer to enter the market before the later date otherwise agreed with the brand manufacturer, if a subsequent filer succeeds in entering the market before that later date. The co-conspirators disclose these terms publicly, thus broadcasting to subsequent filers that even if they incur the substantial expense involved in dislodging the bottleneck, they will be guaranteed to face competition from at least the first filer, and likely others. By eliminating all possibility that subsequent filers will enjoy any period of de facto exclusivity, these provisions significantly reduce the value to subsequent filers of obtaining a court decision that would break the bottleneck. Thus, where a first filer has “parked” its 180-day exclusivity and agreed to such a provision, subsequent filers have comparatively less to gain by obtaining a court decision of invalidity and/or non-infringement and are therefore willing to settle for much less time on the market than they otherwise would have.

**3. Manufacturers shift the market from one version of their product to another to thwart generic competition.**

63. To be substitutable for a branded product at the pharmacy counter, and approvable by FDA as AB-rated to a particular branded product, a generic product must be, among other things, “pharmaceutically equivalent” (same dosage form and strength) and “bioequivalent” (exhibiting the same drug absorption characteristics) as the branded product.

64. FDA regulations, which are concerned only with safety and effectiveness and not with effects on competition, permit brand manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. A brand manufacturer that anticipates the onset of generic competition to its drug can modify the dosage form, strength, or some other characteristic of its product from, say, A to A1, for no reason other than to prevent generic competition to A. Before the generic manufacturer receives FDA approval for the generic version of A and enters the market, the brand manufacturer might get approval for A1 and use

various tactics to cause physicians to write prescriptions only for A1 instead of A, including discontinuing the sale of A. The brand manufacturer's modification of A to A1 may thereafter cause the manufacturer of the generic version of A to garner few or no sales, because its product is not substitutable for A1.

## V. FACTUAL ALLEGATIONS

### A. Solodyn is based on an old antibiotic but has sales in the hundreds of millions of dollars annually.

65. Medicis sells Solodyn, a brand name, prescription drug for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients age 12 and older. Non-nodular acne is the bright red pimples on the surface layer of the skin. Solodyn uses a once daily, minocycline hydrochloride extended release tablet with a unique dissolution rate to treat this form of acne.

66. Minocycline is an industry mainstay antibiotic ingredient approved to treat acne. Minocycline is a broad-spectrum tetracycline antibiotic and is the most lipid-soluble of the tetracycline-class antibiotics, giving it the greatest penetration into the prostate and brain, but also the greatest amount of central nervous system-related side effects, such as vertigo. Other side effects include diarrhea, skin discoloration, and autoimmune disorders that are not seen with other drugs in the class. Minocycline is not a naturally-occurring antibiotic, but was synthesized semi-synthetically from natural tetracycline antibiotics by Lederle Laboratories in 1972, which subsequently marketed it under the brand name Minocin.

67. Antibiotics like minocycline go after the particular bacterial culprits responsible for non-nodular acne. *P.acnes* is the anaerobic bacterium species that is widely thought to cause this particular form of acne inflammation. The strain has the ability to change, perpetuate, or adapt to the abnormal cycle of inflammation, oil production, and inadequate sloughing activities

of acne pores. In contrast to antibiotic acne medications, isotretinoin medications such as Roaccutane, Accutane, and Claravis treat acne primarily by reducing the secretion of oils from the glands.

68. Solodyn's active ingredient is minocycline hydrochloride, which is a semi-synthetic 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 isotretinoin, which require multiple doses per day. Extended release medications like Solodyn have special coatings or ingredients that control how fast the drugs are released from the pill into the patient's body, allowing the patient to take these medications 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 minocycline with eight FDA-approved dosing strengths."

69. Solodyn's pharmacological profile, and thus its side effect and efficacy profile, is different than 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."

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:

<b>YEAR</b>	<b>SALES</b>
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. Medicis unlawfully protected those revenues by executing an anticompetitive scheme that used a variety of unlawful monopolistic tools.

**B. The ‘838 Patent—the primary patent Medicis claims protects Solodyn—is unenforceable and invalid**

**1. In applying for the patent in 1998, Medicis knew the claimed invention in the ‘838 Patent had been available for more than a year in the U.S., a bar to patentability.**

73. Eugene H. Gans, Ph.D., Chairman of Medicis’s Central Research Committee, filed the application that lead to the ‘838 Patent on February 19, 1998. At that time, public use or sale in the United States of the claimed invention more than one year prior to the date of the filing of the patent application classified the invention itself as prior art and thus operated as a bar to patentability.<sup>6</sup> The claimed invention in the ‘838 Patent – “a method for the treatment of

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<sup>6</sup> 35 U.S.C. § 102(b) (2010), amended by Pub. L. No. 112-29 (2011).

acne... which results in the reduction of vestibular side effects following administration of oral tetracycline antibiotics” and is based upon achieving a slower dissolution rate than typical for tetracyclines – had been available as early as 1993 and sold by Medicis as a slow-dissolving treatment for acne under the trade name Dynacin. The claimed invention was not patentable.

74. In 1990, FDA approved Medicis’s ANDA to sell minocycline hydrochloride capsules for the treatment of acne in the United States under the trade name Dynacin. Although FDA had approved Dynacin as an AB-rated therapeutic equivalent to Minocin, an immediate release minocycline hydrochloride product, Dynacin in fact dissolved and entered the bloodstream more slowly than Minocin and other immediate release minocycline hydrochloride products. Medicis sold and patients used this slower dissolving Dynacin in the United States since 1993, and well before February 18, 1997, a year before the filing of the ‘838 Patent application, the relevant priority date for the ‘838 Patent.

75. In October 1997, in Medicis’s Clinical Acne Reviews, Dr. Gans published a study comparing the side effects of Dynacin capsules with Vectrin, another commercially available minocycline hydrochloride product that is therapeutically equivalent to Minocin.<sup>7</sup> This “Dynacin Study” compared the two minocycline hydrochloride products to examine the effect of differences in in vitro dissolution rates on the occurrence and magnitude of, among other things, vestibular side effects in vivo. (The vestibular system contributes to balance and spatial orientation; vestibular side effects include dizziness, vertigo, and blurred vision.)

76. Vectrin releases its minocycline almost immediately in vitro (100% within 15 minutes) and anecdotal reports from dermatologists indicated that Vectrin produced significant

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<sup>7</sup> Donachie et al., “A comparison of the side effects produced by Vectrin and Dynacin after normal dosage,” *Clinical Acne Reviews* Vol. 2; 1997 (“Dynacin Study”).

vestibular side effects in some patients. Dynacin has a slower in vitro dissolution (90% within 45 minutes) and was not known to cause similar vestibular side effects. Dr. Gans and his co-authors compared fast dissolving Vectrin with slower dissolving Dynacin (which they termed “regulated release”), understanding that vestibular side effects might depend in part on “the speed with which the drug enters the bloodstream and becomes transferred to vestibular and other organs.”<sup>8</sup>

77. The Dynacin Study demonstrated that while both Vectrin and Dynacin provided complete dissolution and bioavailability, patients taking Vectrin had more than five times the number of vestibular side effects than patients taking Dynacin. Dr. Gans and his co-authors theorized in their Medicis-funded, Medicis-published Dynacin Study that the difference in vestibular side effects stemmed from the difference in dissolution rates between the fast dissolving dosage form (Vectrin) and the slower dissolving dosage form (Dynacin) – that the slower, or “regulated” release of minocycline in Dynacin led to fewer vestibular side effects.

78. Medicis funded the Dynacin Study, published the Dynacin Study, and used the Dynacin Study to promote Dynacin to doctors, claiming superiority to Vectrin and other generic minocycline hydrochloride products based on a lower incidence of vestibular effects due to its slower regulated release. By at least October 1997, Medicis distributed promotional materials that touted the Dynacin Study as demonstrating that Dynacin was “over five times less likely to cause vestibular symptoms than Vectrin,” and that Vectrin “produced significantly higher levels (over five times higher) of the common vestibular side effects, dizziness and vertigo, in terms of incidence, severity and duration, compared with Dynacin.”<sup>9</sup> At the same time, Medicis

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<sup>8</sup> Dynacin Study at 1.

<sup>9</sup> Warning Letter from FDA to J. Shacknai, dated December 22, 1998 at 4.

promoted Dynacin as achieving greater clinical efficacy than other minocycline hydrochloride products that were also AB-rated to Minocin.

**2. Medicis deliberately omits and misrepresents information in securing the ‘838 Patent to cover Solodyn, a fact that would have emerged in future patent litigation.**

79. Medicis used data from the Dynacin Study to mislead the United State Patent and Trademark Office (the “USPTO”) in applying for and securing the ‘838 Patent that Medicis claims covers Solodyn. The ‘838 Patent application claimed “a method for 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.”<sup>10</sup> The ‘838 Patent application relied entirely on data from Dynacin and the Dynacin Study without disclosing to the USPTO that (a) the data was based on Dynacin and the Dynacin Study, (b) Dynacin had been publicly used and sold in the United States long before February 18, 1997 (one year prior to the application for the ‘838 Patent was filed), or (c) Medicis had been promoting Dynacin to doctors on the basis of results of the Dynacin Study and the lower incidence of vestibular side effects due to the product’s slower dissolution profile.

80. Dr. Gans and Medicis had a legal duty of candor to and a duty of good faith in dealing with the USPTO, including the duty to disclose information material to patentability, “which includes a duty to disclose to the [USPTO] all information known to that individual to be

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<sup>10</sup> ‘838 Patent Claim 1. The original application contained nine claims. After amendment in November 1998 and as eventually granted, the application contained eighteen claims.

material to patentability as defined in this section.”<sup>11</sup> Dr. Gans signed a declaration acknowledging these duties in the ‘838 Patent application.

81. Dr. Gans and Medicis violated these duties. For example, the ‘838 Patent application contains data identical to that in the Dynacin Study, without attribution to Dynacin, a product that had been on the market for eight years. Table 1 of the ‘838 Patent describes the same results reported in the Dynacin Study for vestibular side effects, but Medicis scrubbed all reference to Dynacin in the ‘838 Patent application: where the Dynacin Study reports the vestibular side effects for “Dynacin,” the ‘838 Patent refers only to an unidentified “slower-dissolving minocycline,” thus obscuring that the data was based on an FDA-approved, publicly used, on sale drug sold by Medicis and touted for its slow-dissolving qualities.

82. 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 omitted from the ‘838 Patent application and supporting materials any and all references to Dynacin. Dr. Gans and Medicis, despite their legal duty of candor to the USPTO, intentionally omitted this critical information because they knew that the prior public use and sale of Dynacin before February 19, 1997 would have classified the claimed invention of the ‘838 Patent as prior art and thus been a bar to patentability.

83. Neither Dynacin nor the Dynacin Study were ever disclosed to the USPTO before the ‘838 Patent issued. The fact that Medicis and Dr. Gans knew in 1997 that a slower release composition of minocycline hydrochloride (i.e., Dynacin) was on sale and would reduce vestibular side effects as later claimed in the ‘838 Patent and in Medicis’s promotional materials

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<sup>11</sup> 37 C.F.R. § 1.56(a) (July 1, 1999). See Manual of Patent Examining Procedure § 2001 (7<sup>th</sup> ed. July 1998). Applicants have the duty to disclose promptly, generally before the first office action by the USPTO, but the duty is ongoing. 37 C.F.R. § 1.59 (July 1, 1999).

about Dynacin would have been relevant to a reasonable examiner under 37 C.F.R. §1.56, and would have rendered the application and claimed invention un-patentable.

84. Instead, on June 1, 1999, the USPTO, without knowing that Medicis had been employing the method of use disclosed in the patent application in the United States since 1993 in the form of Dynacin, issued U.S. Patent No. 5,908,838. 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.

85. The ‘838 Patent suffered not only from the inequitable conduct Medicis committed in the original application but was also invalid and unenforceable, and Medicis knew it. Indeed, when the USPTO reexamined the ‘838 Patent nearly a decade after its issuance—which reexamination was likewise marred by Medicis’s misrepresentations and omissions—Medicis was forced to cancel claims 1-2, 5-11, and 15-18 of the ‘838 Patent, amend claims 3, 4, 12, and 13 to be independent, and come up with new claims 19-34. Although the USPTO ultimately reissued the ‘838 Patent on June 1, 2010 (after Medicis had asserted it in patent litigation, and entered exclusion payment agreements with Impax and Sandoz), none of the original ‘838 Patent claims survived without amendment. Medicis knew that the ‘838 Patent was invalid as originally issued. And the reissued ‘838 Patent is also invalid due to the public use and sale of Dynacin prior to February 18, 1997.

86. Given its invalidity and/or unenforceability, the ‘838 Patent was unlikely to prevent a generic Solodyn product from coming to market in advance of patent expiration. Medicis recognized this, cautioning 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.”

87. But the invalidity and unenforceability of the ‘838 Patent did not deter Medicis from executing its plan to use that patent to delay generic competition, including as a conduit to illegal exclusionary payment agreements.

**C. In 2006, Medicis gains approval for Solodyn in Legacy Strengths: 45mg, 90mg, and 135mg but recognizes the drug’s immediate vulnerability to generic competition.**

88. On June 30, 2005, Medicis submitted NDA No. 50-808 seeking FDA approval to market Solodyn extended release tablets in the 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. FDA approved Medicis’s Solodyn NDA for the Legacy Strengths on May 8, 2006 (and would grant approval for five additional Add-On Strengths in 2009 and 2010).

89. FDA grants many newly approved drugs one or more periods of marketing exclusivity as an incentive to develop new products. For example, manufacturers can obtain new chemical entity exclusivity or new clinical trial exclusivity. Because the active ingredient in Solodyn is the “old antibiotic” minocycline, which has been marketed since at least the early 1970s, those periods of marketing exclusivity did not apply. Additionally, because at the time Medicis submitted and FDA approved its NDA for Solodyn in the Legacy Strengths the ‘838 Patent was not and could not have been listed in the Orange Book, Medicis could not use the ‘838 Patent to automatically trigger the 30-month Hatch-Waxman stay. This, in combination with the invalid, and/or unenforceable ‘838 Patent, left Solodyn particularly vulnerable to the drastic loss of sales that would accompany the start of AB-rated generic competition.

90. Knowing Solodyn was critical to its overall financial performance, Medicis embraced a strategy to impede generic competition to Solodyn. As Medicis explained to its investors: “you can be sure that in every conceivable respect, we are attempting to protect

Solodyn,”<sup>12</sup> “keeping it alive as long as we can.”<sup>13</sup> 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.<sup>14</sup>

91. In fact, during an earnings call on February 27, 2008, Shacknai outlined Medicis’s strategy to insulate Solodyn from generic competition. In reality, Medicis’s strategy included using the unenforceable and invalid ‘838 Patent (and any other patents it could convince the USPTO to grant) to file sham litigations against potential generic competitors to delay generic competition and/or serve as conduits for entering into agreements—including illegal exclusion payment agreements—with those generic competitors to delay the launch of generic Solodyn. Medicis would also use the time bought by its delay tactics to develop and launch “other generations of Solodyn”—the Add-On Strengths—that cannot be automatically substituted with generic Legacy Strength Solodyn when those strengths belatedly enter the market. Mr. Shacknai characterized Medicis’s plan as a “fairly complex strategy to defend the brand to the utmost of our ability.” Medicis systematically executed its scheme to delay and impair competition from generic versions of Solodyn.

**D. In 2008, Medicis lays the foundation for its scheme and enters the first unlawful Exclusion Payment Agreement.**

**1. In late 2007, Impax attempts to bring a generic Solodyn to market and Medicis stands in its way.**

92. On or about October 5, 2007, Impax submitted to the FDA ANDA 90-024 seeking to market generic versions of Solodyn in the 45mg, 90mg, and 135mg Legacy Strengths.

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<sup>12</sup> (Medicis at Credit Suisse Healthcare Conference (Nov. 14, 2007))

<sup>13</sup> (Medicis at Merrill Lynch 19th Global Pharmaceutical, Biotechnology & Medical Device Conference (Feb. 7, 2008)).

<sup>14</sup> (Medicis Earnings Conference Call (Feb. 28, 2007)).

Because there were no Orange Book-listed patents for Solodyn at the time Impax submitted its ANDA, Impax was not required by the Hatch-Waxman Act to notify Medicis of its application to market generic Solodyn or send a Paragraph IV notice informing Medicis that Impax's generic would not infringe any valid or enforceable claim of the '838 Patent. Thus, Medicis could not trigger the 30-month Hatch-Waxman stay by suing Impax.

93. Instead, on December 20, 2007, Impax notified Medicis of its 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. Impax informed Medicis that any attempt 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."

94. Rather than granting Impax's requested covenant not to sue, Medicis informed Impax that it would aggressively and vigorously enforce the '838 Patent against all generic competitors of Solodyn, which was consistent with Medicis's scheme to thwart generic competition to Solodyn and Medicis's public statement that it "intend[s] to enforce with ultimate vigor the patents that have issued."<sup>15</sup>

95. 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 are invalid and not infringed by Impax.

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<sup>15</sup> Medicis at Deutsche Bank 32<sup>nd</sup> Annual Health Care Conference (May 3, 2007).

96. Reflecting Wall Street’s view of the actual strength of Medicis’s patent protection and the strength of competition from Impax, 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.

97. On March 5, 2008, Medicis moved to dismiss Impax’s declaratory judgment complaint. Medicis’s argument that no justiciable Article III controversy existed because Medicis was not then preventing Impax from marketing a generic Solodyn product and Impax had not begun the commercial marketing of its generic Solodyn products ignored its own 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 the public’s interest in increasing competition in the drug industry through lower-priced generic drugs.

**2. Eyeing a future product switch, Medicis seeks approval of new Add-On Strengths of Solodyn.**

98. Due to the weakness of the ‘838 Patent, Medicis knew that the Legacy Strengths of Solodyn would soon face generic competition far before the expiration of the ‘838 Patent. Medicis thus worked to market Solodyn in new strengths that would not be subject to automatic substitution with generic Legacy Strength Solodyn. To that end, on February 29, 2008, Medicis submitted to the FDA a supplemental NDA 50-808/S-007 seeking approval to market 65mg and 115mg strength Solodyn. That sNDA was approved by FDA on July 23, 2009.

**3. Medicis files a frivolous petition to delay approval of generic Solodyn, taking a position opposite to the position it took when seeking approval of Solodyn.**

99. Before the district court could decide whether Impax had standing to challenge the '838 Patent, on March 18, 2008, Medicis filed a frivolous citizen petition (Number FDA-2008-P-0185) asking FDA not to approve any generic versions of Solodyn, including Impax's generic product, without requiring in vivo bioequivalence testing for each strength of Solodyn, something Solodyn had successfully argued against in obtaining approval in the first place ("Medicis's Proportionality Petition").

100. In gaining approval of Solodyn, Medicis convinced the FDA to approve 45mg and 90mg Solodyn on the ground that they are dose-proportional to the 135mg strength, thus in vivo bioequivalence testing was only required for 135mg Solodyn. Medicis made this request because its in vivo pharmacokinetic studies demonstrated that the different strengths of Solodyn result in dose-proportional exposure. Also based on this finding of dose-proportional exposure, FDA designated the highest approved strength of Solodyn tablets, 135mg, as the reference standard against which generic versions of Solodyn must establish in vivo bioequivalence.

101. Accordingly, since at least December 2007, FDA's draft bioequivalence guidelines for Solodyn (minocycline hydrochloride) extended-release tablets, posted on FDA's website, required in vivo bioequivalence testing only for the 135mg tablets of Solodyn, but not for 45mg and 90mg tablets as long as those strengths were "proportionally similar" to the 135mg tablets. This was because Medicis had shown that the different strengths of Solodyn result in dose-proportional exposure.

102. But in its Proportionality Petition, Medicis argued the exact opposite of what it argued in obtaining approval for Solodyn, namely that FDA should not approve 45mg and 90mg strengths of any generic Solodyn products on the basis of bioequivalence testing in comparison

to the 135mg strength because, it now claimed, the 45mg and 90mg strengths of Solodyn are not dose-proportional to the 135mg strength. Indeed, Medicis went a step further, requesting 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, including the 45mg. The FDA denied this frivolous petition in February 2009.

**4. The USPTO begins reexamining the ‘838 Patent, questioning whether it ever should have been granted.**

103. In June 2008, an unidentified third party requested that the USPTO conduct an ex parte reexamination of the ‘838 Patent to determine whether certain identified prior art raised a substantial question of patentability. During an ex parte reexamination, the prior art the USPTO considers includes only patents and printed publications, not evidence or arguments regarding prior public use or sale of the claimed invention.<sup>16</sup> The Dynacin Study misrepresentations and omissions that plagued the initial application process concerned prior public use or sale of the claimed invention.

104. The third party asserted that Medicis failed to disclose three (non-Dynacin) prior art references – patents for Valorose and Doyon and information in the Physician’s Desk Reference regarding Minocin – that bore on patentability.<sup>17</sup> The USPTO began the reexamination process in August 2008.

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<sup>16</sup> 37 C.F.R. §§ 1.552(a), (c).

<sup>17</sup> The three references were: (1) Valorose, Jr. et al., U.S. Patent No. 4,837,030 (“Valorose”); (2) Doyon et al., U.S. Patent No. 5,283,065; and (3) 1989 Physician’s Desk Reference, 43<sup>rd</sup>, pp. 1134-36, MINOCIN, Minocycline Hydrochloride Oral Use.

**5. Medicis and Impax agree to enter into the Medicis/Impax Exclusion Payment Agreement to delay Impax’s generic Solodyn.**

105. 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 timely filed a notice of appeal of the motion to dismiss decision with the United States Court of Appeals for the Federal Circuit on May 12, 2008.

106. Unwilling to risk having to rely on the strength of the sure-to-be invalidated ‘838 Patent to hold off generic competition from Impax, Medicis opted to buy off Impax to keep the generic manufacturer from successfully challenging the ‘838 Patent and to insulate Legacy Strength Solodyn from generic competition.

107. As the Supreme Court recently explained in *Actavis*, Medicis’s ‘838 Patent “may or may not be valid, and may or may not be infringed. ‘[A] valid patent excludes all except its owner from the use of the protected process or product[.]’ And that exclusion may permit the patent owner to charge a higher-than-competitive price for the patented product. But an *invalidated* patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe.”<sup>18</sup> A payment by a brand company to its generic competitor “provide a workable surrogate for [the] patent’s weakness[.]”<sup>19</sup> “An unexplained large reverse payment” – like the payment at issue here – “itself would normally suggest that the patentee has serious doubts about the patent’s survival.”<sup>20</sup>

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<sup>18</sup> See *FTC v. Actavis, Inc.*, 570 U.S. \_\_\_, 133 S. Ct. 2223, 2231 (2013) (citation omitted).

<sup>19</sup> See *id.* at 2236-37.

<sup>20</sup> *Id.* at 2236. A “large” payment is one that exceeds the brand/patentee’s litigation costs saved by entering into its agreement with the generic. *Id.* The reverse payments at issue here easily meet that criterion.

108. In November 2008—with Impax continuing to press its declaratory judgment suit to invalidate the ‘838 Patent—Medicis agreed to provide Impax continuing large and unjustifiable payments in exchange for Impax’s agreement to forestall coming to market with its generic Solodyn products (the “Medicis/Impax Exclusion Payment Agreement”). The agreement allowed Medicis to preserve its dominant position in the market in exchange for sharing its supracompetitive revenues. To obscure the nature of the delay payments to Impax, the Medicis/Impax Exclusion Payment Agreement consisted of two intertwined, cross-referencing agreements, both executed on November 26, 2008: (a) a License and Settlement Agreement (including any amendments) in which Impax agreed to drop its challenge to the ‘838 Patent and keep its Legacy Strength generic Solodyn products off the market until November 2011 and (b) a Joint Development Agreement (including any amendments), specifically referenced in the License and Settlement Agreement, through which Impax received large unjustified continuing payments that far exceed the fair value for any services that may have been performed by Impax under that agreement.

109. Under the Medicis/Impax Exclusion Payment Agreement, Impax agreed to delay launching its Legacy Strength generic Solodyn products until the earlier of: (a) November 26, 2011; (b) [REDACTED] (c)

[REDACTED]

[REDACTED] or (d) [REDACTED]

[REDACTED] In other words, Impax agreed to delay the launch

of its generic Solodyn products until November 26, 2011 unless market entry of another Solodyn product triggered its right to launch earlier.

110. Impax also agreed to refrain from challenging the validity or enforceability of the ‘838 Patent as well as 297 unissued claims from twelve pending patent applications purportedly relating to Solodyn and in doing so purported to admit that its ANDA product infringed the ‘838 Patent (and the claims in the unissued patents). At the time of the agreement, Medicis had not, and could not have, sued Impax for infringement of any of the 297 claims. However, by including those claims in the agreement, Medicis was able to ensure that if any of those claims were ever included in any patent covering any Add-On Strength Solodyn product, it could use that patent to prevent Impax from using its ANDA product to compete.

111. As the quid pro quo for Impax’s agreement to delay entry of its generic Solodyn products and drop its challenge to the ‘838 Patent, Medicis agreed to pay Impax well in excess of \$40 million dollars with substantial additional payments through the Medicis/Impax Joint Development Agreement. The Joint Development Agreement purportedly covers the collaboration on and development of four generic dermatology products and an advanced form of Solodyn by Impax. However, under the terms of the Joint Development Agreement, Impax was entitled to and was paid a “non-creditable, non-refundable payment of Forty Million United States Dollars” for doing nothing more than signing the agreement (and keeping its generic Solodyn off the market). By comparison, the average costs of Hatch-Waxman patent litigation through trial has been reported as \$6 million. The upfront fee was fully non-refundable, meaning Impax kept the payment even if it did not perform under the Joint Development Agreement and even if its development efforts completely failed. This payment is far in excess of any fair value that Medicis could expect in return; it was for delayed generic entry.

112. The \$40 million non-refundable upfront fee was not the only compensation that Impax received for delaying its launch of Legacy Strength generic Solodyn. The Medicis/Impax

Joint Development Agreement further obligated Medicis to pay Impax up to \$23 million in “non-creditable, non-refundable milestone payments” listed in the agreement. The non-refundable milestone payments included payments ranging from [REDACTED]

[REDACTED] To date, Medicis has paid Impax non-refundable milestone payments totaling at least \$15 million in addition to the \$40 million upfront payment. Specifically, Medicis paid Impax milestone payments of (a) \$5,000,000 in September 2009, (b) \$2,000,000 in December 2009, and (c) \$3,000,000 in March 2011. These non-refundable milestone payments are well in excess of the fair value of any services performed by Impax under the agreement. In fact, the preparation and filing costs associated with a typical ANDA are no more than between \$300,000 and \$1,000,000.<sup>21</sup> The payments were made to compensate Impax for continuing to keep its Legacy Strength generic off the market until November 2011.

113. In addition to the non-refundable \$40 million upfront fee for doing nothing and the excessive, unjustifiable and non-refundable milestone payments for, among other things, [REDACTED] the Medicis/Impax Joint Development Agreement included significant royalties for Impax if [REDACTED] If Impax [REDACTED] would receive generous royalties to more than sufficiently compensate it for its efforts; the non-refundable upfront fee and milestone payments instead compensate Impax for delaying the launch of its Legacy Strength generic. According to its August 6, 2014 10-Q, Impax began

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<sup>21</sup> See <http://media.law.stanford.edu/publications/archive/pdf/ssrn-id1736822.pdf> (at p. 5, n. 11).

selling one of four generic products contemplated by the Joint Development Agreement in 2011 and shares gross profits with Valeant on sales of such products.

114. Additionally, the Medicis/Impax License and Settlement Agreement included a promise from Medicis that Impax could sell an authorized generic of 65mg and 115mg Solodyn when a generic of those strengths reached the market.

115. As specifically contemplated by that agreement, on November 13, 2009, Impax and Medicis entered into a Distribution and Supply Agreement whereby Medicis agreed to supply Impax with the authorized generic product at little more than cost and Impax was permitted to pocket [REDACTED] of the 65mg and 115mg AG Solodyn sold in the United States. This arrangement protected Impax from Medicis's plans to switch the Solodyn market from the Legacy Strengths of Solodyn to the Add-On Strengths during the delay period that Medicis bought through the Medicis/Impax Exclusion Payment Agreement. It ensured Impax would be able to sell a generic of some strength of Solodyn at some future time, even if Medicis eliminated or otherwise impaired the opportunity for generic sales of the Legacy Strengths through a market switch. Notably, if Impax breaches the License and Settlement Agreement—by launching its generic earlier than November 2011, for instance—Medicis can cancel the Distribution and Supply Agreement. All of these payments pursuant to the Distribution and Supply Agreement were due to Impax well after the execution of the Medicis/Impax Exclusion Payment Agreement.

116. All of these benefits had substantial value to Impax and are compensation that it could not have obtained even if it had litigated and won the '838 Patent case. These payments caused Impax to agree to stay out of the market longer than it otherwise would have done. Medicis agreed to and did pay Impax to delay entry into the market.

117. In the years that followed entry of the Medicis/Impax Exclusion Payment Agreement, Impax continued to receive those payments and continued with its commitment not to launch a generic equivalent of Legacy Strength Solodyn until November 26, 2011.

118. The large unjustified payments of at least \$55 million from Medicis to Impax pursuant to the Medicis/Impax Exclusion Payment Agreement serve no purpose other than to compensate Impax from keeping its generic Solodyn product off the market until November 2011, allowing the parties to share Medicis's Solodyn monopoly profits and buying time for Medicis to launch its Add-On Strengths of Solodyn. There are no procompetitive justifications for those payments, which are well in excess of any limited value—other than the delay of generic Solodyn—provided by Impax under the agreement. Furthermore, the \$40 million non-refundable upfront payment and up to \$23 million in non-refundable milestone payments far exceed any approximation of the costs to Medicis of continuing to litigate the Impax declaratory judgment action. Additionally, Medicis and Impax cannot establish that those large payments were in consideration for the fair value of any services provided by Impax to Medicis. Indeed, Impax was not required to provide any services (other than its own delayed generic entry) in exchange for the non-refundable \$40 million upfront payment. Furthermore, the large unjustified non-refundable milestone payments for developing ANDAs of between [REDACTED] owed and paid to Impax by Medicis dwarf the \$300,000 to \$1,000,000 preparation and filing costs associated with a typical ANDA and are therefore far in excess of the fair value for any services provided by Impax.

119. Absent Medicis's unlawful continuing payments to Impax under the Medicis/Impax Exclusion Payment Agreement, Medicis and Impax would have settled in a manner less restrictive of competition, such as an earlier agreed entry date, resulting in much less

delay of Impax's generic entry. Under such an agreement, or even without one (such as with a launch by Impax after it received final FDA approval or launch after a court ruling in Impax's favor), Impax would have launched its generic Legacy Strength Solodyn substantially earlier than November 2011.

120. Since Valeant's acquisition of Medicis, Impax has stated, in its annual reports and SEC filings, that its Joint Development Agreement is "with Valeant Pharmaceuticals International, Inc.," and that it receives payment from Valeant pursuant to the Joint Development Agreement.

**E. In 2009, Medicis continues the scheme, filing baseless patent infringement suits against multiple potential generic competitors, misleading the USPTO again, and entering an Exclusion Payment Agreement with a second conspirator.**

**1. Medicis improperly lists the '838 Patent in FDA's Orange Book and sues three ANDA filers, sparing only Impax because of the Medicis/Impax Exclusion Payment Agreement.**

121. On October 8, 2008, Congress enacted the QI Act, which amended the FDCA to create select Hatch-Waxman provisions for "old" antibiotics, including minocycline, permitting the listing of relevant patents in the Orange Book by NDA holders (affording them the benefits of the provisions of the Hatch-Waxman Act) and allowing ANDA filers who add a Paragraph IV certification of non-infringement, invalidity, or unenforceability of a newly listed antibiotic drug patent to receive a first filer status (for 180-day exclusivity purposes), even if that results in multiple ANDA filers with first filer status.

122. Although the QI Act made the Orange Book patent listing provisions of Hatch-Waxman generally applicable to old antibiotics like Solodyn, any such patents still had to meet all of the other requirements for Orange Book listing, i.e. the patent must be valid and

enforceable. Medicis knew the '838 Patent was neither but, on December 3, 2008, submitted it to FDA for Orange Book listing anyway as part of its plan to delay generic competition.

123. Before passage of the QI Act in 2008, the Paragraph IV and 30-month stay provisions of Hatch-Waxman did not apply to Solodyn. For any ANDA on file before December 3, 2008, when Medicis listed the '838 Patent in the Orange Book, Medicis was not entitled to and 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 the Paragraph IV certification.

124. After improperly listing the '838 Patent in the Orange Book, Medicis received timely Paragraph IV notifications from multiple generic manufacturers amending their ANDAs for generic Solodyn products. Those Paragraph IV notifications each contained certifications that the '838 Patent was invalid, unenforceable and/or would not be infringed by the respective generic products.

125. On or about December 5, 2008, Mylan served a notice letter regarding its Paragraph IV certification for ANDA 09-0911 for 45mg, 90mg, and 135mg extended release minocycline hydrochloride tablets.

126. On or about December 8, 2008, Sandoz served a notice letter regarding its Paragraph IV certification for ANDA 09-0422 for 45mg, 90mg, and 135mg extended release minocycline hydrochloride tablets.

127. On or about December 12, 2008, Impax served a notice letter regarding its Paragraph IV certification for its ANDA for 45, 90, and 135 mg extended release minocycline hydrochloride tablets. Of course, Medicis and Impax had already entered into the Medicis/Impax Exclusion Payment Agreement by this time. Impax served the Paragraph IV

notice to preserve its first-to-file status, which would allow it to launch if another generic manufacturer successfully invalidated the '838 Patent.

128. On or about December 23, 2008, Teva Pharmaceuticals USA, Inc. ("Teva") served a notice letter regarding its Paragraph IV certification for ANDA 64-485 for 45mg, 90mg, and 135mg extended release minocycline hydrochloride tablets. The notice letter was submitted by Barr Pharmaceuticals, which, as of December 23, 2008, became a wholly owned subsidiary of Teva.

129. Because Mylan, Sandoz, Impax, and Teva had each timely submitted a Paragraph IV certification to the newly-listed '838 Patent, these four generic manufacturers shared 180-day exclusivity for the 45mg, 90mg, and 135mg strengths of generic Solodyn.

130. On January 13, 2009, Medicis filed suit against Mylan, Teva, and Sandoz in the United States District Court for the District of Delaware, claiming infringement of the '838 Patent. At that time, the USPTO was in the process of reexamining the '838 Patent and would, within two months, reject all of the original claims in the '838 Patent. Because Mylan, Teva, and Sandoz each filed a Legacy Strength ANDA before December 3, 2008, the 30-month Hatch-Waxman stay of FDA approval did not apply to any of Medicis's meritless suits; the lack of the automatic stay did not make the actions any less of a sham, however.

131. No reasonable litigant could have realistically expected to succeed on Medicis's claims that Mylan, Teva, Sandoz—or any generic manufacturer—infringed the invalid and unenforceable '838 Patent. Medicis filed and prosecuted the '838 Patent infringement suits to unlawfully delay generic competition.

132. Medicis commenced the lawsuits against Teva, Sandoz, and Mylan not with any reasonable expectation of obtaining a favorable outcome on the merits of the claims, but with the

wrongful intent to achieve an anticompetitive result and maintain its monopoly position through the improper use of the judicial process and the settlement of those suits.

**2. FDA denies Medicis’s frivolous Proportionality Petition and FDA subsequently approves Impax’s ANDA, but Impax does not launch pursuant to the Medicis/Impax Exclusion Payment Agreement.**

133. On February 3, 2009, FDA denied Medicis’s Proportionality Petition, explaining 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.” FDA also noted that Solodyn’s own labeling states that “[a] single-dose, four-way 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, 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.”

134. The same day that FDA denied Medicis’s Proportionality Petition, February 3, 2009, FDA gave final approval to Impax’s ANDA for generic 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets.

135. Impax, however, did not launch its generic versions of the Solodyn Legacy Strengths that day. 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—as agreed to in the Medicis/Impax Exclusion Payment Agreement, Impax delayed its entry into the market for almost three years, until November 26, 2011 (though, as discussed below, entry at that late date was practically worthless to consumers because Medicis moved the market to the Add-On Strengths).

136. 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.

**3. Medicis files a second frivolous petition that is swiftly disposed of by FDA.**

137. Just ten days after FDA denied Medicis's frivolous Proportionality Petition, on February 13, 2009, Medicis—attempting to leverage its recently-filed sham patent suits against Teva, Sandoz, and Mylan—submitted a second 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 notice: (a) the ANDAs submitted by Mylan, 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”).

138. On March 17, 2009, FDA swiftly 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.”

**4. Medicis keeps Teva from opening the floodgates of generic competition to Legacy Strength Solodyn.**

139. FDA approved Teva’s generic Solodyn ANDA on March 17, 2009, the same date it denied Medicis’s 30-Month Stay Petition. Teva commenced shipment of its generic Solodyn product immediately after receiving FDA’s approval of its ANDA.



Medicis/Impax Exclusion Payment Agreement, it was permitted to come to market in March 2009 when Teva launched. However, Impax did not come to market in March or May of 2009, but instead accepted an additional [REDACTED] from Medicis to dismiss the lawsuit in June 2009 and to continue to stay off the market and abide by the Medicis/Impax Exclusion Payment Agreement.

**6. Upon reexamination, the USPTO rejects all 18 of ‘838 Patent’s original claims. Medicis responds with further omissions and misrepresentations.**

144. On March 13, 2009, the USPTO issued a Non-Final Office Action rejecting claims 1-18 of the ‘838 Patent – all of the claims – as anticipated by, and/or obvious in light of, the prior art references cited by the third party in its request for ex parte reexamination.

145. Medicis replied on May 13, 2009, with a narrative response and a declaration under oath by Jonah Shacknai, Medicis’s CEO, to attempt to convince the USPTO to overturn the rejection. Both the Shacknai Declaration and the narrative contained numerous willful and knowing omissions and misrepresentations of fact.

146. For example, Shacknai falsely stated that before the launch of Solodyn and the filing of the ‘838 Patent, “practitioners generally believed that the use of slower-dissolving minocycline rather than a faster-dissolving form would only decrease the effectiveness of the minocycline without any commensurate reduction in vestibular side effects.”<sup>22</sup> But Shacknai cited literature from 1977 – more than a decade before Medicis started selling Dynacin, two decades before the Dynacin Study demonstrated that Dynacin’s slower dissolving form would significantly decrease vestibular side effects, and two decades before Medicis used the Dynacin

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<sup>22</sup> Declaration of Jonah Shacknai Under 37 C.F.R. § 1.132, May 12, 2009 at ¶ 13 (“Shacknai Declaration”).

Study to promote Dynacin to practitioners as producing fewer vestibular effects because of its slower dissolution profile and without any reduction in efficacy.

147. Elsewhere, Mr. Shacknai stated that “[p]rior to the filing of the ‘838 Patent, the only oral dosage form of minocycline approved by the FDA was the faster-dissolving immediate release form.”<sup>23</sup> But Mr. Shacknai, Dr. Gans, and Medicis knew that Dr. Gans characterized Dynacin as a “regulated release” product in the Medicis-funded, Medicis-published Dynacin Study and that Dynacin was the “slower-dissolving minocycline” product reported in the ‘838 Patent.

148. Mr. Shacknai told the USPTO that “dermatologists treating acne would not have used a dosage form that was slower dissolving than known faster-dissolving forms of minocycline prior to the filing of the ‘838 patent because the administration of such a slower-dissolving form of minocycline would not have been expected to be as effective for acne treatment.” *Id.* ¶18. In fact, however, Mr. Shacknai, along with Medicis, Dr. Gans and/or the prosecuting attorney, knew that Dynacin—which had been prescribed by dermatologists since at least 1993—was slower-dissolving, as represented in the Dynacin Study and in the ‘838 Patent, and as effective as faster-dissolving products.

149. Mr. Shacknai further misled the USPTO, stating that “[c]ontrary to the expectations of such practitioners, large properly controlled human clinical trials of Solodyn have confirmed that methods of acne treatment using the slower-dissolving minocycline forms in the ‘838 patent are in fact effective for the treatment of acne” (*id.* at ¶21) – while omitting that Dynacin was a slower-dissolving minocycline product that was known to be effective for the treatment of acne.

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<sup>23</sup> *Id.* at ¶16.

150. Mr. Shacknai claimed that “at least one [prior art] reference strives for rapid release of minocycline, particularly in the more neutral regions of the small intestine, because such minocycline forms ‘can be better tolerated in terms of CNS side effects’” (*id.*) – while omitting that Medicis sold its slower-dissolving Dynacin since at least 1993 and promoted it to dermatologists by telling them that Dynacin’s slower dissolution profile reduced vestibular effects five-fold.

151. Additionally, Mr. Shacknai stated that “[c]ontrary to the expectations of such practitioners, a lower incidence of side effects was experienced by the individuals using the slower-dissolving minocycline forms of the ‘838 patent during the human clinical trials of Solodyn” (*id.* at ¶24) – while omitting that a lower incidence of side effects was experienced by individuals using Dynacin during the Dynacin Study.

152. Medicis incorporated the above misrepresentations and omissions by Mr. Shacknai into its May 13, 2009 narrative response to the USPTO’s March 13, 2009 Office Action.

153. Medicis went further, stating in the May 13, 2009 narrative response that “the benefits of the inventions claimed in the ‘838 Patent are embodied in the use of Medicis’s commercially available Solodyn product”<sup>24</sup> while omitting that the benefits of the inventions claimed in the ‘838 Patent are embodied in the use of Medicis’s Dynacin product, which was commercially available as early as 1993.

154. In addition, Medicis told the USPTO that “Solodyn solved this long felt need because patients were able to use a slower-dissolving form of minocycline that was effective for the treatment of acne while at the same time reducing the incidence and/or severity of vestibular

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<sup>24</sup> May 13, 2009 Reply to Office Action in Ex Parte Examination at 16.

side effects.” *Id.* at 18. In fact, however, Medicis knew that Dynacin was the product that established that patients could use a slower-dissolving form of minocycline that was effective for the treatment of acne while at the same time reducing the incidence and/or severity of vestibular side effects

155. Although Medicis belatedly submitted the Dynacin study to the USPTO in connection with the reexamination, it buried the study amongst 180 references supplied to the examiner in a February 20, 2009 Information Disclosure Statement from Medicis. Medicis did not specifically bring the Dynacin Study to the examiner’s attention or disclose the truth regarding the study data included in the specification of the ‘838 Patent. As the examiner explained in the November 10, 2009 Office Action regarding the ‘838 Patent, “the requisite degree of consideration to be given to [information submitted by the patentee] will be normally limited by the degree to which the party filing the information citation has explained the content and relevance of the information.”

**7. Medicis and Sandoz conspire, entering into the Medicis/Sandoz Exclusion Payment Agreement to delay Sandoz’s generic product.**

156. 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 its ANDA for Legacy Strength (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 Legacy Strength Solodyn products. Sandoz immediately launched its Legacy Strength generic Solodyn upon approval even though the Medicis patent infringement suit was still pending.

159. Within days, 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 which time Sandoz stopped selling its generic Solodyn product. At the time of the Medicis/Sandoz Exclusion Payment Agreement, the parties had not briefed and the court had not adjudicated the merits of Medicis's sham infringement suit. Rather than continue to litigate and watch its '838 Patent be invalidated and Solodyn monopoly destroyed, Medicis opted instead to buy off Sandoz to insulate Legacy Strength Solodyn from generic competition.

160. Pursuant to the Medicis/Sandoz Exclusion Payment Agreement, Sandoz agreed to: (a) stop selling its generic Solodyn products; (b) delay resuming selling its Legacy Strength generic Solodyn products until November 26, 2011, or earlier under certain circumstances, [REDACTED] and [REDACTED] and (c) not launch an Add-On Strength generic product until [REDACTED] [REDACTED]

[REDACTED] Sandoz also agreed to acknowledge the validity and enforceability of the claims in the '838 Patent, two other patents and unissued claims in eleven patent applications—which was contrary to the positions taken by Sandoz during the '838 Patent litigation. The agreement allowed Medicis to preserve its monopoly position in exchange for sharing its supracompetitive revenues. At the time of the agreement, Medicis had not sued Sandoz for infringement of any patent other than the '838 Patent and did not, and could not have sued Sandoz for infringement of any of the unissued claims. But by including claims from the unissued patents (and for

patents that were not subject to the lawsuit) in the agreement, Medicis ensured that if any of those claims were ever included in any patent covering any Add-On Strength Solodyn product, it could prevent Sandoz from competing with the Add-On Strengths.

161. As the quid pro quo for Sandoz's agreement to drop its challenge to the '838 Patent and delay entry of its Legacy Strength generic Solodyn products until November 2011, Medicis agreed to make large, unjustified and continuing payments to Sandoz.

162. The Medicis/Sandoz Exclusion Payment Agreement includes several intertwined agreements and amendments thereto. First, on August 18, 2009, Medicis and Sandoz executed a Settlement Agreement and Mutual Release ("Medicis/Sandoz Settlement Agreement") settling their '838 Patent litigation and resulting in Sandoz halting its sales of Legacy Strength generic Solodyn. The Settlement Agreement includes commitments from Medicis and Sandoz to negotiate and finalize what the parties euphemistically call a patent license and business partnership agreement, but which really sets forth the terms of Medicis's payments to Sandoz for Sandoz agreeing to stay off the market for two years plus until November 2011. The basic parameters of those payments and the terms of the later-executed agreements are set out in exhibits to the Medicis/Sandoz Settlement Agreement.

163. As agreed to in the Medicis/Sandoz Settlement Agreement on November 27, 2009, the parties executed an Asset Purchase Agreement. Pursuant to the Asset Purchase Agreement, Medicis agreed to pay Sandoz over [REDACTED] [REDACTED] for which there was no viable market because the brand manufacturer of the reference listed drug, Warner Chilcott, had pulled its [REDACTED] from the market and switched to [REDACTED] four years before Medicis and Sandoz entered into their agreement. Sandoz's [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Hence, [REDACTED] was worth little or nothing. Yet, the Asset Purchase Agreement obligated Medicis to (i) pay Sandoz [REDACTED] cash upfront for the virtually worthless [REDACTED] (ii) [REDACTED] [REDACTED] and (iii) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

164. These payments to Sandoz are in addition to Medicis’s agreement in the Medicis/Sandoz License Agreement—also executed on November 27, 2009 pursuant to the Medicis/Sandoz Settlement Agreement—to “pay to Sandoz an amount equal to Sandoz’s total, reasonable and out-of-pocket attorneys fees and costs, including, but not limited to, the costs of any expert(s) and/or consultant(s), incurred by Sandoz in connection with the action captioned *Medicis Pharms. Corp. v. Sandoz, Inc., et al.*, 09-033-JJF in the U.S. District Court for the District of Delaware.” Notably, this is not an agreement by Medicis to pay to Sandoz an amount approximating the attorneys’ fees and costs Medicis would incur if the litigation would continue, but is instead a commitment to make an uncapped payment covering Sandoz’s attorneys’ fees and costs.

165. All of these benefits had substantial value to Sandoz, and other than the attorneys’ fees, are compensation that it could not have obtained even if it had litigated and won the patent case. And these payments caused Sandoz to agree to stay out of the market longer than it

otherwise would have done. Medicis agreed to and did pay Sandoz to delay Sandoz's launch of its generic version of Solodyn in Legacy Strengths.

166. The large, unjustified payments from Medicis to Sandoz pursuant to the Medicis/Sandoz Exclusion Payment Agreement serve no purpose other than to compensate Sandoz for keeping its generic Solodyn product off the market until November 2011, allowing the parties to share Medicis's Solodyn monopoly profits and buying time for Medicis to launch its Add-On Strength Solodyn products. There are no procompetitive justifications for those payments which are well in excess of any limited value—other than the delay of generic Solodyn—provided by Sandoz under the agreement. The more than [REDACTED] paid by Medicis to Sandoz for Sandoz's [REDACTED] far exceeds any approximation of the costs to Medicis of continuing to litigate the '838 Patent litigation. The uncapped reimbursement for the fees and costs Sandoz incurred in defending the '838 Patent litigation are in no way tied to and are likely in excess of the costs to Medicis of continuing to litigate the '838 Patent litigation (where the only savings are for the incremental costs of including Sandoz in Medicis's continuing lawsuit against Mylan). Medicis and Sandoz cannot establish that those large payments were in consideration for the fair value of the ANDA rights and generic Doryx capsules provided by Sandoz to Medicis because the market for those capsules had collapsed years before the Asset Purchase Agreement was executed. Indeed, to date, Medicis has not sold a single [REDACTED]. The [REDACTED] paid to Sandoz was to compensate Sandoz for keeping its generic Solodyn off the market, not for the right to sell generic Doryx capsules.

167. Absent Medicis's unlawful payments to Sandoz under the Medicis/Sandoz Exclusion Payment Agreement, Medicis and Sandoz would have settled in a manner less restrictive of competition, resulting in much less delay of Sandoz's generic entry. Under such an

agreement, or even without one (for instance, a launch upon receiving FDA approval—as Sandoz did here—or launch after a court ruling in Sandoz’s favor), Sandoz would have launched and kept on the market its generic Legacy Strength Solodyn substantially earlier than November 2011.

**F. In 2010 and 2011, Medicis caps off the scheme, settling its sham litigation against potential generic competitors, entering into additional Exclusion Payment Agreements to delay generic competition, and impairing the market for the Legacy Strengths.**

**1. Medicis’s misrepresentations and omissions to the USPTO work and the agency reissues the ‘838 Patent, but with all new or amended claims**

168. Medicis continued to undergo ex parte reexamination of the ‘838 Patent through 2009 and into 2010. During the reexamination, Medicis acknowledged that none of the original claims could stand and instead moved to cancel several of the original (and, as of March 2009, tentatively rejected) claims in the ‘838 Patent, amended others, and added new claims 19-34.

169. On November 11, 2009, the USPTO rejected amended claims 3, 4, 12 and 13 and new claims 19-34 of the ‘838 Patent. Among other things, the examiner found that it would have been obvious to use the slow-release formulations of minocycline disclosed by Valorose to treat acne while reducing the well-known vestibular side effects of minocycline.

170. On January 8, 2010, Medicis filed a reply to the November 10, 2009 Office Action. Medicis argued, inter alia, that (a) the Valorose reference did not teach the administration of minocycline pursuant to a method of reducing vestibular side effects resulting from the treatment of acne, or a slowly dissolving dosage form as measured under standard U.S. Pharmacopeia test conditions; and (b) it would not have been obvious to use the minocycline dosage forms disclosed in Valorose in treating acne because only “*rapidly dissolving* dosage

forms” had been known to treat acne and Valorose did not involve testing at standard U.S. Pharmacopeia conditions.<sup>25</sup>

171. In its attempt to distinguish the prior art, Medicis did not disclose to the examiner that slower-dissolving Dynacin had been on sale since at least 1993 for the treatment of acne, and Dynacin produced less vestibular effects than other minocycline hydrochloride products due to its slower dissolution – as demonstrated by the Dynacin Study, Medicis’s promotional materials related to the Dynacin Study, and the data reported in the ‘838 Patent.

172. Medicis’s statement that only rapidly dissolving dosage forms of minocycline had been used in the prior art to treat acne was unmistakably false.

173. On March 11, 2010, the USPTO reversed course and issued its Reasons for Patentability/Confirmation, finding claims 3, 4, 12, 13 and 19-34 were not obvious over the prior art Valorose reference. On June 1, 2010, the USPTO issued the Ex Parte Reexamination Certificate for the ‘838 Patent with four amended and sixteen new claims.

174. In connection with the reexamination of the ‘838 Patent, Mr. Shacknai, 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. A reasonable examiner would have considered each of these misrepresentations and deliberate omissions material to the patentability of the claims of the ‘838 Patent and would not have reissued the ‘838 Patent knowing the truth, including the existence of Dynacin as prior art.

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<sup>25</sup> Jan. 8, 2010 Reply at 13 (emphasis in original).

**2. Medicis keeps Mylan from starting generic Legacy Strength Solodyn competition earlier than Impax and Sandoz agreed.**

175. Medicis had also sued Mylan on January 13, 2009, 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.

176. On July 20, 2010, FDA granted Mylan final approval to market its generic 45mg, 90mg, and 135mg Legacy Strength Solodyn products. Mylan immediately launched its Legacy Strength generic Solodyn products.

177. On July 22, 2010, Medicis and Mylan entered into an agreement settling the litigation (the “Mylan Settlement Agreement”). Pursuant to that agreement, Mylan agreed to: (a) stop selling its 45mg, 90mg, and 135mg generic Solodyn products; (b) delay resuming selling those Legacy Strength generic Solodyn products until November 2011, or earlier under certain circumstances; and (c) delay launching its generic Solodyn products in 65mg and 115mg strengths until [REDACTED]

[REDACTED] Mylan also agreed to refrain from challenging the validity or enforceability of the ‘838 Patent, the claims in two other patents and 10 pending patent applications solely with regard to Mylan’s Solodyn ANDA products.

178. Medicis agreed to release Mylan from any purported liability for its abbreviated launch of its generic Solodyn products and paid Mylan [REDACTED]

[REDACTED]<sup>26</sup>

**3. Medicis again pays Impax in January 2011 to continue to stay off the market and maintain the Medicis/Impax Exclusion Payment Agreement**

179. As noted above, under the Medicis/Impax Exclusion Payment Agreement, Medicis agreed [REDACTED]

[REDACTED] If Medicis authorized another generic manufacturer to sell such generic Solodyn products before Impax's licensed entry date of November 2011, Impax [REDACTED]

[REDACTED] As it did with regard to the abbreviated Teva launch in 2009, Impax filed suit against Medicis [REDACTED]

180. Subsequent to the Medicis/Sandoz Exclusionary Payment Agreement and just days after Medicis settled with Mylan, on July 27, 2010, Impax filed suit against Medicis in the Superior Court of the State of Arizona in and for the County of Maricopa alleging that Impax's right to launch its generic Solodyn product had been triggered by Sandoz's and Mylan's generic Solodyn sales. It was Impax's view that under the terms of the Medicis/Impax Exclusion Payment Agreement, it was permitted to come to market as early as August 2009 when Sandoz launched its generic Solodyn product. But, Impax did not come to market in August 2009 when Sandoz launched or in July 2010 when Mylan launched. Nor did Impax launch after pursuing its

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<sup>26</sup> On May 4, 2010, Medicis settled with Ranbaxy, Inc. and Ranbaxy Laboratories Limited (collectively, "Ranbaxy"), who were sued for infringement of the '838 Patent, on similar terms, securing Ranbaxy's agreement to (a) delay launching its generic Solodyn products in the 45mg, 90mg, and 135mg strengths until November 2011, or earlier under certain circumstances and (b) delay launching its generic Solodyn products in the 65mg and 115mg strengths until after Teva launched its generic versions of those products.

lawsuit against Medicis to resolution. Instead, on January 21, 2011, in an affirmative act in continuation of the conspiracy with Medicis under the Medicis/Impax Exclusion Payment Agreement, Impax dismissed the state litigation against Medicis, accepting an additional [REDACTED] [REDACTED] from Medicis for renewing its commitment to keep its Legacy Strength generic Solodyn off the market—insulating Medicis from competition not only from Impax, but Sandoz, Teva and Mylan (all of whom could launch if Impax launched) as well—until November 2011. This overt act furthered and reaffirmed the conspiracy between Medicis and Impax to delay generic competition for the Legacy Strengths of Solodyn.

181. The agreement settling Impax’s Arizona litigation against Medicis explicitly referenced and indeed, amended the Impax/Medicis Joint Development Agreement, demonstrating the clear interdependent relationship between the Medicis/Impax License and Settlement Agreement and Joint Development Agreement in forming the Medicis/Impax Exclusion Payment Agreement. In total, pursuant to and in furtherance of the Medicis/Impax Exclusion Payment Agreement, Medicis paid Impax a total of [REDACTED] consisting of (a) a \$40 million non-refundable upfront payment, (b) \$15 million in milestone payments and (c) [REDACTED] [REDACTED] in payments to compensate Impax for continuing to stay off the market despite the abbreviated launches of Teva, Sandoz and Mylan—to keep its generic Solodyn product off of the market. Additionally, Impax is entitled to up to an additional \$8 million in milestone payments and royalties on the sales of various future products and [REDACTED] of 65mg and 115mg Solodyn authorized generic sales.

**4. Medicis battles other potential generic competitors over the invalid and/or unenforceable ‘838 Patent.**

182. 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 Legacy Strengths. Lupin's Paragraph IV certification stated that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic products.

183. 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 its ANDA for 45mg, 90mg, and 135mg Solodyn. Because Lupin filed its ANDA after passage of the QI Act and the '838 Patent was by then listed in the Orange Book, this sham suit triggered the automatic 30-month Hatch-Waxman stay.

184. On November 24, 2009 (as to the 65 mg) and December 23, 2009 (115 mg), Lupin served Medicis with Paragraph IV notices regarding the amendment or supplement of its ANDA to cover additional these strengths of Solodyn, each time asserting that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product. Medicis responded by amending its baseless complaint to cover those strengths as well.

185. On March 4, 2010, Lupin answered Medicis's complaint, asserting defenses of non-infringement, 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.

186. After the USPTO issued the Ex Parte Reexamination Certificate for the '838 Patent, Medicis doubled down, filing a third amended complaint on July 1, 2010, alleging that Lupin infringed the '838 Patent as amended pursuant to the June 1, 2010 Ex Parte Reexamination Certificate.

187. As early as April 2007, Medicis engaged in extensive efforts to convince the USPTO to issue additional patents ostensibly covering Solodyn that Medicis could use to pursue

additional lawsuits against generic filers—particularly those seeking to market Add-On Strength generic products. One such patent, U.S. Patent No. 7,790,705 titled “Minocycline Oral Dosage Forms for the Treatment of Acne” (the “’705 Patent”), was issued on September 7, 2010. The ‘705 Patent covers the method of use of dosing extended release minocycline hydrochloride according to weight to prevent some adverse effects. This method of use was well-known; indeed, Medicis sold Solodyn in several strengths for this reason. Medicis submitted the application for the ‘705 Patent on October 17, 2008 (just before Medicis bought off Impax); the ‘705 Patent is set to expire in 2025.<sup>27</sup>

188. On September 9, 2010, just two days after the ‘705 Patent was issued, Medicis had the ‘705 Patent listed in the Orange Book for Solodyn in 45mg, 65mg, 90mg, 115mg, and 135mg strengths, aiming to use the weak patent to sue generic filers to further delay entry of generic Solodyn.

189. 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 its ANDA did not infringe the ‘705 Patent. On cue, 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 on October 18, 2010. As the ‘705 Patent was listed in the Orange Book after Lupin filed its ANDA, it could not result in a 30-month stay.

190. Thereafter, the pattern continued. On December 3, 2010 (as to the 55mg and 80mg) and January 24, 2011 (105mg), Lupin served Medicis with Paragraph IV notices

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<sup>27</sup> Medicis also obtained U.S. Patent No. 7,541,347 (issued on June 2, 2009) (the “’347 Patent”), and U.S. Patent No. 7,544,373 (issued June 9, 2009) (the “’373 Patent”) each of which purportedly cover the use of the 90mg controlled-release oral dosage form of minocycline to treat acne. Medicis has never sued a generic manufacturer for infringement of either of these patents.

regarding the amendment or supplement of its ANDA to cover additional strengths of Solodyn, each time asserting that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product and that the '705 Patent would not be infringed. Medicis responded by amending its baseless complaint to cover those strengths as well on January 10, 2011 (55mg and 80mg) and March 2, 2011 (105mg), alleging that Lupin's 105mg generic Solodyn product would infringe the '838 and '705 Patents.

191. Like the suits before it, no reasonable litigant could have realistically expected Medicis to succeed on its claims that Lupin had infringed the invalid and unenforceable '838 Patent. Medicis filed and prosecuted the '838 Patent infringement suits solely to delay generic competition.

**5. Medicis uses the delay it bought to switch the market from the Legacy Strengths to the Add-On Strengths of Solodyn, greatly reducing generic Legacy Strengths sales when they belatedly entered the market.**

192. Through the various anticompetitive tactics described above, which successfully delayed the onset of unrestrained generic competition to Medicis's Legacy Strength Solodyn until November 2011, Medicis literally bought itself time to switch the market for those strengths to Add-On Strength Solodyn (i.e., 55mg, 65mg, 80mg, 105mg, and 115mg) that did not face imminent generic competition.

193. On February 29, 2008, Medicis had submitted a supplemental NDA # 50-808/S-007 to FDA seeking approval to market Solodyn in the 65 mg and 115 mg strengths. On July 23, 2009, FDA approved Medicis's application. In August 2010, FDA also approved a supplemental NDA # 50-808/S-013 revising the Solodyn label to include the 55mg, 80mg, and 105mg strengths.

194. A key benefit to the Add-On Strengths from Medicis's perspective was that the Legacy Strength generics finally set to come to market in November 2011 would not be "AB-rated" to brand Add-On Strength Solodyn, and therefore pharmacists could not automatically substitute less-expensive generic Solodyn in one of the Legacy Strengths for Add-On Strength prescriptions. Such automatic substitution of less-expensive AB-rated generics at the pharmacy counter is the primary means by which generic competition reduces drug costs.

195. Engaging in the anticompetitive behavior described herein was critical to Medicis's ability to successfully move the Solodyn market from the Legacy Strengths to the Add-On Strengths. Medicis needed to delay Legacy Strength generic entry until after it gained FDA approval to market Solodyn in the Add-On Strengths and had some time to launch and market those new strengths. It is well known in the pharmaceutical industry that if generic versions of the original brand product (here, the Legacy Strengths) enter the market before the brand follow-on product (here, the Add-On Strengths), the brand follow on product will make very few sales compared to a situation in which launch of the original generic is delayed until after launch of the follow-on brand product. For example, one brand manufacturer estimated that it would make ten times more sales on its brand follow-on product if it beat generic versions of the original product onto the market.<sup>28</sup> Similarly, in a detailed inquiry into the pharmaceutical industry, the European Commission concluded that "it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity."<sup>29</sup> Industry analysts in the United States echo that conclusion, warning brand

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<sup>28</sup> Shadowen, Steve D. and Leffler, Keith B. and Lukens, Joseph T., *Anticompetitive Product Changes in the Pharmaceutical Industry* (October 10, 2010). *Rutgers Law Journal*, Vol. 41, No. 1-2, Fall/Winter 2009 at 52.

<sup>29</sup> European Commission, *Final Report*, p. 356 (8 July 2009), available at [http://www.europa-nu.nl/id/vi6wej7amsx3/pharmaceutical\\_sector\\_inquiry\\_fianl?start-006-00c=10](http://www.europa-nu.nl/id/vi6wej7amsx3/pharmaceutical_sector_inquiry_fianl?start-006-00c=10).

manufacturers that “it is essential that the brand holder switch their patients to the new formulation prior to generic launch.”<sup>30</sup>

196. It was also known in the pharmaceutical industry that for Medicis’s product switch strategy to work, it needed to switch the market to the Add-On Strengths sufficiently in advance of generic Legacy Strength competition in November 2011 and that Medicis’s Exclusion Payment Agreements with Impax and Sandoz and settlements of the sham litigations against Teva and Mylan 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.

197. Once Medicis had approval for the 65mg and 115mg Add-On Strengths, but before Legacy Strength generics came to market because of the various agreements, Medicis worked to eliminate prescriptions for Legacy Strength Solodyn, converting those prescriptions to the new Add-On Strengths by discontinuing sales of the Legacy Strengths and by using its army of sales force detailers.

198. Medicis’s CEO Shacknai confirmed that strategy, which included pulling Legacy Strength Solodyn altogether in July 2011, in an August 8, 2011 earnings call, explaining that Medicis’s purpose in withdrawing the Legacy Strengths from the market was to “deplete channel

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<sup>30</sup> Stephen Perrett, *The Modified-Release Drug Delivery Landscape: The Commercial Perspective*, in II MODIFIED-RELEASE DRUG DELIVERY TECHNOLOGY 1, 3 (Michael J. Rathbone et al. eds., 2d ed. 2008).

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 Add-On Strengths and withdrawal of the Legacy Strengths would “have the effect of reducing the impact significantly of generic launches at the end of November 2011.”

199. As a result, by the time generic Solodyn became available in November 2011, the prescription base for those strengths was virtually non-existent.

200. Of course, Medicis’s ability to switch the market from the Legacy Strengths to the Add-On Strengths was dependent on the delayed launch—until November 2011—of Legacy Strength generics. Absent the anticompetitive conduct that delayed generic entry of generic Legacy Strength products, the switch of the Solodyn prescription base would either have not occurred at all or been unsuccessful because the availability of Legacy Strength generics would have significantly impinged on Medicis’s market shifting efforts.

201. But for Medicis’s unlawful exclusion payment agreements and other anticompetitive conduct, generic Solodyn would have been available long before November 2011, and Medicis would not have launched the Add-On Strengths or, if it had, it would have made far fewer sales of those strengths.

#### **6. Medicis’s Additional Anticompetitive Conduct to Impair Competition to the Add-On Strengths**

202. 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.

203. As a result of Medicis’s market switching efforts, the 65mg and 115mg dose strengths (two of the Add-On Strengths) comprised approximately three-quarters of Solodyn

sales. Medicis needed to protect these Solodyn sales from generic competitors if it was to retain the bulk of its supracompetitive Solodyn profits.

204. Knowing that Medicis's '838 Patent was invalid and unenforceable, generic manufacturers—who had not already been bought off—sought FDA approval to market generic versions of the Add-On Strengths. To continue to reap the benefits of its anticompetitive scheme, Medicis needed to delay and impair this new competitive threat.

205. Medicis filed sham litigation against Teva, the first-filer with respect to the 65mg and 115mg strengths, and then settled with Teva, creating a bottleneck by causing Teva to “park” its 180 day exclusivity; and (2) paid the later-filing generic manufacturer, Lupin, not to unplug the bottleneck that Medicis created by settling with Teva and to create a bottleneck in the 55mg strength for which Lupin had first-to-file exclusivity.

206. 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 again stated that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Teva's generic product. Teva could do so because in its first settlement agreement, it only “admitted” that the '838 Patent was valid and enforceable as to its Legacy Strength generic product, not that the patent was generally valid and enforceable.

207. 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.

208. 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.

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

210. 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 Reexamination Certificate.

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

212. On September 7, 2010, the USPTO issued the '705 Patent and Medicis had it listed in the Orange Book for Solodyn in 45mg, 65mg, 90mg 115mg, and 135mg strengths. As the patent was listed in the Orange Book after Teva filed its ANDA, it could not result in a 30-month stay as to Teva's ANDA.

213. 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.

214. 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.

215. On or about February 25, 2011, Medicis and Teva entered into an agreement settling the litigation (the "Second Teva Settlement 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.

216. Pursuant to that agreement, Teva agreed to: (a) admit that the '838 Patent and '705 Patent are valid and enforceable (only as generic Add-On Strength Solodyn); (b) admit that the '838 Patent and '705 Patent are infringed by Teva's generic Solodyn 65mg and 115mg products and other generic Add-On Strength products; (c) delay entry of generic 65mg and 115mg Solodyn products until February 2018, or earlier under certain circumstances; and (d) delay entry of generic 55mg, 80mg and 105mg Solodyn products until February 2019, or earlier under certain circumstances .

217. Because Teva was the first filer as to the 65mg and 115mg strengths and was entitled to 180 days of marketing exclusivity on those strengths, the agreement created a bottleneck that impaired later-filing generics' ability to get their 65mg and 115mg products onto the market. Medicis then entered into another exclusion payment agreement to ensure that Lupin, a later filer, would not be able to dislodge the bottleneck.

218. On May 18, 2012, Teva received final approval for its 65mg and 115mg strength generic Solodyn. However, pursuant to the terms of the Second Teva Settlement Agreement, Second, Teva is precluded from launching its generic product until February 2018 unless another generic manufacturer invalidates the '838 and '705 Patents.

**7. Medicis bribes Lupin to stay off of the market with the Medicis/Lupin Exclusion Payment Agreement.**

219. Ever reluctant to rely on its '838 Patent and very concerned about the strength of its '705 Patent, Medicis once again opted to pay a generic, this time Lupin, to keep its generic products off the market, keep the 65mg/115mg bottleneck in place and create a bottleneck on the 55mg strength rather than litigate. Medicis did so to avoid Lupin successfully invalidating the '838 and '705 Patents and irreparably destroying its fragile Solodyn monopoly.

220. On July 21, 2011, Medicis and Lupin entered into the Medicis/Lupin Exclusion Payment Agreement pursuant to which Lupin received large, continuing, unjustifiable payments in exchange for agreeing to forestall coming to market with its generic Solodyn products. The Medicis/Lupin Exclusion Payment Agreement included two related written agreements, a License and Settlement Agreement, a Joint Development Agreement and amendments thereto. At the time of the agreement, neither the parties nor the district court had addressed the substantive merits of Medicis's infringement suit. The agreement allowed Medicis to preserve its monopoly position in exchange for sharing its supracompetitive revenues.

221. Pursuant to the Medicis/Lupin Exclusion Payment Agreement, Lupin agreed to: (a) delay launching its generic Solodyn products in 45mg, 90mg, and 135mg Legacy Strengths until November 26, 2011, or earlier under certain circumstances; (b) delay launching its generic Solodyn products in 65mg and 115mg strengths until February 2018, or earlier under certain circumstances; and (c) delay launching its generic Solodyn products in 55mg, 80mg, and 105mg strengths until February 2019, or earlier under certain circumstances. Lupin also admitted that the claims of the '838 and '705 Patents and three additional patents and eight patent applications are valid, enforceable, and infringed by Lupin's proposed generic Solodyn products.

222. Notwithstanding the foregoing admissions with respect to Medicis's patent rights, Lupin explicitly retained its right to maintain its Paragraph IV certification—which certification includes an assertion by Lupin that Medicis's patents are unenforceable—thereby creating an FDA approval bottleneck on the 55mg strength of generic Solodyn. Because Lupin is the first generic filer on 55mg Solodyn and because it maintained its Paragraph IV certification against Medicis, no other generic can come to market with 55mg Solodyn until after Lupin in February 2019.

223. 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 over \$20 million dollars. Medicis's payments to Lupin under the Agreement took a variety of forms.

224. First, Medicis provided Lupin with non-refundable and non-creditable upfront payments totaling \$20 million under the guise of a Joint Development Agreement. Those upfront payments included [REDACTED] for access to Lupin's intellectual property—which did not include a single issued patent—for the development of formulations containing [REDACTED] [REDACTED] and [REDACTED] for access to Lupin intellectual property—which again, did not include a single issued patent—for [REDACTED] [REDACTED]. Notably, the parties entered into an Amended Joint Development Agreement on or about March 30, 2012, whereby the [REDACTED] was swapped for a different product: [REDACTED] [REDACTED]. Medicis was required to make an additional upfront payment to Lupin of \$2.5 million. The total upfront payments to Lupin amounted to \$22.5 million.

225. The \$22.5 million upfront payments received by Lupin were fully non-refundable, meaning Lupin kept the money even if it did not perform under the Joint Development Agreement and even if its development efforts completely failed (see, e.g., the upfront payment for the SPB Product).

226. The \$22.5 million in upfront payments were not the only compensation that Lupin received for agreeing to (i) settle Medicis's sham lawsuit and (ii) delay the launch of generic Solodyn by Lupin on all strengths (and consequently other generic filers for the 55mg strength). The Joint Development Agreement further obligated Medicis to pay Lupin up to \$35.5 million in "non-refundable and non-creditable milestone payment[s]" listed in the agreement. None of the milestone payments required Lupin to [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] To date, Lupin has received at least \$6.5 million in non-refundable and non-creditable milestone payments from Medicis pursuant to the Joint Development Agreement.

227. All of these benefits had substantial value to Lupin, and are compensation that it could not have obtained even if it had litigated and won the patent case. And these payments caused Lupin to agree to stay out of the market longer than it otherwise would have done. Medicis agreed to and did pay Lupin to delay entry into the market.

228. The large unjustified payments from Medicis to Lupin of \$29 million and as much as \$58 million pursuant to the Medicis/Lupin Exclusion Payment Agreement serve no purpose other than to compensate Lupin for keeping its generic Solodyn product off of the market for years, allowing the parties to share Medicis's Solodyn monopoly profits. There are no procompetitive justifications for those payments which are well in excess of any limited value—

other than the delay of generic Solodyn—provided by Lupin under the agreement. Furthermore, the \$22.5 million non-refundable upfront fees, up to \$35.5 million in non-refundable milestone payments, far exceed any approximation of the costs to Medicis of continuing to litigate is infringement case against Lupin. Additionally, Medicis and Lupin cannot establish that those large payments were in consideration for the fair value of any services provided by Lupin to Medicis under the Joint Development Agreement. Indeed, Lupin was not required to provide any services in exchange for the non-refundable \$22.5 million upfront payments and has received large unjustified non-refundable milestone payments regardless of Lupin’s success in developing any marketable products and in addition [REDACTED]

[REDACTED] Such amounts far exceed any fair value for the services performed by Lupin under the Joint Development Agreement.

229. Absent Medicis’s unlawful continuing payments to Lupin under the Medicis/Lupin Exclusion Payment Agreement, Medicis and Lupin would have settled in a manner less restrictive of competition, resulting in much less delay of Lupin’s generic entry. Under such an agreement, or even without one (such as with a launch by Lupin when it received final approval from FDA or launch after a court ruling in Lupin’s favor), Lupin would have launched its Add-On Strength Solodyn products substantially earlier than 2018 or 2019 as agreed to in the Medicis/Lupin Exclusion Payment Agreement.

**8. Medicis could not have successfully used the patents purportedly covering Solodyn to delay generic competition.**

230. In addition to the ‘838 and ‘705 Patents (and the ‘347 and ‘373 Patents on which Medicis never sued), Medicis obtained two other patents purportedly covering Solodyn:

- U.S. Patent No. 7,919,483 (the “‘483 Patent”), issued on April 5, 2011, that purports to cover methods of using a controlled-release oral dosage form of minocycline to treat acne in all eight of Solodyn’s eventual dosages and expires in 2027; and

- U.S. Patent No. 8,268,804 (the “804 Patent”), issued on September 8, 2012, that purports to cover a method for the treatment of acne and relates to all strengths of Solodyn and expires in 2025.

231. None of the later issued patents (i.e., the ‘705, ‘347, ‘373, ‘483 and ‘804 Patents) would have prevented generic Solodyn products from entering the market before those patents expired. At the time Medicis filed sham lawsuits with respect to the ‘838 Patent, and entered the Medicis/Impax Exclusion Payment Agreement, 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 all the reasons discussed above. In fact, Teva, Sandoz and Mylan all launched without regard for the ‘838 Patent and while Medicis was pursuing sham lawsuits against them alleging infringement thereof. Although the ‘347 and ‘373 patents had issued by the time of the Medicis/Sandoz Exclusion Payment Agreement, and the ‘705 and ‘483 patents had also issued by the time of the Medicis/Lupin Exclusion Payment Agreement, none of those patents would have prevented earlier generic entry by Generic Defendants or other generics. 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.

232. 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 Defendants’ or other generics’ 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. In fact, Medicis has never sued any generic manufacturer for infringement of any of the later issued patents other than the '705 Patent.

## **VI. ANTICOMPETITIVE PURPOSE AND EFFECTS OF DEFENDANTS' CONDUCT**

233. Defendants' anticompetitive conduct delayed and substantially impaired competition from generic Solodyn products in the United States, and unlawfully enabled Medicis to sell Legacy and Add-On Strength Solodyn at artificially inflated prices and volumes, including after July 2009 and continuing to this date and beyond.

234. But for the Medicis/Impax Exclusionary Payment Agreement, Impax would have begun marketing its generic Legacy Strength products long before November 11, 2011 and likely by July 2009. Instead, Impax did not launch its Legacy Strength generic products until November 2011, when Medicis had already shifted the prescription base to the Add-On Strengths.

235. Impax's entry would have significantly reduced the prices Plaintiffs and members of the Class paid for minocycline hydrochloride extended release tablets and would have drastically reduced Medicis's market share.

236. Furthermore, absent Medicis's sham patent litigation and the Medicis/Impax Exclusion Payment Agreement, Teva would have launched as soon as receiving final FDA approval on March 17, 2009 (as it did) and would have remained on the market because Teva would have had no incentive to execute the Teva Settlement Agreement. If Impax had not yet launched by March 2009 when Teva received approval and launched, Impax would have launched then. The vast majority of existing prescriptions for the Legacy Strengths would have been swiftly and permanently converted to generic Solodyn, long before Medicis could switch the market to the Add-On Strengths.

237. The entry and sustained availability of two generics in the market would have reduced the prices Plaintiffs and members of the Class paid for minocycline hydrochloride extended release tablets and pulled even more Solodyn sales away from Medicis.

238. With Impax and Teva on the market, Sandoz would have launched its Legacy Strength generic Solodyn as soon as receiving final approval on August 13, 2009 (as it did) and Sandoz would have stayed on the market, further driving down prices for Solodyn/generic Solodyn and stripping Medicis's market share.

239. As such, by the time Medicis was able to come to market with its 65mg and 115mg Add-On Strength Solodyn products after receiving approval from FDA on July 23, 2009, there would have been two, and shortly thereafter three, Legacy Strength generics on the market. As explained above, without sufficient time to switch doctors' prescription writing habits from Legacy Strength to Add-On Strength, Medicis's 65mg and 115mg launch would have been largely unsuccessful, if Medicis launched those strengths at all.<sup>31</sup> Indeed, despite the fact that Medicis launched the 65mg and 115mg Solodyn in July 2009, as late as August 2010 the Legacy Strengths still accounted for over 40% of the Solodyn prescriptions and it was not until May 2011 that sales of the Legacy Strengths dipped below 10%. And these percentages reflected a period during which (other than the abbreviated launches by Teva and Sandoz), only branded Legacy Strength Solodyn was on the market. This explains why Medicis needed to literally buy time to launch the Add-On Strengths.

240. But for Medicis's anticompetitive conduct that bought it the time necessary to effectuate its switch strategy, Medicis would not have developed or marketed Solodyn in the new

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<sup>31</sup> If Medicis were to abandon its efforts to launch the Add-On Strengths, it likely would have launched a Legacy Strength Authorized Generic soon after Impax and/or Teva launched in 2009 to capture revenue otherwise lost to competing generics, thus further reducing the prices paid by Plaintiffs and the Class.

Add-On Strengths and switched a substantial portion of sales to that product before generic Legacy Strength Solodyn was available. Even assuming Medicis nonetheless marketed the Add-On Strengths, generic Solodyn in Legacy Strengths would have entered the market before or contemporaneous with the new Add-On Strengths and Medicis would have been able to switch very few prescriptions to the higher priced Add-On Strengths.

241. Furthermore, absent the Medicis/Impax and Medicis/Sandoz Exclusionary Payment Agreements, Mylan would have launched its generic Legacy Strength product as soon as receiving final FDA approval on July 20, 2010 (as it did) and would have remained on the market, thus further reducing what Plaintiffs and Class members paid for Solodyn and further reducing Medicis's market share. Instead, other than the abbreviated launch, Mylan did not launch its Legacy Strength generic products until November 2011, when Medicis had already shifted the prescription base to the Add-On Strengths.

242. Accordingly, by August 7, 2010 when Medicis received approval for the 55mg, 80mg and 150mg Add-On Strengths of Solodyn, there would have been at least four Legacy Strength generics on the market (five if Medicis launched an AG) making any efforts to move the market from the Legacy Strengths to the Add-On Strengths virtually, if not entirely, impossible.

243. In the event Medicis were to continue to market Add-On Strength Solodyn, generic versions, including from Lupin, would have become available after Teva obtained FDA approval on May 18, 2012, and well before the delayed launch dates in 2018 and 2019 established in Medicis's various agreements. This is because, absent the exclusion payment, Medicis and Lupin would still have settled the case, but for an earlier entry date untarnished by a payment, or Lupin would have continued to pursue the invalidation of the '838 Patent.

## VII. ANTICOMPETITIVE EFFECTS AND DAMAGES TO THE CLASS

244. The Exclusion Payment Agreements and Medicis's sham litigations and the settlements thereof, enabled Medicis to (a) delay entry of less expensive generic versions of Solodyn in the United States, (b) fix, raise, maintain or stabilize the price of Solodyn in the United States, (c) maintain a monopoly in the United States market for Solodyn and its generic equivalents, and (d) allocate the market for Solodyn—first Legacy Strength, then Add-On Strengths—and its generic equivalents almost exclusively to Medicis. Defendants' conduct had the effect of delaying competition for Legacy Strength Solodyn for well over two years and impairing competition for the Legacy Strengths since actual entry, and continues to delay the entry for generic Add-On Strength Solodyn.

245. But for the anticompetitive conduct alleged above, generic manufacturers—including the Generic Defendants—would have been able to enter the market with generic Legacy Strength Solodyn unimpeded (either by (a) prevailing in a patent litigation and then entering, (b) entering while a patent litigation was pending, or (c) agreeing to an earlier entry date as part of a settlement that did not involve a reverse payment), and compete on the merits against Medicis.

246. As discussed in detail above, if Medicis had continued to pursue the sham litigations against the generics, Medicis would have lost those litigations because the '838 Patent was invalid, unenforceable and procured through inequitable conduct, allowing all generics to come to market. The '838 Patent suits filed by Medicis were objectively baseless suits and Medicis had no realistic expectation of prevailing in them. Medicis also knew that the '705

Patent was weak and likely would not have kept generics off the market.<sup>32</sup> Medicis knew that it could not use its patents (by, for example, obtaining an injunction from a court) to keep generic Solodyn off the market.

247. Furthermore, it was well-known within the pharmaceutical industry that generics were and are willing to introduce generic products while patent litigation was ongoing (i.e., launch “at risk”). In fact, Teva,<sup>33</sup> Sandoz, and Mylan all did just that here, having launched their generic Solodyn products with Medicis’s sham patent litigations pending. Similarly, Lupin has a history of launching at risk, having launched generic Fortamet at-risk on September 30, 2011.<sup>34</sup>

248. Alternatively, but for the substantial payments Medicis made to Impax and later Sandoz in exchange for their agreements to delay marketing Legacy Strength generic Solodyn products, Medicis and one or more of the generics would have agreed to a licensed entry date significantly earlier than November 2011 for generic Solodyn in the Legacy Strengths (and, to the extent Medicis would have even marketed the Add-On Strengths, significantly earlier than February 2018 for generic versions of the 65mg and 115mg strengths and February 2019 for the 55mg, 80mg, and 105mg strengths). That Medicis did not need to resort to illegal payments to the Generic Defendants in order to resolve the patent litigations is confirmed by empirical studies. According to the FTC, “the vast majority of patent settlements (greater than 70%)” are

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<sup>32</sup> 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. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration*, at 20 (July 2002), available at [www.ftc.gov/os/2002/07/genericdrugstudy.pdf](http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf).

<sup>33</sup> 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. See Press Release, “Teva and Barr Announce Launch of Generic Allegra Tablets By Teva Under Agreement With Barr,” available at [http://www.tevapharm.com/pr/2005/pr\\_544.asp](http://www.tevapharm.com/pr/2005/pr_544.asp).

<sup>34</sup> See Shionogi & Co., Ltd. and Shionogi Inc. Announce a Favorable Decision In FORTAMET® Preliminary Injunction Proceedings, Business Wire, Dec. 7, 2011, available at <http://www.businesswire.com/news/home/20111207005999/en/Shionogi-Ltd.-Shionogi-Announce-Favorable-Decision-FORTAMET%C2%AE>.

resolved “without compensation to the generic manufacturer.”<sup>35</sup> 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.<sup>36</sup> 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; 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. Here, Medicis could and likely would have entered into agreements with the Generic Defendants and other generic manufacturers containing such provisions (but without large reverse payments) but for the Exclusion Payment Agreements and other conduct alleged herein.

249. But for the anticompetitive conduct alleged above, Medicis’s efforts to switch the market from Legacy Strength to Add-On Strength Solodyn either would not have occurred at all, or would not have significantly affected the generics’—particularly, Impax, Teva and Sandoz—ability to make sales of generic Legacy Strength Solodyn because absent the delay paid for and obtained by Medicis, those generics would have launched well before Medicis launched and/or established a market for Add-On Strength Solodyn, and the vast bulk (on the order of 90%) of

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<sup>35</sup> FTC Bureau of Competition, Overview of Agreements Filed in FY 2012, at 2 (Jan. 17, 2013), available at <http://www.ftc.gov/os/2013/01/130117mmareport.pdf>.

<sup>36</sup> See FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition (2006), available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>; FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004: A Report by the Bureau of Competition (2005), available at <http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>.

the sales of Solodyn would have switched to the generics before the launch or establishment of a market base for Add-On Strength Solodyn (assuming it would have still launched at all).

250. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Solodyn from generic competition.

251. Impax, Teva, Sandoz, Mylan, and Lupin have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand.

252. Defendants' anticompetitive conduct, which delayed introduction and sustained marketing into the United States marketplace of generic versions of Solodyn, has caused Plaintiffs and the Class to pay more than they would have paid for Legacy Strength and Add-On Strength minocycline hydrochloride extended release tablets absent Defendants' illegal conduct.

253. Typically, generic drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, nearly all brand drug purchases are rapidly substituted for generic equivalents of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand drug loses even more of its brand sales to the generic versions of the drug.

254. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices; (b) purchase generic equivalents of the drug at a lower price, sooner; and/or (c) purchase the brand drug at a reduced price. Consequently, brand

manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

255. But for Defendants' anticompetitive conduct, Plaintiffs and members of the Class would have paid less for minocycline hydrochloride extended release tablets by: (a) substituting purchases of less-expensive AB-rated generic Solodyn for their purchases of more-expensive brand Solodyn; (b) receiving discounts on their remaining brand Solodyn purchases; and (c) purchasing generic Solodyn at lower prices sooner.

### **VIII. ANTITRUST IMPACT**

256. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of brand Solodyn indirectly from Defendants and/or purchased substantial amounts of AB-rated bioequivalent generic Solodyn indirectly from Defendants or others. As a result of Defendants' illegal conduct, members of the End-Payor Class were compelled to pay, and did pay, artificially inflated prices for their minocycline hydrochloride extended release tablets requirements. Those prices were substantially greater than those that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand Solodyn was artificially inflated by Defendants' illegal conduct; (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Solodyn; and/or (3) the price of AB-rated Solodyn generic was artificially inflated by Defendants' illegal conduct.

257. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

258. Overcharges at a higher level of distribution generally result in higher prices at every level below. This case is no exception.

259. General economic theory recognizes that any overcharges in the form of supracompetitive prices at a higher level of distribution in the chain of distribution results in higher prices at every level below. Herbert Hovenkamp, *Federal Antitrust Policy, the Law of Competition and Its Practice* 624 (1994). Professor Herbert Hovenkamp goes on to state that “[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top.” He also acknowledges that “[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level.”

260. Wholesalers and retailers passed on the inflated prices of Solodyn and AB-rated generic Solodyn to the End-Payors defined herein.

261. Defendants’ anticompetitive conduct enabled them to indirectly charge end-payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants’ anticompetitive conduct.

262. The supracompetitive prices were inflated as a direct and foreseeable result of Defendants’ anticompetitive conduct.

263. The overcharges paid by the End-Payor Class are traceable to, and the foreseeable result of, the supracompetitive prices that were raised, fixed, and stabilized by Defendants.

## **IX. EFFECT ON INTERSTATE AND INTRASTATE COMMERCE**

264. At all material times, Medicis manufactured, promoted, distributed, and sold substantial amounts of Solodyn in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

265. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Solodyn and/or its AB-rated generic equivalents.

266. In furtherance of their efforts to monopolize and restrain competition in the market for Solodyn and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of and have substantially affected interstate commerce.

267. Defendants' anticompetitive conduct has had substantial intrastate effects in that, among other things, retailers within each state were foreclosed from offering less expensive generic, bioequivalent versions of Solodyn to end-payors within each state. The foreclosure of generic Solodyn directly impacts and disrupts commerce for end-payors within each state.

268. During the relevant time period, Solodyn was shipped into each state and was sold to or paid for by end-payors at supracompetitive prices within each state.

#### **X. MARKET POWER AND MARKET DEFINITION**

269. At all relevant times, Medicis had substantial market power (i.e., monopoly power) with respect to minocycline hydrochloride extended release tablets—including Solodyn and its AB-rated generic equivalents—because it had the power to maintain the price of the drug it sold as Solodyn at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable. This market power may be shown directly, and therefore no relevant market needs to be defined.

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

271. 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.

272. The existence of other medications for the treatment of non-nodular moderate to severe acne did not constrain Medicis's ability to raise or maintain Solodyn prices without losing substantial sales, and therefore those other drug products are not in the same relevant antitrust market with Solodyn. Therapeutic alternatives are not the same as economic alternatives.

273. 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 substantially supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Solodyn would render Medicis unable to profitably maintain substantially supracompetitive prices for Solodyn.

274. Medicis knew that entry of a generic version of Solodyn would be a uniquely significant market event. The entry of other products indicated to treat non-nodular severe to moderate acne (or generic versions of those other brands) did not take substantial sales from Solodyn or cause Medicis to lower its price. By contrast, the competitive impact of an AB-rated generic version of Solodyn on brand Solodyn would be substantial, causing brand Solodyn to immediately lose well more than half of its unit sales. Among other things, the entry of an AB-rated generic Solodyn would deliver hundreds of millions of dollars of savings to purchasers.

275. 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.

276. Medicis had, and exercised, the power to exclude and restrict competition to Solodyn and its AB-rated bioequivalents.

277. 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.

278. To the extent that Plaintiffs are legally required to prove substantial market power circumstantially by first defining a relevant product market, Plaintiffs alleges that the relevant product market is minocycline hydrochloride extended release tablets or narrower markets contained therein. During the relevant time, Medicis has been able to profitably maintain the price of minocycline hydrochloride extended release tablets substantially above competitive levels.

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

280. At all relevant times, until the entry of AB-rated generic competition, Medicis's market share in the relevant market was at or near 100%, implying a substantial amount of market power.

## **XI. CLASS ACTION ALLEGATIONS**

281. Plaintiffs bring this action on behalf of themselves and, under Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), as representative of an End-Payor Class defined as:

All persons or entities in the United States and its territories and possessions including the Commonwealth of Puerto Rico, who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Solodyn 45mg, 65mg, 80 mg, 90mg, 105mg, 115mg, and/or 135mg tablets and/or generic versions of one or more of these dosages, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, at any time from July 23, 2009 until the anticompetitive effects of Defendants' unlawful conduct cease.

282. The following persons or entities are excluded from the proposed End-Payor Class:

- a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;
- b. All federal or state governmental entities, excluding cities, towns, or municipalities with self-funded prescription drug plans;

- c. All persons or entities who purchased Solodyn or its generic equivalents for purposes of resale or directly from the Defendant or their affiliates;
- d. Fully insured health plans (plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);
- e. Pharmacy Benefits Managers;
- f. Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs); and
- g. The judges in this case and any members of their immediate families.

283. Members of the Class are so numerous and geographically dispersed that joinder is impracticable. Plaintiffs believe that there are thousands of End-Payor Class members.

284. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants, i.e., they paid artificially inflated prices for minocycline hydrochloride extended release tablets and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of minocycline hydrochloride extended release tablets as a result of Defendants' wrongful conduct.

285. Plaintiffs will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiffs are coincident with, and not antagonistic to, those of the Class.

286. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

287. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on

grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate.

288. Questions of law and fact common to the Class include, but are not limited to:

- a. whether Medicis conspired with each or any of the Generic Defendants to willfully maintain and/or enhance Medicis's monopoly power over Solodyn and its generic equivalents;
- b. whether Medicis obtained the '838 Patent by deceiving USPTO;
- c. whether Medicis improperly listed the '838 Patent in FDA's Orange Book;
- d. whether Medicis engaged in baseless sham patent litigation against one or more of the Generic Defendants or other actual or would-be generic manufacturers;
- e. whether Medicis unlawfully excluded competitors and potential competitors from the market for Solodyn and its generic equivalents;
- f. whether Medicis conspired with each or any of the Generic Defendants to suppress generic competition to Solodyn;
- g. whether Medicis entered into an unlawful agreements in restraint of trade with each or any of the Generic Defendants;
- h. whether, pursuant to the Exclusion Payment Agreements, each or any of the Generic Defendants agreed to delay its entry into the market with generic Solodyn;
- i. whether, pursuant to the Exclusion Payment Agreements, Medicis compensated each or any of the Generic Defendants;
- j. whether Medicis's compensation to each or any of the Generic Defendants was for any purpose other than delayed entry of generic Solodyn;
- k. whether Medicis's compensation to each or any of the Generic Defendants was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;
- l. whether one or more of the Exclusion Payment Agreements is illegal;
- m. whether Medicis possessed substantial market power over Solodyn and its AB-rated generic equivalents;
- n. whether the law requires definition of a relevant market when direct proof of monopoly power is available and, if so, the definition of the relevant market;

- o. whether Medicis maintained monopoly power over Solodyn by unlawfully suppressing generic competition to Solodyn;
- p. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
- q. whether, and to what extent, Defendants' conduct caused antitrust injury (i.e., overcharges) to Plaintiffs and the members of the Class; and
- r. the quantum of aggregate overcharge damages to the Class.

289. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

290. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

## **XII. CLAIMS FOR RELIEF**

### **FIRST CLAIM FOR RELIEF MONOPOLIZATION UNDER STATE LAW (Against Medicis and Valeant Defendants)**

291. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

292. 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.

293. As alleged above, Medicis knowingly and willfully engaged in anticompetitive conduct designed to unlawfully extend and maintain its monopoly power.

294. Through the anticompetitive conduct alleged extensively herein, Medicis willfully maintained its monopoly power through restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for Solodyn and injured Plaintiffs and the Class thereby.

295. The goal, purpose, and effect of Medicis's anticompetitive conduct was to delay and impair the sale of generic Solodyn products in the United States at prices significantly below Medicis's prices for Solodyn, thereby effectively preventing the average market price of extended-release minocycline hydrochloride products from declining dramatically.

296. By engaging in the foregoing conduct, Medicis has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the state antitrust and consumer protection statutes listed below.

297. But for Medicis's unlawful conduct, the Generic Defendants and other generic manufacturers would have launched earlier than they finally did: (a) "at-risk" (that is, while the patent litigation was still pending); or (b) after winning the patent suit; or (c) via a lawful settlement agreement without a large reverse payment from Medicis.

298. Plaintiffs and members of the End-Payor Class have been injured in their business or property by reason of Defendants' antitrust violations alleged herein. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis's conduct from July 2009 and continuing to the present. These injuries are of the type the antitrust and consumer

protection laws of the below States, the District of Columbia and the territories were designed to prevent, and flow from that which makes Medicis's conduct unlawful.

299. As a successor in interest to Medicis, Valeant is liable for all of Medicis's anticompetitive conduct in connection with Solodyn. And by joining an ongoing unlawful agreement to restrain trade, Valeant is liable for all conduct that occurred prior to the date on which it joined the ongoing unlawful course of conduct. In addition, Valeant is liable for its own unlawful conduct.

300. By engaging in the foregoing misconduct, Medicis has violated the following state antitrust laws:

- a. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Ariz. Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Solodyn in Arizona by members of the End-Payor Class.
- b. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Solodyn in California by members of the End-Payor Class.
- c. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Solodyn in the District of Columbia by members of the End-Payor Class.
- d. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Fla. Stat. §§ 542.19, *et seq.* and 501.201, *et seq.*, with respect to purchases of Solodyn in Florida by members of the End-Payor Class.
- e. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Haw. Rev. Stat. §§ 480, *et seq.*, with respect to purchases of Solodyn in Hawaii by members of the End-Payor Class.
- f. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Iowa Code §§ 553, *et seq.*, with

respect to purchases of Solodyn in Iowa by members of the End-Payor Class.

- g. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Me. Rev. Stat. Ann. tit.10, §§ 1102, *et seq.*, with respect to purchases of Solodyn in Maine by members of the End-Payor Class.
- h. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Solodyn in Massachusetts by members of the End-Payor Class.
- i. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Solodyn in Michigan by members of the End-Payor Class.
- j. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Minn. Stat. § 325D.52, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of Solodyn in Minnesota by members of the End-Payor Class.
- k. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Miss. Code Ann. § 75-21-3, *et seq.*, with respect to purchases of Solodyn in Mississippi by members of the End-Payor Class.
- l. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Neb. Rev. Stat. Ann. §§ 59-802, *et seq.*, with respect to purchases of Solodyn in Nebraska by members of the End-Payor Class.
- m. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Solodyn in Nevada by members of the End-Payor Class.
- n. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of N.H. Rev. Stat. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to purchases of Solodyn in New Hampshire by members of the End-Payor Class.
- o. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*,

with respect to purchases of Solodyn in New Mexico by members of the End-Payor Class.

- p. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Solodyn in North Carolina by members of the End-Payor Class.
- q. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Solodyn in North Dakota by members of the End-Payor Class.
- r. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of the Puerto Rico Antitrust Act 10 L.P.R.A. 263, *et seq.*, with respect to purchases of Solodyn in Puerto Rico by members of the End-Payor Class.
- s. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases of Solodyn in Rhode Island by members of the End-Payor Class.
- t. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Solodyn in South Dakota by members of the End-Payor Class.
- u. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Utah Code Ann. §§ 76-10-1301, *et seq.*, with respect to purchases of Solodyn in Utah by members of the End-Payor Class who reside in Utah.
- v. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of Solodyn in Vermont by members of the End-Payor Class.
- w. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Solodyn in West Virginia by members of the End-Payor Class.
- x. Medicis has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with

respect to purchases of Solodyn in Wisconsin by members of the End-Payor Class.

**SECOND CLAIM FOR RELIEF  
ATTEMPTED MONOPOLIZATION UNDER STATE LAW  
(Against Medicis and Valeant Defendants)**

301. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

302. At all relevant times, Medicis possessed substantial market power (i.e., monopoly power) or possessed a dangerous probability of achieving monopoly power.

303. With the specific intent to achieve a monopoly, Medicis attempted to acquire and/or willfully maintain monopoly power by means of restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for Solodyn.

304. The goal, purpose, and effect of Medicis's conduct was to delay and impair the sale of generic Solodyn products in the United States at prices significantly below Medicis's prices for Solodyn, thereby effectively preventing the average market price for Solodyn and its generic equivalent products from declining dramatically.

305. By engaging in the foregoing conduct, Medicis has intentionally and wrongfully attempted to monopolize the relevant market in violation of the state antitrust and consumer protection statutes listed below.

306. But for Medicis's unlawful conduct, the Generic Defendants and other generic manufacturers would have launched earlier than they finally did: (a) "at-risk" (that is, while the patent litigation was still pending); or (b) after winning the patent suit; or (c) via a lawful settlement agreement without a large reverse payment from Medicis.

307. Plaintiffs and members of the End-Payor Class have been injured in their business or property by reason of Defendants' antitrust violations alleged herein. Their injuries consist of:

(1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis's conduct from July 2009 and continuing to the present. These injuries are of the type the antitrust and consumer protection laws of the below States, the District of Columbia and the territories were designed to prevent, and flow from that which makes Medicis's conduct unlawful.

308. As a successor in interest to Medicis, Valeant is liable for all of Medicis's anticompetitive conduct in connection with Solodyn. And by joining an ongoing unlawful agreement to restrain trade, Valeant is liable for all conduct that occurred prior to the date on which it joined the ongoing unlawful course of conduct. In addition, Valeant is liable for its own unlawful conduct.

309. By engaging in the foregoing misconduct, Medicis has violated the following state antitrust laws:

- a. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Ariz. Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Solodyn in Arizona by members of the End-Payor Class.
- b. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Solodyn in California by members of the End-Payor Class.
- c. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Solodyn in the District of Columbia by members of the End-Payor Class.
- d. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Fla. Stat. §§ 542.19, *et seq.* and 501.201, *et seq.*, with respect to purchases of Solodyn in Florida by members of the End-Payor Class.

- e. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Haw. Rev. Stat. §§ 480, *et seq.*, with respect to purchases of Solodyn in Hawaii by members of the End-Payor Class.
- f. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Iowa Code §§ 553, *et seq.*, with respect to purchases of Solodyn in Iowa by members of the End-Payor Class.
- g. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Me. Rev. Stat. Ann. tit.10, §§ 1102, *et seq.*, with respect to purchases of Solodyn in Maine by members of the End-Payor Class.
- h. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Solodyn in Massachusetts by members of the End-Payor Class.
- i. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Solodyn in Michigan by members of the End-Payor Class.
- j. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of Solodyn in Minnesota by members of the End-Payor Class.
- k. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Solodyn in Mississippi by members of the End-Payor Class.
- l. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Neb. Rev. Stat. Ann. §§ 59-802, *et seq.*, with respect to purchases of Solodyn in Nebraska by members of the End-Payor Class.
- m. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Solodyn in Nevada by members of the End-Payor Class.

- n. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of N.H. Rev. Stat. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to purchases of Solodyn in New Hampshire by members of the End-Payor Class.
- o. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Solodyn in New Mexico by members of the End-Payor Class.
- p. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Solodyn in North Carolina by members of the End-Payor Class.
- q. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Solodyn in North Dakota by members of the End-Payor Class.
- r. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of the Puerto Rico Antitrust Act 10 L.P.R.A. 263, *et seq.*, with respect to purchases of Solodyn in Puerto Rico by members of the End-Payor Class.
- s. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases of Solodyn in Rhode Island by members of the End-Payor Class.
- t. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Solodyn in South Dakota by members of the End-Payor Class.
- u. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Utah Code Ann. §§ 76-10-1301, *et seq.*, with respect to purchases of Solodyn in Utah by members of the End-Payor Class who reside in Utah.
- v. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of Solodyn in Vermont by members of the End-Payor Class.

- w. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Solodyn in West Virginia by members of the End-Payor Class.
- x. Medicis has intentionally and unlawfully attempted to maintain its monopoly power in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Solodyn in Wisconsin by members of the End-Payor Class.

**THIRD CLAIM FOR RELIEF  
CONSPIRACY AND COMINATION IN RESTRAINT OF TRADE UNDER  
STATE LAW  
(Against Medicis, Valeant and Impax)**

310. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

311. In or about November 2008 and at times before the formal execution thereof, 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 substantial payments to Impax in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or 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 and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

312. The purpose and effect of the payments flowing from Medicis to Impax under their agreement was to delay and impair generic competition to Solodyn, and there is no legitimate, nonpretextual, procompetitive business justification for the payments that outweighs their harmful effects.

313. The Medicis/Impax Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

314. As a direct and proximate result of Medicis's and Impax's unlawful restraint of trade and unlawful maintenance of and conspiracy to maintain Medicis's monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for Solodyn and its generic equivalents as described herein, and were harmed as a result.

315. By engaging in the foregoing conduct, Medicis and Impax have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the state antitrust and consumer protection laws listed below.

316. But for Medicis's and Impax's unlawful conduct, the Generic Defendants and other generic manufacturers would have launched earlier than they finally did: (a) "at-risk" (that is, while the patent litigation was still pending); or (b) after winning the patent suit; or (c) via a lawful settlement agreement without a large reverse payment from Medicis.

317. Plaintiffs and members of the Class have been injured in their business or property by reason of Medicis's and Impax's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis's and Impax's conduct from July 2009 and continuing to the present. These injuries are of the type the state antitrust and consumer protection laws were designed to prevent, and flow from that which makes Medicis's and Impax's conduct unlawful.

318. As a successor in interest to Medicis, Valeant is liable for all of Medicis's anticompetitive conduct in connection with Solodyn. And by joining an ongoing unlawful

agreement to restrain trade, Valeant is liable for all conduct that occurred prior to the date on which it joined the ongoing unlawful course of conduct. In addition, Valeant is liable for its own unlawful conduct.

319. By engaging in the anticompetitive conduct alleged herein, Defendants have intentionally and unlawfully engaged in one or more combinations and/or conspiracies in restraint of trade in violation of the following state laws:

- a. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Ariz. Rev. Stat. §§ 44-1402, et seq., with respect to purchases of Solodyn in Arizona by members of the End-Payor Class.
- b. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Cal. Bus. & Prof. Code §§ 16720, et seq., and Code §§ 17200, et seq., with respect to purchases of Solodyn in California by members of the End-Payor Class.
- c. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of D.C. Code Ann. §§ 28-4503, et seq., with respect to purchases of Solodyn in the District of Columbia by members of the End-Payor Class.
- d. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. Stat. §§ 542.18, et seq. and 501.201, et seq., with respect to purchases of Solodyn in Florida by members of the End-Payor Class.
- e. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Hawaii Code §§ 480, et seq., with respect to purchases of Solodyn in Hawaii by members of the End-Payor Class.
- f. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases of Solodyn in Illinois by members of the End-Payor Class.
- g. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Iowa Code §§ 553.4, et seq., with respect to purchases of Solodyn in Iowa by members of the End-Payor Class.

- h. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases of Solodyn in Kansas by members of the End-Payor Class.
- i. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. tit. 10, §§ 1101, et seq., with respect to purchases of Solodyn in Maine by members of the End-Payor Class.
- j. Defendant have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, et seq., with respect to purchases of Solodyn in Massachusetts by members of the End-Payor Class with thousands of Massachusetts end-payors paying substantially higher prices for Solodyn in actions and transactions occurring substantially within Massachusetts.
- k. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases of Solodyn in Michigan by members of the End-Payor Class.
- l. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.51, et seq., with respect to purchases of Solodyn in Minnesota by members of the End-Payor Class.
- m. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases of Solodyn in Mississippi by members of the End-Payor Class.
- n. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases of Solodyn in Nebraska by members of the End-Payor Class.
- o. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases of Solodyn in Nevada by members of the End-Payor Class, in that thousands of sales of Solodyn took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.
- p. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-

1-1, et seq., with respect to purchases of Solodyn in New Mexico by members of the End-Payor Class.

- q. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases of Solodyn in New York by members of the End-Payor Class.
- r. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases of Solodyn in North Carolina by members of the End-Payor Class.
- s. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. Cent. Code §§ 51-08.1-02, et seq., with respect to purchases of Solodyn in North Dakota by members of the End-Payor Class.
- t. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.725, et seq., with respect to purchases of Solodyn in Oregon by members of the End-Payor Class.
- u. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of 10 L.P.R.A. § 258 with respect to purchases of Solodyn in Puerto Rico by members of the End-Payor Class.
- v. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of R.I. Gen. Laws §§ 6-36-4, et seq., with respect to purchases of Solodyn in Rhode Island by members of the End-Payor Class.
- w. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. §§ 37-1-3.1, et seq., with respect to purchases of Solodyn in South Dakota by members of the End-Payor Class.
- x. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the End-Payor Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee being forced to purchase a more expensive branded Solodyn product.

- y. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases of Solodyn in Utah by members of the End-Payor Class who reside in Utah.
- z. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Vt. Stat. Ann. tit. 9, §§ 2453, et seq., with respect to purchases of Solodyn in Vermont by members of the End-Payor Class.
- aa. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of W. Va. Code §§ 47-18-3, et seq., with respect to purchases of Solodyn in West Virginia by members of the End-Payor Class.
- bb. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Wis. Stat. §§ 133.01, et seq., with respect to purchases of Solodyn in Wisconsin by members of the End-Payor Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin being forced to purchase a more expensive branded Solodyn product.

**FIFTH CLAIM FOR RELIEF  
CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER  
STATE LAW  
(Against Medicis, Valeant and Sandoz)**

320. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

321. In or about August 2009 and at times before the formal execution thereof, 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 substantial payments to Sandoz in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or 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 and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

322. The purpose and effect of the payments flowing from Medicis to Sandoz under their agreement was to delay and impair generic competition to Solodyn, and there is no legitimate, nonpretextual, procompetitive business justification for the payments that outweighs their harmful effects.

323. The Medicis/Sandoz Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

324. As a direct and proximate result of Medicis's and Sandoz's unlawful restraint of trade and unlawful maintenance of and conspiracy to maintain Medicis's monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for Solodyn and its generic equivalents as described herein, and were harmed as a result.

325. By engaging in the foregoing conduct, Medicis and Sandoz have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the state antitrust and consumer protection statutes listed below.

326. But for Medicis's and Sandoz's conduct, the Generic Defendants and other generic manufacturers would have launched earlier than they finally did: (a) "at-risk" (that is, while the patent litigation was still pending); or (b) after winning the patent suit; or (c) via a lawful settlement agreement without a large reverse payment from Medicis.

327. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release

minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis's and Sandoz's conduct from July 2009 and continuing to the present. These injuries are of the type the state antitrust and consumer protection statutes were designed to prevent, and flow from that which makes Medicis's and Sandoz's conduct unlawful.

328. As a successor in interest to Medicis, Valeant is liable for all of Medicis's anticompetitive conduct in connection with Solodyn. And by joining an ongoing unlawful agreement to restrain trade, Valeant is liable for all conduct that occurred prior to the date on which it joined the ongoing unlawful course of conduct. In addition, Valeant is liable for its own unlawful conduct.

329. By engaging in the anticompetitive conduct alleged herein, Defendants have intentionally and unlawfully engaged in one or more combinations and/or conspiracies in restraint of trade in violation of the following state laws:

- a. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Ariz. Rev. Stat. §§ 44-1402, et seq., with respect to purchases of Solodyn in Arizona by members of the End-Payor Class.
- b. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Cal. Bus. & Prof. Code §§ 16720, et seq., and Code §§ 17200, et seq., with respect to purchases of Solodyn in California by members of the End-Payor Class.
- c. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of D.C. Code Ann. §§ 28-4503, et seq., with respect to purchases of Solodyn in the District of Columbia by members of the End-Payor Class.
- d. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. Stat. §§ 542.18, et seq. and 501.201, et seq., with respect to purchases of Solodyn in Florida by members of the End-Payor Class.

- e. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Hawaii Code §§ 480, et seq., with respect to purchases of Solodyn in Hawaii by members of the End-Payor Class.
- f. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases of Solodyn in Illinois by members of the End-Payor Class.
- g. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Iowa Code §§ 553.4, et seq., with respect to purchases of Solodyn in Iowa by members of the End-Payor Class.
- h. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases of Solodyn in Kansas by members of the End-Payor Class.
- i. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. tit. 10, §§ 1101, et seq., with respect to purchases of Solodyn in Maine by members of the End-Payor Class.
- j. Defendant have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, et seq., with respect to purchases of Solodyn in Massachusetts by members of the End-Payor Class with thousands of Massachusetts end-payors paying substantially higher prices for Solodyn in actions and transactions occurring substantially within Massachusetts.
- k. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases of Solodyn in Michigan by members of the End-Payor Class.
- l. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.51, et seq., with respect to purchases of Solodyn in Minnesota by members of the End-Payor Class.
- m. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases of Solodyn in Mississippi by members of the End-Payor Class.

- n. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases of Solodyn in Nebraska by members of the End-Payor Class.
- o. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases of Solodyn in Nevada by members of the End-Payor Class, in that thousands of sales of Solodyn took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.
- p. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases of Solodyn in New Mexico by members of the End-Payor Class.
- q. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases of Solodyn in New York by members of the End-Payor Class.
- r. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases of Solodyn in North Carolina by members of the End-Payor Class.
- s. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. Cent. Code §§ 51-08.1-02, et seq., with respect to purchases of Solodyn in North Dakota by members of the End-Payor Class.
- t. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.725, et seq., with respect to purchases of Solodyn in Oregon by members of the End-Payor Class.
- u. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of 10 L.P.R.A. § 258 with respect to purchases of Solodyn in Puerto Rico by members of the End-Payor Class.
- v. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of R.I. Gen. Laws §§ 6-36-4, et seq., with respect to purchases of Solodyn in Rhode Island by members of the End-Payor Class.

- w. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. §§ 37-1-3.1, et seq., with respect to purchases of Solodyn in South Dakota by members of the End-Payor Class.
- x. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the End-Payor Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee being forced to purchase a more expensive branded Solodyn product.
- y. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases of Solodyn in Utah by members of the End-Payor Class who reside in Utah.
- z. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Vt. Stat. Ann. tit. 9, §§ 2453, et seq., with respect to purchases of Solodyn in Vermont by members of the End-Payor Class.
- aa. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of W. Va. Code §§ 47-18-3, et seq., with respect to purchases of Solodyn in West Virginia by members of the End-Payor Class.
- bb. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Wis. Stat. §§ 133.01, et seq., with respect to purchases of Solodyn in Wisconsin by members of the End-Payor Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin being forced to purchase a more expensive branded Solodyn product.

**SIXTH CLAIM FOR RELIEF  
CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER  
STATE LAW  
(Against Medicis, Valeant and Lupin)**

330. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

331. In or about July 2011 and at times before the formal execution thereof, 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 substantial payments to Lupin in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or 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 and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

332. The purpose and effect of the payments flowing from Medicis to Lupin under their agreement was to delay and impair generic competition to Solodyn, and there is no legitimate, nonpretextual, procompetitive business justification for the payments that outweighs their harmful effects.

333. The Medicis/Lupin Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

334. As a direct and proximate result of Medicis's and Lupin's unlawful restraint of trade and unlawful maintenance of and conspiracy to maintain Medicis's monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for Solodyn and its generic equivalents as described herein, and were harmed as a result.

335. By engaging in the foregoing conduct, Medicis and Lupin have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the state antitrust and consumer protection statutes listed below.

336. But for Medicis's and Lupin's unlawful conduct, the Generic Defendants and other generic manufacturers would have launched earlier than they finally did: (a) "at-risk" (that is, while the patent litigation was still pending); or (b) after winning the patent suit; or (c) via a lawful settlement agreement without a large reverse payment from Medicis.

337. Plaintiffs and members of the Class have been injured in their business or property by reason of Medicis's and Lupin's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis's and Lupin's conduct from July 2009 and continuing to the present. These injuries are of the type the state antitrust and consumer protection statutes were designed to prevent, and flow from that which makes Medicis's and Lupin's conduct unlawful.

338. As a successor in interest to Medicis, Valeant is liable for all of Medicis's anticompetitive conduct in connection with Solodyn. And by joining an ongoing unlawful agreement to restrain trade, Valeant is liable for all conduct that occurred prior to the date on which it joined the ongoing unlawful course of conduct. In addition, Valeant is liable for its own unlawful conduct.

339. By engaging in the anticompetitive conduct alleged herein, Defendants have intentionally and unlawfully engaged in one or more combinations and/or conspiracies in restraint of trade in violation of the following state laws:

- a. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Ariz. Rev. Stat. §§ 44-1402, et seq., with respect to purchases of Solodyn in Arizona by members of the End-Payor Class.
- b. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Cal. Bus. & Prof. Code

§§ 16720, et seq., and Code §§ 17200, et seq., with respect to purchases of Solodyn in California by members of the End-Payor Class.

- c. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of D.C. Code Ann. §§ 28-4503, et seq., with respect to purchases of Solodyn in the District of Columbia by members of the End-Payor Class.
- d. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. Stat. §§ 542.18, et seq. and 501.201, et seq., with respect to purchases of Solodyn in Florida by members of the End-Payor Class.
- e. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Hawaii Code §§ 480, et seq., with respect to purchases of Solodyn in Hawaii by members of the End-Payor Class.
- f. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases of Solodyn in Illinois by members of the End-Payor Class.
- g. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Iowa Code §§ 553.4, et seq., with respect to purchases of Solodyn in Iowa by members of the End-Payor Class.
- h. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases of Solodyn in Kansas by members of the End-Payor Class.
- i. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. tit. 10, §§ 1101, et seq., with respect to purchases of Solodyn in Maine by members of the End-Payor Class.
- j. Defendant have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, et seq., with respect to purchases of Solodyn in Massachusetts by members of the End-Payor Class with thousands of Massachusetts end-payors paying substantially higher prices for Solodyn in actions and transactions occurring substantially within Massachusetts.

- k. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases of Solodyn in Michigan by members of the End-Payor Class.
- l. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.51, et seq., with respect to purchases of Solodyn in Minnesota by members of the End-Payor Class.
- m. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases of Solodyn in Mississippi by members of the End-Payor Class.
- n. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases of Solodyn in Nebraska by members of the End-Payor Class.
- o. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases of Solodyn in Nevada by members of the End-Payor Class, in that thousands of sales of Solodyn took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.
- p. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases of Solodyn in New Mexico by members of the End-Payor Class.
- q. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases of Solodyn in New York by members of the End-Payor Class.
- r. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases of Solodyn in North Carolina by members of the End-Payor Class.
- s. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. Cent. Code §§ 51-08.1-02, et seq., with respect to purchases of Solodyn in North Dakota by members of the End-Payor Class.

- t. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.725, et seq., with respect to purchases of Solodyn in Oregon by members of the End-Payor Class.
- u. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of 10 L.P.R.A. § 258 with respect to purchases of Solodyn in Puerto Rico by members of the End-Payor Class.
- v. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of R.I. Gen. Laws §§ 6-36-4, et seq., with respect to purchases of Solodyn in Rhode Island by members of the End-Payor Class.
- w. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. §§ 37-1-3.1, et seq., with respect to purchases of Solodyn in South Dakota by members of the End-Payor Class.
- x. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the End-Payor Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee being forced to purchase a more expensive branded Solodyn product.
- y. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases of Solodyn in Utah by members of the End-Payor Class who reside in Utah.
- z. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Vt. Stat. Ann. tit. 9, §§ 2453, et seq., with respect to purchases of Solodyn in Vermont by members of the End-Payor Class.
- aa. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of W. Va. Code §§ 47-18-3, et seq., with respect to purchases of Solodyn in West Virginia by members of the End-Payor Class.
- bb. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Wis. Stat. §§ 133.01, et

seq., with respect to purchases of Solodyn in Wisconsin by members of the End-Payor Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payers in Wisconsin being forced to purchase a more expensive branded Solodyn product.

**SEVENTH CLAIM FOR RELIEF  
DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE  
CLAYTON ACT FOR VIOLATIONS AND SECTIONS 1 AND 2 OF THE  
SHERMAN ACT  
(Against All Defendants)**

340. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

341. Plaintiffs' allegations described herein and in the preceding and succeeding Claims comprise violations of Sections 1 and 2 of the Sherman Act, in addition to the state law violations alleged herein.

342. Plaintiffs and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a) hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Sections 1 and 2 of the Sherman Act.

343. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

**EIGHTH CLAIM FOR RELIEF  
CONSUMER PROTECTION AND DECEPTIVE TRADE PRACTICES UNDER  
STATE LAW  
(Against All Defendants)**

344. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

345. Defendants engaged in unfair competition or unfair or unconscionable acts or practices in violation of the state consumer protection statutes listed below.

346. There was a gross disparity between the price that Plaintiffs and the End-Payor Class members paid for the brand product and the value received, given that a less expensive substitute generic product should have been available.

347. As a direct and proximate result of Defendants' unfair competition or unfair or unconscionable acts or practices in violation of the state consumer protection statutes listed below, Plaintiffs and End-Payor Class members were deprived of the opportunity to purchase a generic version of Solodyn and forced to pay higher brand prices.

348. By engaging in the foregoing conduct, Defendants have violated the following state unfair trade practices and consumer fraud laws:

- a. Defendants have engaged in unfair competition or unfair acts or practices in violation of Ariz. Rev. Stat. §§ 44-1522, et seq.
- b. Defendants have engaged in unfair competition or unfair acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, et seq.
- c. Defendants have engaged in unfair competition or unfair acts or practices or made false representations in violation of D.C. Code §§ 28-3901, et seq.
- d. Defendants have engaged in unfair competition or unfair acts or practices in violation of Fla. Stat. §§ 501.201, et seq.
- e. Defendants have engaged in unfair competition or unfair acts or practices in violation of Haw. Rev. Stat. §§ 480, et seq.
- f. Defendants have engaged in unfair competition or unfair acts or practices in violation of Iowa Code §§ 714.16, et seq.
- g. Defendants have engaged in unfair competition or unfair acts or practices in violation of Idaho Code Ann. §§ 48-601, et seq.
- h. Defendants have engaged in unfair competition or unfair acts or practices in violation of 815 Ill. Comp. Stat. Ann. §§ 505/1, et seq.

- i. Defendants have engaged in unfair competition or unfair acts or practices in violation of Kan. Stat. Ann. §§ 50-623, et seq.
- j. Defendants have engaged in unfair competition or unfair acts or practices in violation of Me. Rev. Stat. tit. 5 §§ 207, et seq.
- k. Defendants have engaged in unfair competition or unfair acts or practices in violation of Mass. Gen. Laws ch. 93A, et seq.
- l. Defendants have engaged in unfair competition or unfair acts or practices in violation of Mich. Comp. Laws Ann. §§ 445.901, et seq.
- m. Defendants have engaged in unfair competition or unfair acts or practices in violation of Mo. Ann. Stat. §§ 407.010, et seq.
- n. Defendants have engaged in unfair competition or unfair acts or practices in violation of Mont. Code Ann. §§ 30-14-101, et seq.
- o. Defendants have engaged in unfair competition or unfair acts or practices in violation of Neb. Rev. Stat. §§ 59-1601, et seq.
- p. Defendants have engaged in unfair competition or unfair acts or practices in violation of Nev. Rev. Stat. §§ 598.0903, et seq.
- q. Defendants have engaged in unfair competition or unfair acts or practices in violation of N.H. Rev. Stat. Ann. §§ 358-A:1, et seq.
- r. Defendants have engaged in unfair competition or unfair acts or practices in violation of N.M. Stat. Ann. §§ 57-12-1, et seq.
- s. Defendants have engaged in unfair competition or unfair acts or practices in violation of N.Y. Gen. Bus. Law §§ 349, et seq.
- t. Defendants have engaged in unfair competition or unfair acts or practices in violation of N.C. Gen. Stat. §§ 75-1.1, et seq.
- u. Defendants have engaged in unfair competition or unfair acts or practices in violation of R.I. Gen. Laws §§ 6-13.1-1, et seq.
- v. Defendants have engaged in unfair competition or unfair acts or practices in violation of Tenn. Code Ann. §§ 47-18-101, et seq.
- w. Defendants have engaged in unfair competition or unfair acts or practices in violation of Utah Code Ann. §§ 13-11-1, et seq.

- x. Defendants have engaged in unfair competition or unfair acts or practices in violation of Vt. Stat. Ann. tit. 9 §§ 2451, et seq.
- y. Defendants have engaged in unfair competition or unfair acts or practices in violation of W. Va. Code §§ 46A-6-101, et seq.

349. Plaintiff and the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or unconscionable acts alleged herein. Their injury consists of being forced to purchase a more expensive branded Solodyn product. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

350. As a successor in interest to Medicis, Valeant is liable for all of Medicis's anticompetitive conduct in connection with Solodyn. And by joining an ongoing unlawful agreement to restrain trade, Valeant is liable for all conduct that occurred prior to the date on which it joined the ongoing unlawful course of conduct. In addition, Valeant is liable for its own unlawful conduct.

**NINTH CLAIM FOR RELIEF  
UNJUST ENRICHMENT  
(Against All Defendants)**

351. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

352. To the extent required, this claim is pled in the alternative to the other claims in this Complaint.

353. Defendants have benefited from the overcharges on sales of Solodyn made possible by the unlawful and inequitable acts alleged in this Complaint.

354. Defendants' financial benefits are traceable to Plaintiffs' and the End-Payor Class members' overpayments for Solodyn.

355. Plaintiffs and the End-Payor Class members have conferred an economic benefit upon the Defendants in the nature of profits resulting from unlawful overcharges, to the economic detriment of Plaintiffs and the End-Payor Class.

356. It would be futile for Plaintiffs and the End-Payor Class members to seek a remedy from any party with whom they had or have privity of contract. Defendants have paid no consideration to anyone for any of the benefits they received indirectly from Plaintiffs and the End-Payor Class.

357. It would be futile for Plaintiffs and the End-Payor Class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Solodyn, as those intermediaries are not liable and would not compensate Plaintiffs and the End-Payor Class for Defendants' unlawful conduct.

358. The economic benefit Defendants derived from charging monopolistic and artificially inflated prices for Solodyn is a direct and proximate result of Defendants' unlawful practices.

359. The financial benefits Defendants derived rightfully belong to Plaintiffs and the End-Payor Class, who paid anticompetitive prices that inured to Defendants' benefit.

360. It would be inequitable under unjust enrichment principles under the laws of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, the District of Columbia

and Puerto Rico for Defendants to retain any of the overcharges Plaintiffs and the End-Payor Class paid for Solodyn that were derived from Defendants' unfair and unconscionable methods, acts, and trade practices.

361. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiffs and the End-Payor Class.

362. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiffs and the End-Payor Class.

363. A constructive trust should be imposed upon all unlawful or inequitable sums the Defendants received that are traceable to Plaintiffs and the End-Payor Class.

364. Plaintiffs and the End-Payor Class have no adequate remedy at law.

365. As a successor in interest to Medicis, Valeant is liable for all of Medicis's anticompetitive conduct in connection with Solodyn. And by joining an ongoing unlawful agreement to restrain trade, Valeant is liable for all conduct that occurred prior to the date on which it joined the ongoing unlawful course of conduct. In addition, Valeant is liable for its own unlawful conduct.

### **XIII. DEMAND FOR JUDGMENT**

WHEREFORE, Plaintiffs, on their own behalf and on behalf of the proposed End-Payor Class, demands a judgment that:

- A. Determines that this case may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), directs that reasonable notice of this case be given to class members under Rule 23(c)(2), and declares that End-Payor Plaintiffs are proper representative of the class;
- B. Declares that Defendants' conduct violated Sections 1 and 2 of the Sherman Act, the other statutes set forth above, and the common law of unjust enrichment;
- C. Enjoins Defendants from continuing their illegal activities;

- D. Enters joint and several judgments against Defendants and in favor of End-Payor Plaintiffs and the End-Payor Class;
- E. Grants End-Payor Plaintiffs and the End-Payor Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy the Defendants' unjust enrichment;
- F. Awards the End-Payor Class damages and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial, including interest;
- G. Awards End-Payor Plaintiffs and the End-Payor Class their costs of suit, including reasonable attorneys' fees as provided by law; and
- H. Grants further relief as necessary to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, as the Court deems just.

#### **XIV. JURY DEMAND**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs, on behalf of themselves and the proposed End-Payor Class, demand a trial by jury on all issues so triable.

Dated: September 12, 2014

Respectfully Submitted,

/s/ Glen DeValerio

Glen DeValerio (BBO #122010)

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*Executive Committee for the Proposed End-  
Payor Class*

**CERTIFICATE OF SERVICE**

I, Glen DeValerio, hereby certify that the foregoing Consolidated Amended Class Action Complaint, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as non-registered participants on September 12, 2014.

/s/ Glen DeValerio  
Glen DeValerio