James E. Cecchi
Lindsey H. Taylor
CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO
5 Becker Farm Road
Roseland, New Jersey 07068
(973) 994-1700

Michael M. Buchman
Adam G. Kurtz
POMERANTZ HAUDEK GROSSMAN &
GROSS LLP
100 Park Avenue, 26th Floor
New York, New York 10017
(212) 661-1100

Richard J. Burke
Jeff A. Leon
COMPLEX LITIGATION GROUP LLC
1010 Market Street, Suite 660
St. Louis, Missouri 63101
(314) 880-7000

James R. Dugan, II
Douglas R. Plymale
David Franco
Kevin Oufnac
DUGAN LAW FIRM, PLC
One Canal Place
365 Canal Street, Suite 1000
New Orleans, LA 70130
(504) 648-0180

Kenneth A. Wexler
Mark R. Miller
Justin N. Boley
WEXLER WALLACE LLP
55 W. Monroe Street, Suite 3300
Chicago, Illinois 60603
(312) 346-2222

Jeffrey L. Kodroff
Theodore M. Lieverman
John Macoretta
SPECTOR, ROSEMAN, KODROFF &
WILLIS, P.C.
1818 Market Street, Suite 2500
Philadelphia, Pennsylvania 19103
(215) 496-0300

Plaintiffs Executive Committee

Lisa J. Rodruguez
Nicole M. Acchione
TRUJILLO RODRIGUEZ
& RICHARDS, LLC
258 Kings Highway East
Haddonfield, New Jersey 08033
(215) 795-9002

Liaison Counsel

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re EFFEXOR XR ANTITRUST LITIGATION This Document Relates To: All End Payor Class Actions	Civil Action No. 11-5590(JAP)(LHG) **INDIRECT PURCHASER CLASS PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT AND JURY DEMAND**

TABLE OF CONTENTS

I. INTRODUCTION

1. Indirect Purchaser Class Plaintiffs (whose full names and addresses are given below in paragraphs 21 through 30) bring this antitrust, consumer protection and unjust enrichment class action against Defendants Wyeth and Teva (described in paragraphs 31 through 38) for damages and injunctive relief resulting from the delayed market entry of generic versions of Wyeth's branded antidepressant Effexor XR, an encapsulated extended release version of the compound venlafaxine.

2. Effexor XR is a prescription antidepressant used to treat three types of anxiety disorder in adults:[1] generalized anxiety disorder, panic disorder and social anxiety disorder.

3. Indirect purchasers are consumers and third-party payors (such as insurers and employee benefit plans) who paid or reimbursed some or all of the price of Effexor XR or its generic versions for use and not for resale. They are the last person or entity in the chain of distribution.

4. Although Wyeth's marketing exclusivity for the original venlafaxine compound patent lapsed on June 13, 2008, the first generic equivalent of Effexor XR was foreclosed for two more years, until June 2010. Other generics were foreclosed until June 2011. The reason: Wyeth engaged in an anticompetitive scheme to prevent and delay the approval and marketing of generic versions of Effexor XR. Wyeth's scheme included (i) fraudulently procuring three patents for extended release formulations of venlafaxine hydrochloride; (ii) wrongfully listing those patents in the Food and Drug Administration ("FDA") Orange Book as covering Effexor

[1] The Important Safety Information for Effexor XR (Black Box) warns that it is not approved for use in children or teens. http://www.Effexorxr.com/about-Effexor/antidepressant-information.aspx. Indeed, "antidepressants increase[d] the risk of suicidal thinking and behavior (suicidality) in studies in children, teenagers, and young adults ages 18 to 24 with depression and other psychiatric disorders." http://www.Effexorxr.com/about-Effexor/antidepressant-information.aspx

XR; (iii) engaging in serial sham litigation to block and delay multiple generic companies; (iv) entering into a horizontal market-allocation and price-fixing agreement with generic manufacturer Teva; and (v) negotiating settlements with subsequent generic applicants to preserve and protect its monopoly and market-division agreement with first-filer Teva.

5. The early phase of Wyeth's blocking strategy had to overcome two challenges.

6. *First*, by the 1990s pharmaceutical formulators knew so much about how to slow down the release of chemicals like venlafaxine that there were few novel approaches left. *Second*, the kind of narrow formulation patent that might properly emerge in this setting would be a low bar; generic competitors could and would simply design around the specific formulation.

7. In order to hold onto its patent monopoly, Wyeth resorted to fraud.

8. *Wyeth's Fraudulent Patent Procurement.* Through a series of fraudulent acts, Wyeth was able to obtain broad method-of-use claims in three patents that primarily addressed specific formulations of extended release venlafaxine: U.S. Patent Nos. 6,274,171 ("the '171 patent), 6,419,958 ("the '958 patent"), and 6,403,120 ("the '120 patent"). These three patents ostensibly lengthened Wyeth's monopoly on extended release venlafaxine hydrochloride capsules by nine years, until March 20, 2017. However, Wyeth was only able to obtain these patents by misrepresenting and concealing material information to the U.S. Patent and Trademark Office (the "PTO"). Wyeth knew that under the scrutiny of patent infringement litigation there was no realistic likelihood that a court would, ultimately, enforce the '171, '958, or '120 patents against a generic manufacturer. But Wyeth needed only a patent to use as a vehicle to bring an infringement action. Wyeth would avoid the inevitable loss by settling the lawsuits before courts ruled on the merits.

9. Wyeth's overarching scheme included three separate frauds on the PTO.

10. *Wyeth's Nausea Fraud.* All three fraudulently obtained patents included method-of-use claims for decreasing the incidence of nausea and vomiting. Wyeth told the PTO that clinical data showed that Wyeth's extended release version of venlafaxine hydrochloride, Effexor XR, reduced the incidence of nausea and vomiting associated with instant release Effexor. Wyeth offered no other support for these claims. In truth, no such clinical data existed. The nausea method of use claims would never have issued but for Wyeth's misrepresentations to the PTO.

11. *Wyeth's Unexpected Discovery Invalidity and Fraud.* Wyeth fraudulently claimed that its purported discovery of an extended release version of Effexor was "completely unexpected," despite knowing that (i) an earlier Wyeth patent (the Upton patent) had disclosed extended release versions of Effexor; (ii) an earlier, published, patent application by a Wyeth collaborator (the '589 PCT application) had also disclosed extended release versions of Effexor; (iii) one skilled in the art would be aware of several methods for achieving extended or sustained release formulations; (iv) Wyeth had already successfully created a long-acting formulation of propranolol (Inderal LA), a similarly soluble compound with a similar peak blood concentration time; and (v) Wyeth had already successfully developed an Effexor XR formulation by substituting venlafaxine for propranolol in the Inderal LA formulation. In reality, extended release venlafaxine was expected and easily created. None of the claims of any of the three fraudulently obtained patents would have issued if Wyeth had not made the intentional and highly material misrepresentations that its supposed discovery of extended release venlafaxine was "completely unexpected".

12. *Wyeth's Prior Rejection Invalidity and Fraud.* Wyeth used a Trojan horse to obtain method-of-use claims in a series of ostensible formulation patents for a specific encapsulated spheroid approach to extending the release of venlafaxine. Wyeth's patent

applications included a few ambiguously phrased method-of-use claims. One reading of the claims limited the method-of-use claims to Wyeth's encapsulated spheroid formulations. But another interpretation would appear to protect *any* method of using extended release venlafaxine to spread the dosage over time – *regardless* of the particular formulation. Ironically, the first PTO examiner reviewed Wyeth's first application, caught onto Wyeth's sleight of hand, observed that the method-of-use claims could be interpreted broadly, and rejected Wyeth's broad method-of-use claims as unpatentable – since these methods of use would be obvious to one skilled in the art.

13. Once discovered, Wyeth agreed to amend its method-of-use claims to be tied to the particular formulations Wyeth was seeking to patent, but then abandoned that application (including formulation claims the first examiner had found patentable), opting to try again with another patent examiner. Wyeth refiled applications that included the previously rejected method-of-use claims. Wyeth then failed to disclose to later examiners (i) that the original patent examiner had found its method-of-use claims unpatentable and (ii) that Wyeth had agreed with this rejection.

14. *Wyeth's Wrongful Orange Book Listings and Serial Sham Litigation.* After obtaining the '171, '120, and '958 patents, Wyeth used them to continue its scheme to block generic versions of Effexor XR from the market. Wyeth listed all three patents in the Orange Book and promptly filed baseless patent infringement litigation against each and every generic manufacturer that tried to bring an extended release venlafaxine product to market. Wyeth alleged that generic manufacturers were infringing its '171, '120, and '958 patents – patents Wyeth knew to be invalid and/or unenforceable – in seventeen sham lawsuits as of the date of the filing of this Complaint. Every generic manufacturer responded by pointing out that Wyeth's

patents were invalid and/or unenforceable, but each suit triggered an automatic 30-month stay of FDA approval.

15. *Wyeth and Teva's Conspiracy.* Wyeth then settled all the sham lawsuits before a court determined whether the fraudulently obtained method-of-use claims were invalid and/or unenforceable. The settlements were "win-win" for Wyeth and first generic filer Teva – they prolonged Wyeth's market exclusivity far beyond its lawful protection of mid-2008 and enabled Teva to maintain and extend its generic exclusivity rights. Teva received significant additional benefits in exchange for its agreement not to market its generic version of Effexor XR until June 2010, including reciprocal agreements by Wyeth (i) not to compete with Teva during its period of generic exclusivity by launching its own generic version of Effexor XR, and (ii) to seek to preserve Teva's exclusivity by resolving any subsequent generic lawsuits before they advanced to findings of invalidity and/or non-infringement (findings that otherwise would have triggered Teva's exclusivity rights as the first generic filer and permitted Teva to introduce its generic Effexor XR product before July 1, 2010).

16. If Wyeth had not fraudulently obtained the method-of-use claims, listed the fraudulently obtained patents in the Orange Book, brought sham infringement actions, and/or colluded with Teva, generic extended release venlafaxine products would have launched for sale in June of 2008. Absent its fraud and other wrongful conduct, Wyeth could not have extended its monopoly in the market for extended release venlafaxine hydrochloride capsules beyond June 2008 through the settlements of its improper patent lawsuits – since those lawsuits would not have existed absent Wyeth's fraud in obtaining and/or listing the allegedly infringed patents.

17. As a result of Wyeth's fraud and other exclusionary conduct, generic versions of Effexor XR were illegally blocked from the marketplace from at least June 2008 through at least June 2010. During this period of foreclosure, U.S. retail sales of Effexor XR topped *$4.5 billion*.

Indirect purchasers paid significantly more for extended release venlafaxine hydrochloride capsules during this two year window (and continue to pay more for Effexor XR and its generic equivalents) than they would have in the absence of Wyeth's illegal anticompetitive acts.

II. JURISDICTION AND VENUE

18. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) in that this is a class action in which the amount in controversy exceeds $5,000,000, exclusive of interest and costs, and at least one member of the putative class is a citizen of a different State than that of one of the Defendants.

19. 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 Defendants' violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2. The Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367.

20. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) in that Wyeth's principal place of business is in this District, and all other Defendants are subject to personal jurisdiction in this District and, thus, also "reside" in this District, in accordance with 28 U.S.C. § 1391(c).

III. THE PARTIES

21. Plaintiff A. F. of L. – A.G.C. Building Trades Welfare Plan (the "AFL Plan") is a self-insured health and welfare benefit plan with its principal place of business in Mobile, Alabama. The AFL Plan represents participants who reside, *inter alia*, in Alabama and Florida. Plaintiff AFL Plan purchased and/or provided reimbursement for Effexor XR or its generic equivalent during the Class Period. Plaintiff AFL Plan paid more than it would have absent Defendants' unlawful scheme to prevent generic entry. Plaintiff AFL Plan purchased and/or

provided reimbursement for Effexor XR or its generic equivalent in the State of Florida in 2008 and 2009.

22. Plaintiff Daryl Deino is a citizen of the State of California. Plaintiff purchased Effexor XR during the Class Period, for which she paid more than she would have absent Defendants' unlawful monopolization of scheme to prevent generic entry.

23. Plaintiff IBEW - NECA Local 505 Health & Welfare Plan (the "IBEW Plan") is a self-insured health and welfare benefit plan with its principal place of business in Mobile, Alabama. The IBEW Plan represents participants who reside in various states. Plaintiff IBEW Plan purchased and/or provided reimbursement for Effexor XR or its generic equivalent during the Class Period. Plaintiff IBEW Plan paid more than it would have absent Defendants' unlawful scheme to prevent generic entry. Plaintiff IBEW Plan purchased and/or provided reimbursement for Effexor XR or its generic equivalent in the State of Kansas in 2008.

24. Plaintiff Louisiana Health Service Indemnity Company d/b/a Bluecross/Blueshield of Louisiana ("BCBSLA") is a domestic health insurance corporation licensed to conduct business in the State of Louisiana. Plaintiff BCBSLA purchased and/or paid for Effexor XR or its generic equivalent during the Class Period and, along with other members of the Class, paid more than it would have absent Defendants' unlawful scheme to prevent generic entry. Plaintiff BCBSLA purchased and/or paid for Effexor XR or its generic equivalent in the following states during the class period: Alaska, Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Mississippi, Montana, New Jersey, Nevada, New Hampshire, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, West Virginia, and Wyoming. It also purchased and/or

provided reimbursement for Effexor XR or its generic equivalent during the class period in the Virgin Islands.

25. Plaintiff Man-U Service Contract Trust Fund ("the Man-U Fund") is a trust fund established and maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act, 29 U.S.C. § 186(c)(5), and is an employee benefit plan established and maintained pursuant to the Employee Retirement Income Security Act, 29 U.S.C. § 1001, *et seq.*, for the purpose of providing health benefits, including prescription drug coverage, to eligible participants and beneficiaries. The Man-U Fund maintains its principal place of business at 4600 Powder Mill Road, Suite 100, Beltsville, Maryland 20705. The Man-U Fund provides comprehensive health coverage, including prescription drug coverage, for approximately 1,200 participants and beneficiaries located in Maryland, Delaware, Virginia, North Carolina, Pennsylvania and Washington, D.C. During the Class Period as described herein, the Man-U Fund has to date paid for some or all of the purchase price of Effexor XR or its generic equivalent prescribed to one or more of its participants or beneficiaries in Virginia and Maryland and has thereby been injured, and continues to be injured, as a result of Defendants' conduct.

26. Plaintiff MC - UA Local 119 Health and Welfare Plan (the "UA" Plan") is a self-insured health and welfare benefit plan with its principal place of business in Mobile, Alabama. The UA Plan represents participants who reside, *inter alia*, in Alabama and Florida. Plaintiff UA Plan purchased and/or provided reimbursement for Effexor XR or its generic equivalent during the Class Period. Plaintiff UA Plan paid more than it would have absent Defendants' unlawful scheme to prevent generic entry. Plaintiff UA Plan purchased and/or provided reimbursement for Effexor XR and/or its generic equivalent in the State of Wisconsin in 2008 and 2009.

27. Plaintiff, New Mexico United Food And Commercial Workers Union's And Employers' Health And Welfare Trust Fund, ("NMUFCW"), is a Taft-Hartley fund with its

principle place of business in Albuquerque, New Mexico. Plaintiff NMUFCW purchased and/or provided reimbursement for Effexor XR or its generic equivalent in the State of New Mexico in 2008 and 2009.

28. Plaintiff Plumbers and Pipefitters Local 572 Health and Welfare Fund ("Local 572") is a trust fund administered pursuant to the requirements of the Taft-Hartley Act, 29 U.S.C. §1 86, by an equal number of trustees appointed by labor representatives and union representatives. Local 572 is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to § 302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. § 186(c)(5), and is defined by §§ 1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001, *et seq*. As such, Local 572 is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). Local 572's office is located in Davidson County, Tennessee. Plaintiff Local 572 paid more than it would have absent Defendants' unlawful scheme to prevent generic entry. Plaintiff Local 572 purchased and/or provided reimbursement for Effexor XR or its generic equivalent in the States of Arizona and Tennessee in 2008.

29. Plaintiff Sergeants Benevolent Association Health and Welfare Fund ("SBA") is a health and welfare benefit fund with its principal place of business at 35 Worth Street, New York, New York, and is involved in the business of providing health benefits for covered lives. Plaintiff SBA is a employee welfare benefit plan and an "employee benefit plan." As such, SBA is a legal entity entitled to bring suit in its own name. Plaintiff SBA purchased and/or provided reimbursement for Effexor XR or its generic equivalent in the State of New York.

30. Plaintiff Patricia Sutter is a citizen of the State of Maine. Plaintiff purchased Effexor XR during the Class Period, for which she paid more than she would have absent Defendant's unlawful monopolization of scheme to prevent generic entry.

31. Defendant Wyeth – a/k/a Wyeth LLC, f/k/a Wyeth, Inc., f/k/a American Home Products – is a corporation organized and existing under the laws of the state of Delaware. Wyeth's principal place of business is Madison, New Jersey. On information and belief, American Home Products changed its name to Wyeth, Inc., and Wyeth, Inc. later changed its name to Wyeth LLC. Wyeth is now a wholly owned subsidiary of Pfizer.

32. Defendant Wyeth Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the state of Delaware with a principal place of business in Collegeville, Pennsylvania. Wyeth Pharmaceuticals, Inc. is a member of Wyeth Pharmaceuticals Division and is a wholly owned subsidiary of Wyeth.

33. Defendant Wyeth-Whitehall Pharmaceuticals ("Wyeth-Whitehall") is a corporation organized and existing under the laws of Puerto Rico and having a place of business at Road No. 3, KM. 142.1, Guayama, Puerto Rico 00784. Wyeth-Whitehall is in the business of pharmaceutical preparation and is a subsidiary of Wyeth.

34. Defendant Wyeth Pharmaceuticals Company ("WPC") is a corporation organized and existing under the laws of Puerto Rico and having a place of business at Road No. 3, KM. 142.1, Guayama, Puerto Rico 00784. WPC is in the business of pharmaceutical wholesale products and is a subsidiary of Wyeth.

35. Defendants Wyeth and Wyeth Pharmaceuticals, Inc., Wyeth-Whitehall and WPC are referred to collectively as "Wyeth."

36. Throughout this complaint, the phrase "the Wyeth applicants" refers to Wyeth, the named inventors of the fraudulently-obtained patents, the prosecuting attorneys of the fraudulently-obtained patents, and agents thereof. The Wyeth applicants include, but are not limited to: inventors John C. Clark, John U. Lamer, Deborah M. Sherman, and Steven A. White

as well as Attorneys Ronald W. Alice, Rebecca Barrett, Egon Berg, Robert Boswell Jr., Steven R. Eck, and Arthur Seifert. The term also includes any agents of these persons from Wyeth.

37. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva USA is in the business of developing, manufacturing and marketing pharmaceutical products, primarily generic products, in the United States. Teva Pharmaceuticals USA is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

38. Defendant Teva Pharmaceutical Industries Ltd. is an Israeli corporation, headquartered and having a place of business at 5 Basel St. Petach Tikva 49131, Israel, engaged in the development, manufacturing, marketing and distribution of pharmaceuticals. Through its subsidiaries, a large portion of Teva Pharmaceutical Industries Ltd.'s sales are in the United States and Teva Pharmaceutical Industries Ltd. has major manufacturing operations in the United States. Teva Pharmaceutical Industries Ltd. is the parent company of Teva Pharmaceuticals USA.

39. Defendants Teva USA and Teva Ltd. are referred to collectively as "Teva."

40. Teva and Wyeth will be referred to hereinafter collectively as "Defendants."

IV. LEGAL AND REGULATORY BACKGROUND

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

41. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. §§ 355(a) & (b).

42. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book." Patents issued after NDA approval may be listed within 30 days of issuance. 21 U.S.C. §§ 355 (b) (1) & (c) (2).

43. The FDA relies completely on the brand manufacturer's truthfulness about a patent's validity and applicability; the FDA has neither the authority nor the resources to check the manufacturer's representations for accuracy or trustworthiness.

1. The Hatch-Waxman Amendments

44. The Hatch-Waxman Amendments enacted in 1984 simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand name drug may file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, but must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug – that is, that the generic drug is bioequivalent to the brand name drug. The FDA assigns generic drugs that are bioequivalent to branded drugs an "AB" rating.[2]

[2] Generic manufacturers can also seek approval of non-AB-rated generics. The FDCA permits "hybrid" applications that are neither full NDAs containing safety and efficacy data, nor ANDA applications showing that the proposed product is the "same" as the NDA product. 21 U.S.C. § 505(b)(2). Drug products approved under this section use a safe and effective active

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

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

47. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies. In 1983, pre-Hatch Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic versions available; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generics totaled $21.6 billion and generic drugs accounted for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion and generic drugs accounted for 75% of all prescriptions.

2. Paragraph IV Certifications

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

---

pharmaceutical ingredient, but modify the drug product in some way so that it differs from the original NDA product, either in dosage form, strength, route of administration, formulation, dosing regimen, or indication. These non-AB-rated generics are not bioequivalent to the innovator product. *See* 21 C.F.R. § 314.54.

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

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

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

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

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

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

51. The high profit margins on brand name drugs, and the predictable effects of generic entry – sales switch quickly from the brand to the generic – create powerful financial

incentives for brand name manufacturers to list patents in the Orange Book – even if such patents are not eligible for listing – and sue any generic competitor that files an ANDA with Paragraph IV certifications – even if the competitor's product does not actually infringe the listed patent(s) and/or the patent is invalid and unenforceable – in order to delay final FDA approval of an ANDA for up to 30 months.

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

B. The Benefits of Generic Drugs

53. Typically, AB-rated generics cost much less than their branded counterparts. Over time, as more generic equivalents compete with each other, prices decline even further. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise).

54. Once a generic equivalent hits the market, the generic quickly captures sales of the branded drug, often capturing 80% or more of the market within the first six months.

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

V. FACTUAL BACKGROUND

A. Wyeth Obtains the Original Compound Patent for Effexor

56. On August 13, 1985, the PTO issued a patent for the compound venlafaxine hydrochloride ("venlafaxine"), U.S. Patent No. 4,535,186 (the "Husbands patent"). The inventors, G.E. Morris Husbands and others, assigned the Husbands patent to American Home Products – now known as Wyeth.

57. Eight years later in December of 1993, FDA approved Wyeth's NDA for Effexor, an antidepressant whose active pharmaceutical ingredient is venlafaxine. Effexor is a tablet that dissolves rapidly, resulting in a rapid increase in blood plasma levels of venlafaxine shortly after administration. Compounds with such rapid dissolution profiles are referred to as "instant release" formulations. Levels of venlafaxine in the blood decrease over time, reaching sub-therapeutic levels in about twelve hours. Effexor is thus usually taken twice a day.

58. The Husbands patent protected venlafaxine generally, and thus it protected any kind of Wyeth venlafaxine products from generic competition before June 13, 2008. (The patent would have expired much earlier than 2008, but Wyeth received a significant extension to reflect the time it took the FDA to approve its NDA for Effexor and an additional six month extension for having conducted pediatric studies).

59. As a result, Wyeth had market exclusivity for venlafaxine products – whether instant release or extended release – for 14½ years. This lawful period of market exclusivity would enable Wyeth to market its venlafaxine products – both Effexor and Effexor XR – without generic competition, resulting in huge sales and profits to Wyeth. But the *quid pro quo* of the patent laws is that after this period of market exclusivity expires, generic companies are permitted to launch competing products, thus dramatically lowering prices to the benefit of American purchasers.

B. Wyeth Develops Extended Release Venlafaxine Products

60. Pharmaceutical development typically involves (i) the development of a pharmaceutical formulation; (ii) clinical testing of the formulation; and (iii) seeking patent protection. During the early 1990s, Wyeth engaged in these activities in order to develop an extended release version for venlafaxine hydrochloride. A description of those efforts sets the stage for Wyeth's 1996 filing of the first patent application that gives rise to the fraudulent patents, sham infringement litigations, and illegal cooperation agreements alleged in this complaint to have blocked generic competition unlawfully.

1. Wyeth's Development of Spheroid Encapsulated Extended Release Venlafaxine.

61. In 1991, the well-known drawbacks associated with immediate release dosage forms (primarily the need to take medication multiple times a day) prompted Wyeth's marketing department to request development of an extended release version of venlafaxine. Early trials with instant release venlafaxine showed that some patients who took Effexor (instant release) reported experiencing negative side effects such as nausea and vomiting. In theory, these adverse symptoms could be attributed to the spikes in the amount of active ingredient in a patient's blood plasma associated with taking multiple doses of a drug.

62. At this time, it was well-known that controlling the release of a drug (*i.e.*, smoothing out the release of the drug in the body over a full day) might avoid peaks in blood plasma levels experienced when a drug is taken multiple times during a day; again, in theory, this might lessen negative side effects associated with unstable plasma levels.

63. Extended release formulation techniques were known in the art since at least the 1950s, and were commonly taught in pharmacy schools for use with a wide variety of active ingredients. By the early 1990s, methods for achieving sustained or extended release of the

active ingredient in pharmaceuticals were well known in the drug industry. It was common knowledge that the rate of drug release from solid dosage forms may be extended by (a) modifying drug dissolution by controlling access of biologic fluids to the drug through use of barrier coatings, (b) controlling drug diffusion rates from dosage forms, and (c) chemical reaction or interaction between a drug substance or its pharmaceutical barrier and site-specific biologic fluids. These methods incorporate the use of coated beads, granules, and microspheres; micro-encapsulated drugs; sustained-release, extended-release, timed-release, controlled-release, or continuous-release tablets or capsules; or embedding the drugs in slowly eroding or hydrophilic matrix systems.

64. A group of Wyeth chemists from the upstate New York area initially attempted to create an extended release venlafaxine formulation using hydrogel tablet technology (where the active ingredient is combined with cellulose ethers and then compressed into a tablet). Inventor Deborah M. Sherman had previous experience with this approach, and in the second half of 1991 set out to make an extended release hydrogel tablet containing venlafaxine. However, by December of that year, Wyeth abandoned its hydrogel approach because the tablets were dissolving too rapidly.

65. Wyeth then turned to two other strategies: (i) in-house development using a conventional coated spheroid approach for active ingredients that are highly soluble, and (ii) a business venture with Alza, a pharmaceutical formulation company specializing in extended release technology and having an available "OROS" technology that might be used to extend the release of venlafaxine.

66. As to its in-house development using the proven coated spheroid approach, Wyeth looked to its prior experience with extending the release of a similar chemical, propranolol

(marketed as Inderal). Inderal LA, a "long acting" or extended release product, had been formulated well over a decade earlier and received FDA marketing approval in April 1983.

67. The Inderal LA approach to extending the release of an active ingredient was a conventional approach; the active ingredient is mixed with off-the-shelf binding agents (microcrystalline cellulose ["MCC"] and hydroxypropylmethylcellulose ["HPMC"]) to form an extrudable plastic mass from which small diameter (e.g., 1 mm) cylinders of the drug/matrix are chopped and transformed into spheroids using standard spheronization equipment. After drying, the spheroids can be film-coated with off-the-shelf cellulose products (ethylcellulose ["EC"] and HPMC) to retard dissolution. Finally, gelatin capsules are filled with the spheroids in the quantity needed for the therapeutic effect.

68. The Inderal LA formulation had been patented long ago in McAinsh *et als*., U.S. patent number 4,138,475 (the "McAinsh patent"), which taught the use of a hard gelatin capsule comprised of spheroids film-coated by a mixture of off-the-shelf EC and HPMC. Thus, this conventional approach to extending the release of a drug was prior art in the early 1990s (when extended release venlafaxine products were being developed and Wyeth was seeking additional patent protection for Effexor XR).

69. The Effexor XR inventors implemented the coated spheroid approach simply by substituting venlafaxine for the propranolol in Wyeth's Inderal LA formulation. Put differently, Wyeth used the *same off-the-shelf excipients, methodology and spheronization machine* used to make extended release propronalol – a film-coated spheroid formulation composed of a therapeutically effective amount of the active ingredient in spheroids (comprised of venlafaxine hydrochloride, MCC, and, optionally, HPMC) coated with a mixture of EC and HPMC.

70. Of course, Wyeth expected that the coated spheroid approach would succeed even before lab work began. The known physical, chemical, and pharmacokinetic properties of

venlafaxine and propranolol were sufficiently similar for these purposes that Wyeth was confident the extended release formulation of venlafaxine would be successful. Richard DeNeale, who was managing the extended-release venlafaxine project, wrote at the time "chances of success with the spheroid approach are high."

71. In 1992, within only six months or so of implementing the spheroid approach, Wyeth deemed the approach successful.

2. Alza's Development of an Osmotic Shell Extended Release Venlafaxine.

72. Meanwhile, the second strategy of using Alza's OROS technology was also being pursued. In 1992, Wyeth entered into a cooperation agreement with Alza to develop an extended release formulation of venlafaxine hydrochloride using Alza's proprietary drug delivery system. The collaboration agreement granted Alza ownership rights in any information generated or acquired during the collaboration, and the patents resulting from the collaboration. Alza also retained the right to use, disclose, and license information from the collaboration to third parties. Both Alza and Wyeth knew they were each simultaneously, developing an extended release version of venlafaxine.

73. Alza sought to use its OROS technology to extend or control the release of many drug products. Basically, the formulation uses a largely insoluble shell having an exit port that is partially permeable to surrounding water or biological fluids but largely impermeable to the active ingredient contained inside the shell. Once swallowed, osmotic action over an extended period of time permits a controlled release of the active ingredient into the bloodstream.

74. By the end of 1992, Alza (using its osmotic approach from the OROS technology) was, like Wyeth, also successful in developing an extended release formulation of venlafaxine.

75. Wyeth then had available to it two formulations of extended release venlafaxine. It chose to pursue its own, encapsulated spheroid approach.

3. Clinical Studies for Wyeth's Extended Release Formulation.

76. Following development of the encapsulated spheroid extended release venlafaxine, Wyeth conducted clinical studies to establish the efficacy and safety of its new formulation. In some studies, Wyeth compared the extended release formulation of venlafaxine to the instant release formulation; in others, it compared the extended release to placebo. While the studies established the FDA minima of efficacy as compared to a placebo, the studies failed to establish any statistically significant improvement of the extended release over the instant release with respect to side effects such as nausea. The product might gain FDA marketing approval (and thus provide the convenience of once-a-day dosing), but Wyeth could not truthfully claim there was any valid scientific basis for claiming that the extended release version reduced side effects when compared to the instant release.

4. Wyeth's Early 1990s Efforts to Get Further Patent Protection for Venlafaxine.

77. In addition to clinical testing, Wyeth began some early efforts to secure further patent protection for venlafaxine. In June of 1993, a different group of Wyeth employees (clinicians based in eastern Pennsylvania) filed a patent application seeking a method-of-use patent for using venlafaxine for an eclectic mix of medical conditions. The application claimed as the "invention . . . a method of treating obesity, generalized anxiety disorder, post-traumatic stress disorder, late luteal phase disphoric disorder (premenstrual syndrome), attention deficient disorder, with and without hyperactivity, Gilles de la Tourette syndrome, bulimia nervosa or Shy Dragger Syndrome . . . by administering . . . an effective amount of [venlafaxine]." It did not seek protection for any specific formulation of venlafaxine.

78. Because it was widely known that instant release venlafaxine would need to be dosed multiple times daily (with the associated inconvenience and potential side effects from

spiking blood plasma levels), this group of Wyeth inventors described "sustained release compositions" of venlafaxine as a likely favored form of administering venlafaxine.

79. After abandoning the original application, in January 1995, Wyeth (through this group of Wyeth employees) filed a series of continuation applications. These applications reiterated that "sustained release compositions" of venlafaxine were the likely favored form of administering venlafaxine. (Eventually, these applications led to a few method-of-use patents for specific, medical conditions).

80. Also in January of 1995, some of the same group of Eastern Pennsylvania-based Wyeth employees filed patent application no. 08/380,093, (the "Upton application"). The Upton application sought a method-of-use patent for using venlafaxine to treat hypothalamic menopause in non-depressed women. It did not seek approval of any formulations of venlafaxine. But, as was the case with the prior method-of-use application for a range of medical conditions, the specification here again disclosed a "sustained oral administration form or time-release form [of venlafaxine], which may be used to spread the dosage over time, such as for once-a-day applications."

81. On April 9, 1996, the Upton application issued as U.S. Patent No. 5,506,270 (the "Upton patent") and was later assigned to Wyeth. The Upton patent contained the same reference to sustained and time release forms of venlafaxine to spread the dosage over time as the proposed specification at column 5, lines 23-27:

> It is understood that … this invention is intended to cover any means of administration to a patient of an active amount of the compounds listed above in the treatment of hypothalamic amenorrhea. Such administrations may also be provided in a bolus form, intermittent-release form, *sustained oral administration form or time-release form, which may be used to spread the dosage over time, such as for once-a-day applications.*

5. Alza's Early 1990s Efforts to Secure Patent Protection.

82. In the early 1990s, Alza also sought patent protection for its extended release osmotic approach for venlafaxine. On May 27, 1993, Alza filed patent application U.S. Serial No. 08/068,480, listing inventors Edgren, *et al.* (the "Edgren application"). The Edgren application eventually matured into U.S. Patent No. 6, 440,457 on August 27, 2002.

83. On December 8, 1994, the World Intellectual Property Organization in Geneva, Switzerland published WO 94/27589, assigned to Alza (the " '589 PCT application"). The '589 PCT application claims priority to the Edgren application and discloses to the public all features of the Edgren application.

84. The '589 PCT application discloses the once-a-day venlafaxine extended release osmotic formulation (in various iterations) developed by Alza in 1992 (along with methods for the administration of venlafaxine extended release formulations, and the hours required for *in vitro* dissolution). But Alza's '589 PCT application *also* describes, repeatedly, the broader notion that the use of extended release venlafaxine would reduce the daily spiking in blood plasma levels that result from multiple daily usage of venlafaxine. In addition, it discloses the notion that extending the release may (theoretically) reduce side effects sometimes thought to be caused by daily spiking for multiple daily doses.

85. For example, Alza explained in the '589 PCT application that conventional instant release formulations result in "large peaks and valleys . . . in the drug blood levels." The applicants stated that there was a "need for a controlled-release dosage form that can administer the drug at a controlled rate over an extended time to provide constant therapy and thereby eliminate the need for multiple dosing." The Alza formulations sought to "provide a drug delivery controlled release system that can deliver a drug for maintaining constant drug levels in the blood, thereby functioning as a controlled release system." Alza further sought "to provide a

once a day controlled release dosage form to deliver [venlafaxine hydrochloride] orally to a patient in need of therapy[,]" and "to provide a method for administering [venlafaxine hydrochloride] in a therapeutic range while simultaneously avoiding a toxic range[.]"

86. The '589 PCT application disclosed venlafaxine hydrochloride specifically as the antidepressant pharmaceutical ingredient. The formulations were to be administered once-a-day in a single dose over a twenty-four hour period. The '589 PCT application indicates that the dosage form successfully maintained constant drug levels in the blood by virtue of its extended release properties.

87. While the '589 PCT and Edgren applications do not report peak blood plasma levels, minimization of the troughs and peaks of blood plasma levels are at the core of the extended release formulations disclosed in the '589 PCT application and the Edgren application. The notion that extending the release of venlafaxine over a 24 hour period would be a method to eliminate peaks and valleys in blood plasma concentration, and that (in theory) might reduce the toxic range inherent in blood plasma spikes, was unequivocably disclosed by Wyeth's development partner Alza in the '589 PCT application.

88. These facts set the stage for Wyeth's fraud.

C. Wyeth Fraudulently Obtains Method-of-Use Claims in Three Effexor XR Patents

89. In the spring of 1996 – after Wyeth had applied for the Upton patent, after Alza's '589 PCT application had been published, and after Wyeth had created extended release venlafaxine by using the Inderal LA approach – Wyeth was gearing up to seek FDA approval for its extended release venlafaxine product (using the film-coated spheroid approach). Although the original Husbands patent (as extended for the time Wyeth spent pursuing NDA approval and pediatric studies) provided Wyeth with a total of 14½ years of market exclusivity for venlafaxine

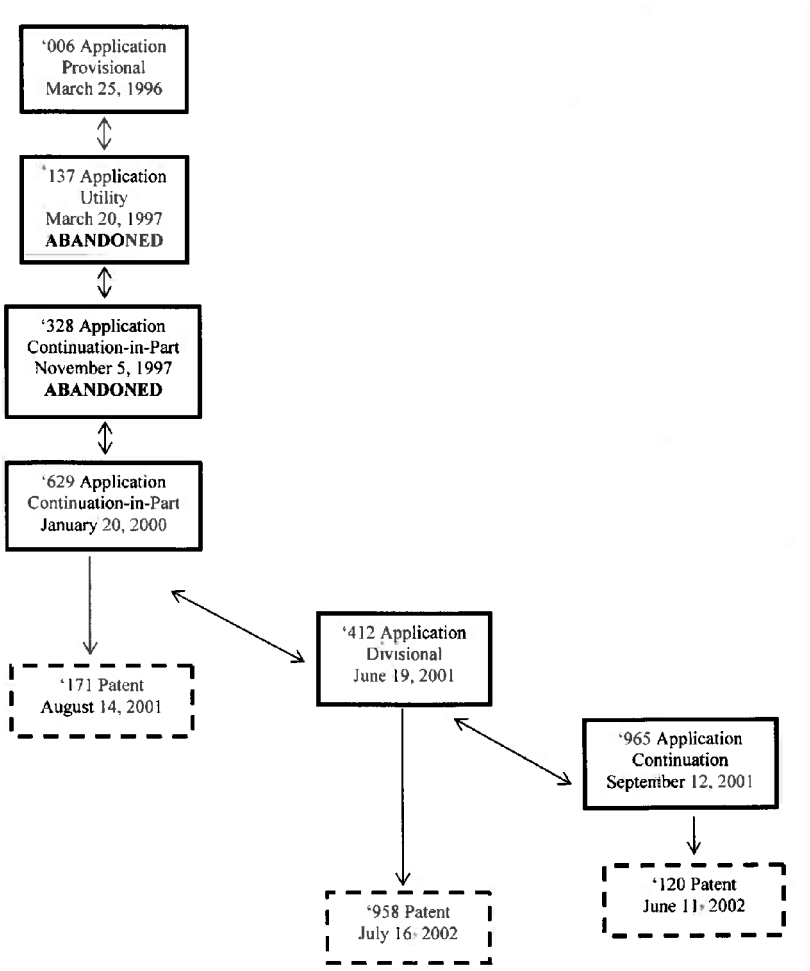
products, and although in 1996 *twelve years* remained on this exclusivity, Wyeth sought to extend the length of its exclusivity *even further*.

90. Beginning in March of 1996, Wyeth submitted six sequential applications that led to three patents, the '171, '958, and '120 patents, each of which contained ostensibly independent method-of-use claims. All three patents are, and have always been, unenforceable: They only issued because Wyeth defrauded the PTO. The fraudulently-obtained patents, the wrongful listing of these patents, and the filing of sham litigation related to these patents, prevented generic extended release venlafaxines from coming to market in June of 2008.

91. Two months later, on May 16, 1996, Wyeth sought FDA approval to sell an encapsulated extended release formulation of venlafaxine hydrochloride called Effexor XR. On October 20, 1997, the FDA approved Wyeth's NDA for Effexor XR. Effexor XR is typically taken once a day.

92. A technical summary of the family history of the patents follows. Wyeth's fraud in securing these patents is then described in detail.

1. The Application History of the Invalid and Unenforceable '171, '958, and '120 Patents



a. Wyeth's Original '006 Application

93. On March 25, 1996, the Wyeth applicants filed a provisional utility patent application, No. 60/014,006 (the "'006 application") with the PTO. A utility patent application seeks to protect a new, useful, or nonobvious process or composition. Provisional patent applications require only a brief written description of the claimed subject matter. Inventors must file a non-provisional application with formal claims within one year. Filing a provisional application essentially allows an inventor to establish a date of invention one full year before the inventor actually submits evidence of his invention's patentability.

b. Wyeth's '137 Application

94. Almost exactly one year after filing the provisional application, on March 20, 1997, the Wyeth applicants filed a non-provisional application, No. 08/821,137 (the "'137 application"). The '137 application claimed priority to the '006 application – meaning, the patentability of the '137 application would be evaluated as though it were filed a year earlier. The examiner required the Wyeth applicants to amend certain claims in light of prior art. On August 5, 1997, the examiner issued a notice of allowance for the amended claims – meaning that the patent (with amended claims) would issue so long as Wyeth paid the necessary fee ($1290.00) within three months. Despite the notice of allowance, the Wyeth applicants abandoned the '137 application.

c. Wyeth's '328 Application

95. On November 5, 1997, the Wyeth applicants filed a continuation-in-part application, No. 08/964,328 (the "'328 application"). A continuation-in-part application repeats most of an earlier parent application but adds information that was not disclosed in the previous application. A continuation-in-part application must be filed while the earlier application is still pending.

96. The '328 application claimed priority to the '137 application and the '006 application. The examiner allowed some claims and rejected others in light of prior art. On February 16, 2000, the Wyeth applicants abandoned the '328 application – including the allowed claims.

d. Wyeth's '629 Application and the '171 Patent

97. On January 20, 2000 – one month before abandoning the '328 application – the Wyeth applicants filed a continuation-in-part application, No. 09/488,629 (the "'629 application") that claimed priority to the '328 application, the '137 application, and the '006

application. The examiner allowed some claims and rejected others. The Wyeth applicants canceled one claim, amended other claims, and added new claims. The examiner allowed the claims (as amended).

98. On August 14, 2001, the '629 Application issued as U.S. Patent No. 6,274,171 B1 (the "'171 patent"). The '171 patent contains 25 claims in total, including claims for (i) an extended release form of venlafaxine hydrochloride with spheroids, (ii) method-of-use claims for decreasing the incidence of nausea and vomiting, and (iii) method-of-use claims for minimizing the troughs and peaks in drug concentration in a patient's blood plasma. The '171 patent expires on March 20, 2017. The '171 patent is assigned to Wyeth.

e. Wyeth's '412 Application and the '958 Patent

99. On June 19, 2001 – two months prior to the issuance of the '171 patent – the Wyeth applicants filed a divisional application, No. 09/884,412 (the " '412 application"). A divisional application is an application for an independent or distinct invention disclosing and claiming (only) a portion of the subject matter disclosed in an earlier application. The '412 application claimed priority to the '629 application (that resulted in the '171 Patent), the '328 application, the '137 application, and the '006 application. The examiner rejected some claims and allowed others. The Wyeth applicants then canceled one claim and added new claims that were substantially similar to claims issued in the '171 patent.

100. On July 16, 2002, the '412 application issued as U.S. Patent No. 6,419,958 B2 (the "'958 patent"). The '958 patent includes claims for (i) methods of use to decrease the incidence of nausea and vomiting and (ii) methods of use for minimizing the troughs and peaks in drug concentration in a patient's blood plasma. The '958 patent included a terminal disclaimer that Wyeth did not seek an additional time period of patent protection beyond that afforded by the '171 patent – that is, through March 20, 2017. The '958 patent is assigned to Wyeth.

f. Wyeth's '965 Application and the '120 Patent

101. On September 12, 2001, Wyeth filed a continuation application, No. 09/950,965 (the "'965 application") that claimed priority to'412 application (which resulted in the '958 patent), the '629 application (which resulted in the '171 patent), the '328 application, the '137 application, and the '006 application. The examiner rejected some claims and allowed others. Wyeth amended some claims to overcome the rejections. The examiner allowed the amended claims.

102. On June 11, 2002, the '965 application issued as U.S. Patent No. 6,403,120 B1 (the "'120 patent"). The '120 patent contains 14 claims, all reciting a method of use for reducing the incidence of nausea and vomiting. The '120 patent also expires on March 20, 2017. The '120 patent is assigned to Wyeth.

2. The Prior Rejection Invalidity and Fraud: Wyeth Failed to Disclose a Previous Examiner's Rejection of Independent Method-of-Use Claims

a. Wyeth Filed Patent Applications For Formulations Claims That Also Include Two Method-of-Use Claims

103. In late 1995 or early 1996, the PTO notified Wyeth that the Upton application (*i.e.*, the patent application for a method to treat menopause in non-depressed women with venlafaxine) would soon issue as a patent. Wyeth knew that particular disclosures that would appear in this patent – those describing extended release venlafaxine as a method to smooth the dosage over time – would be prior art relevant to later patent applications seeking to claim as a new invention the use of extending the release of venlafaxine as a method to control dose rates.

104. This presented an immediate problem for Wyeth – because the Upton patent disclosed once a day venlafaxine formulations that "spread the dosage over time," any later claim for a broad method-of-use patent for extended release venlafaxine would be precluded. To address this, Wyeth rushed to file a provisional application that included nausea/vomiting claims

and "troughs and peaks" claims to avoid the Upton Patent standing as prior art to future extended release venlafaxine claims.

105. On March 25, 1996, the Wyeth applicants filed the '006 provisional application, the first in the family of applications involved in this case.

106. The '006 application is generally a *formulation* application. The title is "Extended Release Formulation." The abstract describes the "invention [as] a 24 hour extended release dosage *formulation*…." The background of the invention compares hydrogel tablet technology formulations as compared to encapsulated drug formulations. The brief description of the invention describes the "invention [as] an extended release (ER), encapsulated *formulation* containing venlafaxine hydrochloride …." The detailed description of the invention describes the "extended release *formulations* of this invention" as being comprised of venlafaxine "in add mixture with [MC] and [HPMC]." The four examples of the invention describe four formulations all using the encapsulated spheroid approach in which venlafaxine is mixed with MC and HPMC, and then coated with a combination of EC and HPMC. Of the ten claims set forth in the '006 application, the first eight claims are expressly formulation and composition claims describing, in various ways, the use of spheroids comprised of venlafaxine, MC and HPMC, coated by a mixture of EC and HPMC.

107. After having claimed extended release formulation approaches set forth in the prior eight claims, the '006 application then set forth the following two claims:

> 9. *A method* of providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis *which comprises* administering orally to a patient in need of thereof, *an encapsulated, extended release formulation that* provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as to the active ingredient. (emphasis added)

> 10. *A method* for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses *which comprises* administering orally to a patient in need thereof, *an encapsulated extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as to the active ingredient. (emphasis added)

108. On their face, and out of context, interpretation of these claims can go in two, wildly different directions.

109. On the one hand, the claim language "encapsulated extended release formulation" might be interpreted in the context of the film-coated spheroid formulation that had been developed by the Wyeth formulators working in upstate New York. The claims would describe a method of using the particular encapsulated formulation set out in the patent specification (and elsewhere) as a means to eliminate peaks and troughs in blood plasma concentration and to diminish nausea and vomiting. An interpretation in this direction defines the method-of-use invention as limited to the new encapsulated spheroid formulation of the old venlafaxine product that slows the release of the drug. Under this interpretation, the specific spheroid formulation and the method of using it might seemingly be patentable by the PTO given the specificity of the claims (although even these formulation claims were obvious given knowledge of spheroid formulation for substantially similar chemicals), and the patent would seemingly provide enough information as to how to make the product (in patent terms, meeting the "enablement" requirement that the patent teach others how to make the invention). But as so limited, the interpretation greatly reduces the ability of Wyeth to block potential generic entry because future generic companies could rather easily design a different extended release formulation.

110. On the other hand, the claim language "encapsulated extended release formulation" might be interpreted as relating to a method of using nearly *any* "extended release formulation" as a means to eliminate peaks and troughs in blood plasma concentration and to diminish nausea and vomiting. An interpretation in this direction would seek to have the asserted claims construed to cover not only the formulations that these Wyeth formulators developed and described in this patent application, but also nearly *every* kind of formulation of venlafaxine that allows for delayed release. A patent with such a broad interpretation would not be valid or enforceable because the notion that extending the release of venlafaxine will eliminate peaks and valleys in blood plasma levels is a pharmacologic tautology.

111. Other reasons for obviousness were (and are) that (i) it would be invalid as obvious, as a method to use extended release venlafaxine to smooth out the dosage over time was already well known in the industry and patent literature, (ii) the "invention" was already disclosed in the Upton patent and Alza's '589 application, (iii) the invention would not be "enabled" because it arguably only taught one way to reduce it to practice (not the limitless ways the broadly interpreted language would claim), and (iv) these chemists had only invented a particular spheroid formulation, not the general notion that extended release venlafaxine of any stripe diminishes peaks and valleys in dosage over time.

112. Nevertheless, once armed with a patent containing claim language capable of this kind of wildly different interpretation, the mere ability to argue for a broad interpretation would enable the patent holder to bring a (sham) lawsuit against almost any potential generic entrant. The holder could then use the regulatory mechanisms to automatically delay generic approval, and wait for a federal court (if given the opportunity) to sort out the inevitable invalidity or unenforceability of the method-of-use claims. The mere existence of claims so framed, even

when known by the holder to be flatly invalid and unenforceable, would equip the holder with a sweeping practical power to delay generic competition.

113. Following the filing of the '006 application, in April of 1996 the PTO issued the Upton patent. This prior art would render broad method-of-use claims related to spreading the dose over time (such as once-a-day dosing) and obvious consequences of spreading the dose over time (such as minimizing the "troughs and peaks" of instant release venlafaxine, or hypothesized reduction in related side effects) unpatentable.

b. Examiner Hulina Rejected Wyeth's Independent Method-of-Use Claims for an Extended Release Venlafaxine in Light of the Upton Patent

114. On March 20, 1997 (shortly within a year of filing the provisional '006 application), the Wyeth applicants filed the '137 application. The '137 application was assigned to Examiner Amy Hulina, and claimed priority to the '006 application.

115. The '137 application was virtually identical to the '006 in all respects, setting forth the Wyeth-developed, encapsulated film-coated spheroid formulation to extend the release of venlafaxine. The '137 application also set forth the same eight formulation claims as the '006 application, along with the two method-of-use claims.

116. Claim 1 recited an extended release formulation of venlafaxine hydrochloride with spheroids:

> 1. An encapsulated, *extended release formulation* of venlafaxine hydrochloride comprising a hard gelatin capsule containing a therapeutically effective amount of *spheroids* comprised of venlafaxine hydrochloride, microcrystalline cellulose and hydroxypropylmethylcellulose coated with ethyl cellulose and hydroxypropylmethylcellulose.[3]

[3] Italics appearing in quotes from Wyeth's patent applications and patent specifications has been added for emphasis.

117. Claim 9 recited a method-of-use claim for reducing incidences of nausea and vomiting associated with venlafaxine:

> 9. A *method* for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period *with diminished incidences of nausea and emesis which comprises* administering orally to a patient in need thereof, *an encapsulated, extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

118. Claim 10 recited a method-of-use claim for reducing the disparities in concentration of venlafaxine in a patient's blood serum:

> 10. A *method* for *eliminating the troughs and peaks of drug concentration in a patient's blood plasma* attending the therapeutic metabolism of plural daily doses of *which comprises* administering orally to a patient in need thereof, *an encapsulated, extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

119. In signing the '137 application, the Wyeth applicants acknowledged their duty to disclose all information material to the application.

120. On July 10, 1997, the Wyeth applicants submitted an informational disclosure statement (an "IDS") listing five U.S. patents, no foreign patents, and no other publications. Wyeth did not list the original Effexor compound patent (Husbands) on the IDS, but referenced it in the specification. Examiner Hulina considered all 5 references reported by Wyeth.

121. The Wyeth applicants *did not list or otherwise disclose the Upton patent, i.e.*, the patent held by Wyeth itself, which had issued in the past year, that was for the same venlafaxine drug, and that already disclosed extended release venlafaxine as a means to spread the dosage over time. The Wyeth applicants also *did not list or otherwise disclose the '589 PCT*

application, *i.e.*, the patent held by Alza, Wyeth's own business partner, for the development of extended release venlafaxine.

122. Examiner Hulina discovered Wyeth's Upton patent in performing her own prior art search.

123. During a telephone interview on July 30, 1997, Examiner Hulina informed Wyeth Attorney Boswell that Claims 9 and 10 (the two method-of-use claims for nausea/vomiting and "troughs and peaks") were not patentable as independent claims in light of the disclosure of extended release formulations of venlafaxine in the Upton patent. She further informed Wyeth that these method-of-use claims would *only* be patentable if Wyeth amended them to depend on the particular formulation of extended release venlafaxine recited in Claim 1. In other words, Examiner Hulina had picked up on the possibly broad language in the method-of-use claims that could be interpreted broadly, and insisted that those claims be limited to the specific encapsulated spheroid formulation developed by Wyeth.

124. The Wyeth applicants had hoped to patent independent method-of-use claims, claims unassociated with a particular formulation of extended release venlafaxine, in order to maximize market exclusivity for extended release venlafaxine. Independent method-of-use claims could be asserted against any generic manufacturer that attempted to market any formulation of extended release venlafaxine. Dependent method-of-use claims could only be asserted against a generic manufacturer that happened to be using the same Wyeth formulation of extended release venlafaxine. Independent method-of-use claims would provide further impediments to generic manufacturers and could translate into many millions more in profit to Wyeth.

125. The Wyeth applicants did not challenge Examiner Hulina's conclusion that claims 9 and 10 were unpatentable as independent claims. Rather, Wyeth Attorney Boswell *agreed*

with Examiner Hulina's conclusion by authorizing the examiner to amend the method-of-use claims in order to avoid rejection. An examiner's amendment, authorized by Attorney Boswell, changed Claims 9 and 10 from independent claims to dependent claims, thereby limiting the method-of-use claims to the specific extended release formulation of venlafaxine hydrochloride recited in Claim 1 of the application. This acknowledged that stand alone method-of-use claims were not patentable in light of the Upton patent.

126. On August 5, 1997, Examiner Hulina issued a notice of allowance for the two amended, now *dependent*, method-of-use claims; these method-of-use claims, now tethered to the specific formulation, were patentable because "[t]he prior art does not teach or suggest the specific extended release claim *formulation* according to claim 1" (emphasis added). The examiner also allowed the seven remaining formulation claims that variously described the encapsulated film-coated spheroid extended release venlafaxine invention, including the basic Claim 1 that simply described encapsulated spheroids using any amounts of venlafaxine, MCC and HPMC coated with any amounts of EC and HPMC.

127. The allowance notice indicated that if Wyeth believed the amendments (to which Wyeth had already agreed with the PTO) were unacceptable, Wyeth should file an amendment. It did not do so.

128. At this time, Wyeth could have finished the process, paid the issue fee by early November 1997 (three months following mailing of allowance), and caused the patent to issue. But doing so would not accomplish Wyeth's true goal – to use this formulation patent application tree as a Trojan horse to obtain method-of-use claims that might be broadly interpreted as precluding all extended release venlafaxines (even if ultimately unenforceable). So the Wyeth applicants decided to abandon the '137 application – presumably in the hopes that a new application might draw a different examiner that would be unfamiliar with the Upton

patent's disclosure of extended release venlafaxine and would, therefore, allow independent nausea/vomiting and "troughs and peaks" method-of-use claims.

c. Wyeth Never Disclosed that the PTO Rejected its Method-of-Use Claims For Obviousness

(1) Wyeth Did Not Disclose the Previous Examiner's Rejection in the '328 Application

129. On November 5, 1997 – the day it abandoned the previous application – the Wyeth applicants filed the '328 continuation-in-part application that re-proposed the identical, independent method-of-use claims previously rejected (and then amended by agreement) by the previous PTO examiner.

130. The only explanation for Wyeth's choosing to abandon the prior application, and pursue this new one, is its effort to escape the prior examiner having noticed the ambiguous phrasing of the method-of-use claims. If Wyeth truly believed it was entitled to broad method-of-use claims for venlafaxine, it could have simply filed an amendment in the '137 application (as noted as an option by the examiner in the allowance) challenging the examiner's approach; Hulina's decision would be tested, and Wyeth could appeal an adverse ruling. And in so doing, Wyeth would have left intact allowances Wyeth had obtained for the seven formulation claims in the '137 application, one of which was for the basic Claim 1 to the formulation.

131. But Wyeth avoided testing its position on Hulina's rejection, and was willing to relinquish its formulation claim gains, in order to take another run at its independent method-of-use strategy.

132. By abandoning the earlier application and filing a new one, Wyeth was able to get the '328 application assigned to a different PTO examiner in a different art unit, James M. Spear in Art Unit 1615.

133. The '328 application proposed sixteen formulation claims (doubled from the original application). The title ("Extended Release Formulation"), abstract ("invention relates to a 24 hour extended release formulation"), background (discussing prior extended release formulations), brief description of the invention ("there is provided an extended release encapsulated formulation"), detailed description (discussing the "extended release formulation of the invention"), and examples are identical to the '137 application. In addition to the 16 formulation claims, the '328 application also contained two independent method-of-use claims, Claims 13 and 14. These claims were nearly *identical* to the two proposed independently written method-of-use Claims 9 and 10 of the '137 application: (i) claims explicitly rejected by Examiner Hulina in light of the Upton patent's reference to an extended release form of venlafaxine hydrochloride that "spread the dosage over time"; (ii) claims the Wyeth applicants had agreed to amend; and (iii) claims that Examiner Hulina had only allowed once amended (to make dependent on formulation claims). The '328 application did not contain any other independent method-of-use claims.

134. In signing the '328 application, the Wyeth applicants acknowledged their duty to disclose all information material to the application. And the Wyeth applicants specifically acknowledged their duty to disclose "material information . . . which occurred between the filing date of the prior ['137'] application and the national date . . . of this application." The Wyeth applicants had a duty to disclose fully and specifically the prior examiner's rejection of the method-of-use claims.

135. On February 9, 1998, the Wyeth applicants submitted an IDS identifying the same five U.S. Patents identified in the IDS for the '137 application. On August 13, 1998, the Wyeth applicants submitted a supplemental IDS, listing three foreign patent documents. The IDSs did not include a copy of the prior examiner's rejection, nor did they flag in any way the prior

rejection. Further, while this time Wyeth did list the Upton patent and the '589 application, Wyeth did not explain their relevance to an application that seemingly was limited to a specific spheroid formulation (and not to an application seeking to patent what essentially amounted to a pharmacologic tautology).

136. The Wyeth applicants knew that the prior examiner had uncovered the ambiguity in the phrasing of the two method-of-use claims, and they knew that (if broadly construed) the claims would be invalid for various reasons, including obviousness – obvious because (among other things) the Upton patent and Alza's '589 application disclosed extended release venlafaxine as a method to spread the dosage over time. The Wyeth applicants knew the prior rejection was material – indeed disclosure of the rejection would immediately tip off the new examiner to Wyeth's gambit. The Wyeth applicants also knew that, in reviewing this new application, any reasonable examiner would need to know (i) that Wyeth had been prosecuting (for over a year) a patent application for a method-of-use claim for venlafaxine that might arguably be construed for a broad method to using almost any formulation of extended release venlafaxine; (ii) that a prior examiner had rejected broad method-of-use claims (requiring them to be limited to a specific formulation); and (iii) that Wyeth had *agreed* with that objection.

137. In addition, Wyeth did not identify to the new PTO examiner the true relevance of the Upton patent or Alza's '589 application. An examiner reviewing the '328 application might likely see it as a formulation application limited to the specific encapsulated film-coated spheroid formulation developed by Wyeth. In this event, review of the Upton patent (addressing the use of venlafaxine to treat menopause in non-depressed women) has marginal interest at best; since Upton addresses a method to treat menopause, an examiner reviewing an application for a drug formulation patent will be looking for art relating to the formulation, not a general use of extended release venlafaxine to smooth dosage over time. The Upton reference (to extending the

release of a venlafaxine to smooth out the dosage over time) contained in a single sentence in the middle of a three page single-spaced specification would not be apparent or relevant to an examiner reviewing the '328 application as an application for a formulation patent.

138. After reviewing the application, Examiner Spear issued a first office action on October 14, 1998. Examiner Spear (i) found that formulation claims that quantified the amounts for the venlafaxine/MCC/HPMC spheroids, and that quantified the ratio, or amount to be used of, EC and HPMC for the film-coating, would be patentable; (ii) allowed Claim 11 because as an independent claim that quantified the amounts it was a patentable formulation; but (iii) rejected Claim 1 (and other claims that depended on it) because its general formulation claim of using any amounts of venlafaxine/MCC/HMPC spheroids film-coated with any amounts of EC/HPMC to extend the release of venlafaxine was obvious. In allowing the encapsulated extended release formulation of venlafaxine in Claim 11, the examiner also allowed Claims 13 and 14, the two claims for methods of diminishing nausea/vomiting or eliminating troughs/peaks by "administering . . . an encapsulated extended release formulation . . .[of] venlafaxine."

139. As a result, Examiner Spear allowed the method-of-use claims (Claims 13 and 14) to issue as independent claims – the very claims that Examiner Hulina had previously required Wyeth to amend to be dependent on a particular formulation. The Wyeth applicants never informed Examiner Spear that the Upton patent identified the existence of an extended release formulation of venlafaxine hydrochloride that rendered their method-of-use claims unpatentable. The Wyeth applicants never disclosed to Examiner Spear that they had previously *agreed* to amend the *very same claims* to be dependent claims. In addition, the Wyeth applicants never disclosed to Examiner Spear that a previous examiner had found the exact same claims to be unpatentable. Indeed, nothing indicates that Examiner Spear was aware of the agreement that was reached between Boswell, Wyeth's in-house counsel, and Examiner Hulina, or that Wyeth

made any attempt to rescind the agreement regarding the narrowing claim amendments. Every bit of this information was material, and precisely the sort of information that Examiner Spear would have needed to know.

140. The examiner's first office action allowed three claims for a single patent. Under 35 U.S.C. § 101, each separate and distinct invention must appear in separate patents. If more than one invention is described in a patent application, a restriction requirement issues and the claims to one of the inventions must be cancelled and re-filed as a separate, continuation application that would lead to a separate patent. Here, however, the first office action contained no such restriction. The action therefore shows that the three claims were considered to describe a single, distinct invention; the examiner viewed the methods of use as relating to the specific formulation claim that was also being allowed. The second examiner had not picked up on the earlier examiner's discovery – that the two method-of-use claims might be read broadly to claim methods of eliminating peaks and troughs in blood plasma levels or diminish nausea/vomiting by extending the release of venlafaxine *regardless* of the type of formulation used.

141. While the first office action achieved the Wyeth goal of obtaining allowance of the method-of-use claims, it had not achieved allowance of the general formulation Claim 1. The Wyeth applicants responded to the examiner's rejections by canceling, amending, and adding new claims. On July 21, 1999, Examiner Spear again rejected Claim 1 (and claims depending on it) for a formulation using any amounts of venlafaxine/MCC/HPMC as obvious, again stating that the Wyeth applicants' arguments to overcome the prior art were not persuasive. The Wyeth applicants responded by filing a petition for an extension of time, but never ultimately responded.

(2) Wyeth Did Not Disclose the Previous Examiner's Rejection in the '629 Application

142. On January 20, 2000 (several weeks before abandoning the '328 application), the Wyeth applicants filed the '629 continuation-in-part application. Because it was filed before the abandonment, Wyeth's latest application was again assigned to Examiner Spear.

143. The '629 application contained a nearly identical specification to the '328 application. Claim 1, again, recited an extended release version of venlafaxine hydrochloride in spheroids that was substantially similar to the claim rejected by Examiner Spear during the prosecution of the '328 application in light of the prior art. The next nineteen claims sought iterations of the spheroid formulation. Claims 21 and 22, again, recited the same independent method-of-use claims originally presented in (rejected) Claims 9 and 10 of the '137 application and (allowed but abandoned) Claims 13 and 14 in the '328 application:

> 21. A *method* for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with *diminished incidences of nausea and emesis* which comprises administering orally to a patient in need thereof, an *encapsulated, extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 22. A *method* for *eliminating the troughs and peaks of drug concentration in a patient's blood plasma* attending the therapeutic metabolism of plural daily doses of which comprises administering orally to a patient in need thereof, an *encapsulated, extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

144. The Wyeth applicants, again, never informed Examiner Spear of Examiner Hulina's rejection of the method-of-use claims. Likewise, Wyeth applicants did not disclose that Wyeth had agreed to amend those claims to be dependent claims in order to avoid a rejection

over the prior art disclosed by Wyeth's own Upton patent. On January 4, 2001, Examiner Spear allowed Claims 21 and 22 – the two method-of-use claims.

145. On April 19, 2000, Attorney Steven R. Eck filed an Information Disclosure Statement in the '629 application which only cited references which had been cited in the '328 application. Upon information and belief, Attorney Eck reviewed the file of at least the '328 application in preparing that Information Disclosure Statement.

146. Had Attorney Boswell or another of the Wyeth applicants not withheld, in the '328 application, the rejection over Upton and the narrowing of the claims in the '137 application, to the extent Attorney Eck and the attorneys handling Wyeth's subsequent application did not previously have actual knowledge of the events in the '137 application, they would have learned of those events when they reviewed the files of the earlier applications at the time they prepared Information Disclosure Statements in the later applications.

147. The Wyeth applicants then added additional method-of-use Claims 23-26. Claims 23 and 24 recite methods of use "with diminished incidence of nausea and emesis." Claims 25 and 26 recite methods of use for "eliminating the troughs and peaks of drug concentration in a patient's blood plasma." All are substantially similar to the method-of-use claims that Examiner Hulina rejected. Nonetheless, in the absence of Wyeth's disclosure of Examiner Hulina's rejection, and in failing to direct the new examiner to the meaning of the Upton patent reference to extending the release of venlafaxine to smooth the dosage over time, Examiner Spear allowed these independent method-of-use claims.

148. On August 14, 2001, the '629 application issued as the '171 patent. The '171 patent contains six independent method-of-use claims: Claims 20 through 25. All recite either diminished incidences of nausea and vomiting or eliminating the troughs and peaks in a patient's

blood plasma. (Due to renumbering, proposed Claims 21 and 22 issued as Claims 20 and 21. Proposed Claims 23 through 26 issued as Claims 22 through 25).

(3) Wyeth Did Not Disclose the Previous Examiner's Rejection in the '412 Application

149. On June 19, 2001, two months before the '171 patent issued, the Wyeth applicants filed the divisional '412 application to pursue rejected Claim 1 of the '629 application. The application was again assigned to Examiner Spear.

150. The specification and claims of the '412 application were identical to those in the '629 application. The Wyeth applicants then cancelled Claims 2-22 and added new, independent method-of-use Claims 23 and 24:

> 23. A *method* for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with *diminished incidences of nausea and emesis* which comprises administering orally to a patient in need thereof, *an extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 24. A *method* for *eliminating the troughs and peaks of drug concentration in a patients blood plasma* attending the therapeutic metabolism of plural daily doses of which comprises administering orally to a patient in need thereof, *an extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

151. Claims 23 and 24 are substantially the same the method-of-use claims originally presented in (rejected) Claims 9 and 10 of the '137 application and allowed Claims 20 and 21 of the '171 patent, differing only by no longer including the word "encapsulated." The Wyeth applicants, again, never informed Examiner Spear that the Upton patent identified the existence of an extended release formulation of venlafaxine hydrochloride that rendered their method-of-use claims unpatentable. The Wyeth applicants, again, never disclosed to Examiner Spear that a

previous examiner determined method-of-use claims virtually identical to Claims 23 and 24 were unpatentable. The Wyeth applicants, again, never disclosed that they had agreed to amend virtually identical claims in order to avoid a rejection over the prior art disclosed by Wyeth's own Upton patent.

152. On June 19, 2001, Wyeth Attorney Barrett filed an Information Disclosure Statement in the '412 application which cited references which had been cited or submitted in the previous '629 application. Upon information and belief, Attorney Eck reviewed the file of at least the prior '629 application in preparing that Information Disclosure Statement.

153. On January 13, 2002, Examiner Spear rejected Claims 23 and 24 as being unpatentable over Claims 20 and 21 of the '171 Patent. The Wyeth applicants contested that Claims 23 and 24 were obvious in light of the '171 patent, but filed a terminal disclaimer confirming that it did not, and would not, seek an additional time period of patent protection beyond that afforded by the '171 patent.

154. The Wyeth applicants also added Claims 25 through 28, additional independent method-of-use claims. Claims 25 through 28 either recite a method-of-use "with diminished incidence of nausea and emesis" or for "eliminating the troughs and peaks of drug concentration in a patient's blood plasma." All are substantially similar to the method-of-use claims rejected by Examiner Hulina. Nonetheless, in the absence of the appropriate disclosures by Wyeth, Examiner Spear allowed Claims 23 through 28.

155. On July 16, 2002, the '412 application issued as the '958 patent. The '958 patent contains six method-of-use claims: Claims 1-6. All related to either diminish incidences of nausea and vomiting or eliminating the troughs and peaks in a patient's blood plasma. (Due to renumbering, proposed Claims 23 and 24 issued as Claims 1 and 2. Proposed Claims 25 through 28 issued as Claims 3 through 6.)

(4) Wyeth Did Not Disclose the Previous Examiner's Rejection in the '965 Application

156. On September 12, 2001, the Wyeth applicants filed the '965 continuation-in-part application. The '965 application was, again, assigned to Examiner Spear.

157. The '965 application contained the same specification and claims as the '412 application (and corresponding '958 patent). The Wyeth applicants canceled Claims 2-22 and added new Claims 23-34. Claim 23 recited a method-of-use claim for diminished incidences of nausea and vomiting, and substantially similar to rejected Claim 9 of the '137 application:

> 23. A *method* for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with *diminished incidences of nausea and emesis* which comprises administering orally to a patient in need thereof, *an extended release formulation* that provides a peak blood plasma level of venlafaxine of no more than 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.

158. The Wyeth applicants, again, never disclosed to Examiner Spear that a previous examiner determined a claim substantially similar to Claim 23 was unpatentable. The Wyeth applicants, again, never disclosed that it had agreed to amend a substantially similar claim in order to avoid a rejection over the prior art disclosed by Wyeth's own Upton patent. Likewise, the Wyeth applicants did not direct the examiner to Upton's reference to extended release venlafaxine hydrochloride.

159. Examiner Spear allowed Claim 23, and objected to Claims 24-34. The Wyeth applicants later amended Claims 24 and 25 to depend from allowed Claim 23. Examiner Spear allowed the amended claims.

160. On June 11, 2002, the '965 application issued as the '120 patent. Due to renumbering, proposed Claim 23 issued as Claim 1:

> 1. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period *with*

> *diminished incidences of nausea and emesis* which comprises administering orally to a patient in need thereof, *an extended release formulation* that provides a peak blood plasma level of venlafaxine of no more than 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.

161. All other claims depended from Claim 1.

d. Wyeth has previously taken the position that another examiner's rejection of an extended release venlafaxine patent in light of prior art likely invalidates a substantially similar claim.

162. In attacking competitor Alza's patent relating to extended release venlafaxine, Wyeth took the position that an examiner's rejections of substantially similar claims makes it "extremely likely" that the proffered claims will not be patentable.

163. In 2006, Alza sued Wyeth for infringing its Edgren patent (the '476 patent) pertaining to extended release venlafaxine. Wyeth responded by asking the Court to stay the proceedings while the PTO conducted reexamination proceedings on the '476 patent.

164. According to Wyeth's motion for stay, Wyeth had initiated a reexamination of Alza's Edgren patent based on the fact that the PTO had rejected substantially similar claims to those included in the '476 in other patent applications bearing identical specifications in light of prior art. Wyeth claimed that it was "extremely likely" that, upon reexamination, the PTO would reject or cancel Alza's Edgren patent:

> In this motion, WYETH seeks a stay of litigation pending the outcome of a reexamination proceeding that WYETH initiated before the United States Patent and Trademark Office ("PTO") on July 28, 2006. In that proceeding, the PTO will consider the patentability of the single claim in the '457 patent over prior art known to Alza, but not considered by the PTO during the prosecution of the application lading to the '457 patent. Significantly, in two of Alza's patent applications having the identical specification as the '457 patent, the PTO-including the PTO's Board of Patent Appeals and Interferences – has rejected substantially similar claims over the same prior art that forms the basis of WYETH's Reexamination Request. Consequently, it is extremely likely that the PTO will reject Alza's '457 patent claim

> over the same prior art and ultimately cancel the claims under 35 U.S.C. § 307(a).

165. Elsewhere in its briefing, Wyeth similarly argued that "the rejection of substantially similar claims in related applications provides evidence that a substantial new question of patentability existed."

e. Wyeth Intentionally Committed Fraud on the PTO by Failing to Disclose Material Information

166. The prosecution history of the '137 application shows that Examiner Hulina judged the independent method-of-use claims (Claims 9 and 10) unpatentable in view of the prior art taught by Wyeth's Upton patent. Claims 9 and 10 became patentable only after Wyeth amended the claims to be dependent on a particular formulation of extended release venlafaxine at the insistence of Examiner Hulina.

167. Throughout the prosecution history of the method-of-use claims in these patents (including the '328, '412, '629 and '956 applications), Wyeth repeatedly misrepresented in its PTO filings that it was providing to the new PTO examiner all material information. This, as Wyeth was well aware, was untrue. Wyeth knowingly and repeatedly withheld material information relating to Examiner Hulina's determination of unpatentability.

168. The Wyeth applicants had a duty to disclose all information material to patentability, including information that by itself renders the claims unpatentable. The Wyeth applicants failed to disclose to new Examiner Spear the contrary findings of the earlier examiner on the identical claims. Perhaps even more egregiously, the Wyeth applicants failed to disclose the basis of the earlier examiner's contrary findings – that there was a possible broad reading of these claims, and that when so read a prior art patent owned by Wyeth itself taught an extended release formulation of venlafaxine. The Wyeth applicants failed to disclose to Examiner Spear the fact that they had already agreed to narrow the scope of identical claims in order to avoid a

rejection over Wyeth's own prior art patent – the Upton patent. The Wyeth applicants failed to disclose to Examiner Spear the fact that they had agreed to amend the claims to overcome the prior art reference and Examiner Hulina found the claims to be patentable once the claims were limited to the Wyeth formulation.

169. The information withheld by the Wyeth applicants was highly material. This information is of the type a reasonable examiner would want to know, as it directly impacts the patentability of the claims. But for the concealment of this information, the PTO would not have issued the method-of-use claims in the fraudulently obtained patents.

170. The Wyeth applicants withheld this material information and thereby breached their duty of disclosure to the PTO. They did so in order to avoid prior art rendering independent method-of-use claims unpatentable; that is, the Wyeth applicants sought to prosecute independent method-of-use claims that were substantially similar to the previously rejected independent method-of-use claims.

171. The Wyeth applicants withheld this material information with intent to mislead or deceive the PTO. This is the *only* plausible reason for Wyeth's actions. The only reason to not tell the second examiner about the first examiners' (authorized) amendment of the method-of-use claims and office action was the hope that the second examiner would not pick up on the fact that the method of use claims could have been read broadly – particularly in light of the fact that the first examiner actually approved Wyeth's formulation claims.

172. The Wyeth applicants failed to amend the independent method-of-use claims in accordance with Examiner Hulina's findings in the subsequent patent applications. The Wyeth applicants had multiple opportunities to amend claims during prosecution of the '171, '120, and '958 patents, and in fact did amend claims several times. But the Wyeth applicants never made the necessary amendments to overcome patent-defeating prior art on identically or substantially

similar claims. They knew, of course, that doing so would prevent them from effectuating their anticompetitive scheme to delay generics by filing baseless litigation.

173. The Wyeth applicants had multiple opportunities to correct the record and bring the rejection of the claims based on the Upton Patent to the attention of Examiner Spear, yet failed to do so. The Wyeth applicants amended the claims several times in each subsequent application; Wyeth amended the specifications of two subsequent applications (the '328 application and the '629 application, which issued as the '171 patent) and amended the inventorship of the '629 application. Each filing presented an opportunity for Wyeth to correct the record, but it failed to do so.

174. Intent to deceive the PTO is the only plausible explanation for the numerous opportunities that Wyeth had to amend claims and specifications and/or bring the prior decision of unpatentability to Examiner Spear's attention but failed to do so; from the fact — known to the Wyeth applicants — that the Examiner in charge of the '137 application was not assigned to the subsequent applications; and from the fact that Wyeth attorneys who prosecuted subsequent applications consistently reviewed one or more prior applications and cited only certain information but never the rejection over Upton and the narrowing of claims in response thereto. The only reasonable explanation for Wyeth's repeated pattern of nondisclosure and withholding highly material information in serial patent applications for virtually identical claims (and abandonment of those applications that no longer included ambiguous method-of-use claims) is that Wyeth meant to deceive the PTO. Accordingly, Wyeth intentionally failed to disclose all pertinent information that was known to them during prosecution of the '171, '120, and '958 patents with an intent to deceive the PTO

175. But for this fraud on the PTO, no independent nausea/vomiting or "troughs and peaks" method-of-use claims would have issued. Specifically, Wyeth's prior rejection fraud

affects at least Claims 20 through 25 of the '171 patent and all of the claims of the '958 and '120 patents. Because Wyeth defrauded the PTO by failing to disclose the previous examiner's rejection, Wyeth is not entitled to immunity for its petitioning activities in seeking the fraudulently obtained '171, '120, and '958 patents. In the stark light of later patent infringement litigation, all three patents would be rendered entirely invalid and unenforceable: invalid as a result of the prior art, and unenforceable as a result of Wyeth's fraud.

3. The Nausea Fraud: Wyeth Fraudulently Claimed Clinical Data Showed a Reduction in Nausea and Vomiting

a. Wyeth Claimed Effexor XR Significantly Reduced the Incidence of Nausea and Vomiting Associated with Effexor

176. In order to obtain a patent that protects a specific method of using a product, the applicants must have a legitimate basis for claiming that the method actually accomplishes what the applicants claim it accomplishes. That is, the applicants cannot just claim a method of using a pharmaceutical that reduces nausea and vomiting; applicants must have a basis for claiming that the method of use reduces nausea and vomiting *and* the method of use must actually reduce nausea and vomiting.

177. In the original '006 provisional application, the Wyeth applicants claimed its patentable invention related to a 24-hour extended release dosage formulation of venlafaxine that "provides a lower incidence of nausea and vomiting than the conventional tablets." Specifically, the Wyeth applicants told the PTO that the use of the once-a-day formulation of venlafaxine hydrochloride capsules (later marketed as Effexor XR) reduced "the level of nausea and incidence of emesis that attends the administration of multiple daily dosing." (The term 'emesis' means vomiting.)

178. In support of this statement, the Wyeth applicants claimed clinical data showed that the incidence of nausea in people taking *extended release* venlafaxine was significantly less than in patients taking *instant release* venlafaxine:

> In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. *Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies.*

179. The Wyeth applicants made the same claim, repeating the *exact same* language, in the specifications accompanying the '137 application, the '328 application, the '629 application, the '412 application, and the '965 application. The *exact same* language appears in the '171 patent, the '958 patent, and the '120 patent.

180. The Wyeth applicants claimed that in light of the clinical data, it was entitled to method-of-use claims for the reduction in the incidence of nausea and vomiting:

> Thus, in accordance with this use aspect of the invention there is provided *a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride* which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

181. The Wyeth applicants made the same claim, repeating the *exact same* language, in the specifications accompanying the '137 application, the '328 application, the '629 application, the '412 application, and the '965 application. The *exact same* language appears in the specifications for the '171, '958, and '120 issued patents.

182. The Wyeth applicants did not provide the PTO with any other evidence of Effexor XR's ability to reduce the incidence of nausea or vomiting. Wyeth did not disclose to the PTO which studies showed the reported reductions. Similarly, Wyeth did not disclose to the PTO the

raw data collected in these studies. Wyeth's sole support for its method-of-use claims for the reduction of nausea and vomiting was the express representation that two eight-week studies and one twelve-week clinical study showed that Effexor XR "showed a statistically significant improvement" in the incidence of nausea and vomiting over conventional Effexor.

b. The Clinical Data Did Not Show That Effexor XR Significantly Reduced the Incidence of Nausea and Vomiting

(1) None of the Three Studies Showed a Reduction in Nausea or Vomiting

183. The Wyeth applicants repeatedly told the PTO that "Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies." The Wyeth applicants first made this statement in its March 25, 1996 '006 provisional application. It was not until nine years later – four years after securing the '171 patent and in the context of patent infringement litigation with generic companies – that Wyeth first identified the "two eight week and one 12 week studies:" "600B-208-US," "600B-209-US," and "600B-367-EU," or Studies 208, 209 and 367, respectively. Wyeth relied on these studies in seeking FDA approval of Effexor XR, but never identified them to the PTO.

184. Study 208 was a double-blind, flexible dose, twelve-week efficacy study of Effexor XR, Effexor, and placebo in outpatients with major depression.

185. Study 209 was a double-blind, flexible dose, eight-week study of Effexor XR and placebo in outpatients with major depression. Study 209 did not use instant release Effexor as a comparator.

186. Study 367 was a double-blind, flexible dose, eight-week efficacy study of Effexor XR, the antidepressant Paxil, and placebo in outpatients with major depression. Study 367 did not use instant release Effexor as a comparator.

187. None of these three clinical studies showed that Effexor XR had a statistically significant improvement in the incidence of nausea or vomiting over Effexor.

188. Studies 209 and 367 could not possibly have shown a reduction in nausea and vomiting over conventional venlafaxine hydrochloride (Effexor) *because they did not include a group of patients taking instant release, conventional Effexor*. Only Study 208 included both patients receiving Effexor XR and patients receiving Effexor. Only Study 208 could have allowed Wyeth to compare the incidence of nausea between the Effexor and Effexor XR groups.

189. However, Study 208 did not show a "statistically significant improvement" over Effexor. In fact, according to a published article describing the study, *the incidence of nausea was exactly the same in the Effexor XR and the Effexor groups*: 45% of Effexor XR patients experience nausea, as compared to 45% of Effexor patients. *See* Lynn M. Cunningham et al., *Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression*, 9(3) ANNALS OF CLINICAL PSYCHIATRY 157 (1997) (reporting results of the venlafaxine XR 208 study group). Wyeth never disclosed this article, (published years before the '120, '171, and '958 patents issued) or its conclusions about rates of nausea to the PTO in any of its patent applications.

190. Study 208 also suffered from serious data corruption. The principal investigator of one of the study sites, Bruce Diamond Ph.D., and one of his sub-investigators, Richard Borison, M.D., Ph.D., were indicted for diversion of research funds on February 19, 1997, almost a full year after Wyeth claimed clinical data showed a significant reduction in the incidence of nausea with Effexor XR based in part on the results of Study 208. Upon learning of these indictments, the FDA noted that the data from Study 208 was "of uncertain reliability" and asked Wyeth to reanalyze the data from Study 208, excluding the data from the corrupted site. Wyeth provided a reanalyzed data to the FDA. Wyeth never informed the PTO about the

corrupted data. Wyeth never provided reanalyzed data – or any data from Study 208 – to the PTO.

191. In September 2004, Wyeth submitted a further revised version of the final clinical report for Study 208. Although characterized as "minor corrections," the revisions included two revised analyses of the data on nausea. These revised analyses were never submitted to the PTO.

(2) Pooled Study Data Did Not Show a Reduction in Nausea or Vomiting

192. The Wyeth applicants told the PTO that *each* of the three studies *independently* showed a statistically significant improvement in the incidence of nausea and vomiting. Wyeth later claimed, in litigation with the generics, that it had not intended to claim the studies independently showed these results, but that "pooled" data showed the professed reduction in nausea and vomiting. However, even if the data from all three studies were combined, or "pooled," it does not show a statistically significant reduction in the incidence of nausea or vomiting.

193. First, because two of the studies did not include an Effexor treatment group, at best the data from the Effexor XR treatment groups in Studies 208, 209, and 367 could be pooled and compared only to the conventional Effexor treatment group in Study 208. This type of comparison is scientifically unacceptable, and cannot support a claim that one drug has fewer instances of side effects than another drug. The combination or "pooling" of patient data from Studies 208, 209, and 367 would be statistically biased, and thus an improper basis for reaching a conclusion that there is a statistically significant improvement in nausea by patients taking Effexor XR as compared to patients taking instant release Effexor

194. Second, even if this incorrect pooling is done, it does not show a statistically significant difference in nausea and vomiting.

195. Throughout the time that Wyeth prosecuted the fraudulently obtained patents, Wyeth had not "pooled" the data from Studies 208, 209, and 367. A decade later, during patent infringement litigation with the generics, Wyeth tried to cover its tracks by having Rule 30(b)(6) deposition witnesses (Dr. Mangano and Dr. Alaburda) present new, never-before seen, elaborate calculations and permutations of the original clinical study data that purportedly showed a diminished incidence of nausea and vomiting. These calculations were done ten years after the clinical studies were completed and nine years after the Wyeth applicants told the PTO that extended release venlafaxine reduced the incidence of nausea and vomiting.

196. Drs. Mangano and Alaburda testified that, according to yet another Wyeth employee, Wilfredo Ortega-Leone, the Wyeth applicants' claim that Effexor XR reduced the incidence of nausea was based on pooling the nausea data for the Effexor XR treatment groups in Studies 208, 209, and 267 and comparing that data to nausea data for conventional Effexor treatment groups in entirely different (undisclosed) studies. Comparing different treatment groups from entirely different studies is wholly inappropriate, statistically biased, and is not a legitimate basis for claiming that one drug has fewer side effects than another drug. Further, just as importantly, Wyeth never disclosed its statistical sleight-of-hand to the PTO.

197. In fact, the only reason that pooled Effexor XR data might possibly have shown a reduction in nausea (as compared to unrelated study data for conventional Effexor) is because it included the results of Study 367. Study 367 reported markedly fewer instances of nausea in the Effexor XR treatment group than were reported by the Effexor XR treatment groups in Studies 208 and 209. Study 367 was conducted in Europe. Studies 208 and 209 were conducted in the United States. Using the same extended release formulation, the European population in Study 367 reported a 17% incidence of nausea, while the U.S. population in Study 209 reported a 36% incidence of nausea.

198. The Wyeth applicants knew, and it was well known at the time, that the European population has a significantly greater tolerance for and/or underreports side effects such as nausea and vomiting (as compared to the U.S. population). By including the European Effexor XR data, it would look like Effexor XR reduced the incidence of nausea, when the real cause of the ostensible reduction in nausea was a known population difference. The Wyeth applicants did not disclose to the PTO that the claimed reduction in nausea and vomiting was a result of studying populations that are less likely to experience and/or report side effects.

199. Further, as the FDA confirmed when analyzing Effexor XR's efficacy, *Study 367 was a complete and utter failure:* "study 367 provided no persuasive evidence of antidepressant efficacy for venlafaxine ER." The Wyeth applicants never disclosed to the PTO that Study 367 failed to show that Effexor XR was effective.

(3) The FDA Refused to Pool Side Effect Data from the 208, 209, and 367 Studies

200. In applying for FDA approval of Effexor XR, Wyeth argued that the FDA should evaluate the incidence of adverse events, including nausea and vomiting, by pooling the data from Studies 208, 209, and 367. The FDA disagreed.

201. On August 13, 1997, the FDA noted that "the incidence of many adverse events in the European study seemed to be substantially lower than in the two domestic studies" and determined that Study 367 could not properly be included in the pooled U.S. data used to assess the adverse events associated with Effexor XR:

> The incidence of many important adverse events appeared to be lower in the European study (367) compared to both U.S. studies (208 and 209). Primarily for this reason, *study 367 was not considered poolable with studies 208 and 209 for purposes of delineating the common adverse event profile of Effexor XR.*

202. The FDA noted that including Study 367's data in the pooled adverse event data would result in a marked reduction in the number of adverse events described on the drug's label. If data from Studies 208, 209, and 367 were pooled, the Effexor XR label would have listed only eight common drug-related adverse events. In contrast, when only the data from studies 208 and 209 were pooled, the Effexor XR label would have listed an *additional* four common drug-related adverse events. The FDA stated that "Effexor XR is placed in a more favorable light if [Wyeth's proposed] pool is used," and therefore refused to allow the adverse event labeling to be based on Wyeth's proposed pooling.

203. Further, the FDA ultimately permitted Wyeth to pool data from Studies 208 and 209, but *not* for the purpose of comparing the incidence of side effects between extended release venlafaxine and instant release venlafaxine. The FDA noted that "the pool of the two domestic studies [Studies 208 and 209] allows for a more conservative presentation of adverse event data in labeling and since Effexor XR will be marketing in the U.S., the pool of the two U.S. studies may be more relevant." The FDA's refusal to pool data from all three studies occurred only a year after Wyeth filed the original '006 application, well before Wyeth filed its subsequent patent applications, and almost 4 years before the first, '171, patent issued.

204. Wyeth knew that including the results of European Study 367 skewed the incidence of adverse events (including nausea) because the FDA told them so at least four years before the '171 patent issued, a patent whose claims were premised on Effexor XR's reported ability to reduce the incidence of nausea experienced by patients taking instant release Effexor. Yet the Wyeth applicants never informed the PTO that the FDA refused to include the data from Study 367 when analyzing the incidence of adverse events associated with Effexor XR – that is, that the FDA refused to assess the incidence of side effects by pooling the data from Studies 208, 209, and 367.

205. The FDA-approved package insert for Effexor XR does not contain any representation that Effexor XR showed a statistically significant improvement in nausea or vomiting over Effexor, even though the package insert compares Effexor XR and Effexor as to the potential for other adverse reactions in the course of their administration.

c. Wyeth Intended for the PTO to Rely on Its Material Misrepresentations

206. The Wyeth applicants intended to deceive the PTO with their misrepresentations about nausea and vomiting. This is the only explanation for its actions.

207. The Wyeth applicants repeatedly made misrepresentations about the incidence of nausea associated with Effexor XR during the prosecution of the '137 application, the '328 application, and each of the final applications for the '171, '120, and '958 patents. The Wyeth applicants affirmatively, and repeatedly, misrepresented that they possessed three clinical studies that showed Effexor XR significantly reduced the incidence of nausea and vomiting associated with Effexor. The Wyeth applicants further affirmatively misrepresented that extended release venlafaxine greatly reduced the probability of developing nausea. Specifically, the Wyeth applicants knowingly included the following sentences in the patent specifications submitted to the PTO:

> In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies.

208. The Wyeth applicants knew these representations were false. The Wyeth applicants knew the only study directly comparing Effexor XR and Effexor (Study 208) did not show the claimed statistically significant improvement. The Wyeth applicants knew Wyeth was not in possession of three clinical studies that showed the claimed statistically significant

improvement in nausea. The Wyeth applicants knew that two out of the three referenced studies did not even compare Effexor XR to Effexor. The Wyeth applicants knew that any claimed reduction in nausea and vomiting was a result of conducting Study 367 among a population that notoriously reports fewer side effects, such as nausea and vomiting. Wyeth knew that the claimed reduction in nausea and vomiting could only be supported, if at all, by inappropriately comparing different treatment groups across different studies. Further, the Wyeth applicants knew the FDA had refused to pool the 208, 209, and 367 Study data when analyzing the incidences of side effects associated with extended release venlafaxine.

209. The Wyeth applicants knew the PTO would read the patent specifications submitted with their various patent applications and thus receive their misrepresentations about Effexor XR's effectiveness in reducing nausea and vomiting and about the results of the three referenced clinical studies.

210. Each individual associated with the filing and prosecution of a patent application has a duty to disclose "all information known to that individual to be material to patentability." 37 C.F.R. § 1.56 (2000). Information is material if it establishes unpatentability, whether by itself or in combination with other information, or if it refutes or is inconsistent with a position taken by an applicant in arguing for patentability. The Wyeth applicants were aware of their individual obligations to disclose material information, and signed certifications acknowledging this duty.

211. The Wyeth applicants knew that their misrepresentations about nausea and vomiting were material. No nausea and vomiting method-of-use claims could have been patented in light of the truth: extended release venlafaxine did not meaningfully reduce the incidence of nausea and vomiting, Wyeth did not have clinical data from three studies that

showed a reduction in nausea and vomiting, and pooled data from three studies did not show a reduction in nausea and vomiting.

212. The Wyeth applicants also failed to inform the examiner about the Cunningham article (reporting results from Study 208) and the FDA's refusal to pool the data. Both were material: a reasonable examiner would want to know about contradicting published materials and another federal regulatory agency's determination about pooling.

213. The Wyeth applicants knew there was a substantial likelihood the PTO would rely on their misrepresentations about nausea in evaluating their numerous nausea and vomiting method-of-use claims because the Wyeth applicants did not provide any other evidence that extended release venlafaxine reduced nausea and vomiting.

214. The PTO did, in fact, rely on the Wyeth applicants' misrepresentations. In the absence of any other basis for substantiating Wyeth's nausea and vomiting claim, the PTO relied on the singular, but oft repeated, statement that clinical studies showed Effexor XR reduced the incidence of nausea and vomiting as compared to Effexor in approving *twenty* claims that began by reciting a method of use that reduces nausea and vomiting:

> A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period *with diminished incidence of nausea and emesis* which comprises administering orally to a patient in need thereof ….

215. The nausea fraud directly affects at least Claims 20, 22, and 23 of the '171 patent; Claims 1, 3, and 4 of the '958 patent; and *all* of the claims of the '120 patent. Because Wyeth defrauded the PTO by claiming a reduction in nausea and vomiting, Wyeth is not entitled to immunity for any claimed petitioning activities in seeking or enforcing the fraudulently obtained '171, '120, and '958 patents.

4. The Unexpected Discovery Invalidity and Fraud: Wyeth Fraudulently Claimed Extended Release Venlafaxine was "Unexpected."

216. An applicant can obtain a patent only if he is the first to invent the subject matter described in the patent application. If earlier publications or patents disclose the invention, or it can be established that someone else invented the subject matter, the invention is not patentable. *See* 35 U.S.C. § 102. Prior invention of the subject matter by someone else may be demonstrated by:

- Printed publications that describe the invention, either in the U.S. or internationally, before the invention thereof by the patent applicant (35 U.S.C. § 102 (a));
- A printed publication that describes the invention, published more than one year before the patent applicant filed a patent application for it (35 U.S.C. § 102 (b));
- A U.S. patent application filed by another inventor describing the invention before the invention thereof by the patent applicant (35 U.S.C. § 102(e)(1)); and
- Evidence of earlier invention by another, including non-public disclosures (35 U.S.C. § 102 (f); *OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1403 (Fed. Cir. 1997)).

217. Throughout the prosecution of the '171, '120, and '958 patents, the Wyeth applicants fraudulently misrepresented Wyeth's "unexpected" discovery of an extended release venlafaxine hydrochloride capsule to the PTO. *Wyeth represented in all of its applications for the '171, '120, and '958 patents that it was "completely unexpected that an extended release formulation containing venlafaxine could be obtained because the hydrochloride of venlafaxine proved to be extremely water soluble."* The Wyeth applicants first made this representation in the provisional '006 application, filed on March 25, 1996. All of the fraudulently obtained patents include this language.

218. However, an extended release version of venlafaxine hydrochloride was not at all unexpected to Wyeth. It was predicted and known. The Wyeth applicants were aware of

extended release versions of venlafaxine hydrochloride long before filing the '006 application. Wyeth long knew of the solubility of venlafaxine hydrochloride. At the time of the '006 application, Wyeth's development partner, Alza, had long developed an extended release venlafaxine despite known solubility of the hydrochloride. Wyeth itself had used conventional spheroid technology it had employed for Inderal LA as a predictably successful approach to extending the release of venlafaxine. Further, Wyeth's own Upton patent disclosed extended release venlafaxine.

219. The Wyeth applicants had multiple opportunities to amend the specifications in its various applications to no longer assert that formulating an extended the release venlafaxine hydrochloride was surprising or unexpected, but failed to do so. Wyeth knew that by making such an amendment, it would no longer be able to claim a formulation of extended release venlafaxine. Its approach had been obvious.

a. Wyeth Did Not Disclose that it Used the Formulation of its Inderal LA Formulation to Develop Effexor XR.

220. Wyeth was selling Inderal LA years before it began its development of Effexor XR. Inderal LA is a sustained release formulation of propranolol used to treat high blood pressure.

221. Propranolol and venlafaxine have similar chemical properties: both have similar molecular weights, both are formulated using the same salt, both are readily soluble in water, and both have similar half-lives. In addition, the necessary dose required for treatment and therapeutic range for both drugs is approximately the same.

222. Because of these similarities, the Wyeth formulators used Inderal LA as a model when they set out to develop Effexor XR. After discarding the hydrogel approach, the formulators simply substituted venlafaxine for propranolol in the Inderal formulation. In

developing Effexor XR, Wyeth scientists, including the named inventors of Effexor XR, used exactly the same methods used to manufacture Inderal LA but used venlafaxine instead of propranolol. They created venlafaxine spheroids using the same manufacturing methods used to create propranolol spheroids and applied exactly the same EC/HPMC solvent-based coating used to coat the propranolol spheroids. The Effexor XR inventors were able to develop the Effexor XR formulation in the first six months of 1992 because Wyeth already created the Inderal LA formulation years earlier.

223. Notwithstanding the fact that the formulation of Effexor XR was for practical purposes the same formulation of Inderal LA (but with a different active ingredient), the Wyeth applicants failed to disclose to the PTO the facts about the simple formulation of extending the release of venlafaxine. Moreover, the inventors affirmatively misrepresented alleged factual differences between venlafaxine and propanalol, differences that were known to be immaterial for the purposes of using the spheroid approach employed here.

b. Wyeth's Failure to Disclose the Role of the Inderal LA Formulation Was Material.

224. During prosecution of Wyeth's patents, PTO Examiner Spear issued a rejection based on the patent that covers the Inderal LA product, U.S. Patent No. 4,138,475 to McAinsh (the "McAinsh patent").

225. Even after receiving express notice that the examiner viewed the propranolol formulation disclosed by the McAinsh patent to be material, Wyeth not only chose to conceal the facts of its development process, it affirmatively misled the PTO. Wyeth argued in the '328 patent application that propranolol was irrelevant because there is "a tremendous difference in the water solubilities" between propranolol and venlafaxine.

226. That Wyeth had already developed an extended release product whose active ingredient was similarly soluble to venlafaxine – *and plugged venlafaxine into the extended release formulation of propranolol to come up with Effexor XR* – would have been of particular importance to the examiner because the patent specifications specifically state that extended release formulations of venlafaxine were "completely unexpected" because the hydrochloride of venlafaxine was extremely water soluble.

227. The label of Inderal LA directly contradicted Wyeth's arguments that propranolol and venlafaxine had significantly different solubilities. The label showed that, like venlafaxine, propranolol was readily soluble in water and had a peak blood level that occurred in about six hours.

228. The role of Inderal LA in the development of Effexor XR and the characteristics of propranolol, including its solubility, were not disclosed in the ʻ171, ʻ958 and ʻ120 patent and would have been highly material to the patent examiner. Wyeth had a duty to disclose this information to the patent examiner who could not have been expected to have obtained the information himself, but properly relied upon Wyeth to comply with its duty of candor.

229. The Inderal fraud tainted the patent application process, undercut Wyeth's claim of unexpected success, and affects all claims of all three patents.

c. Wyeth Intentionally Failed to Disclose this Material Information About the Use of the Inderal LA Formulation to Develop Effexor XR.

230. In light of Examiner Spear's rejection based on the McAinsh patent, the Wyeth applicants were aware of the significance of propranolol to the prosecution of patents related to Effexor XR.

231. Instead of disclosing the role of Inderal LA in the development of Effexor XR, Attorney Seifert responded to the rejection of the ʻ328 Application by telling the examiner that

"the teaching of sustained release formulation of microcrystalline cellulose and propranolol in McAinsh *et al*. is not deemed sufficiently relevant to venlafaxine because the two compounds are not structurally related."

232. This statement was plainly false. The Wyeth applicants knew that the Inderal LA formulation was relevant to the patentability of Effexor XR. They used that very formulation to develop the extended release venlafaxine formulation that they sought to patent.

233. Rather than disclose the use of Inderal LA process during prosecution, Wyeth chose to disclose their dead-end experience with Lodine SR, another commercially available Wyeth product. In the background of invention section of the '171, '120, and '958 patents, the inventors disclosed that in developing extended release venlafaxine they started with the hydrogel formulation of Lodine SR. As the patent explains, however, numerous attempts to produce extended release venlafaxine tablets using hydrogel technology proved to be fruitless because "the compressed tablets were either physically unstable (poor compressibility or capping problems) or dissolved too rapidly."

234. The only inference that can be drawn from the inventors' choice to disclose their consideration of the failed Lodine SR formulation but not their consideration of the successful Inderal LA formulation is that they intended to deceive the patent examiner by making him believe that the Effexor XR formulation was new and novel.

d. Wyeth's Upton Patent Disclosed Extended Release Venlafaxine

235. Wyeth's own Upton patent disclosed extended release venlafaxine (*see infra*, ¶¶ 123-127). Wyeth applied for the Upton patent on January 30, 1995, more than a year before Wyeth claimed extended release venlafaxine was surprising in the '006 application. The Upton patent issued to Wyeth on April 9, 1996, one month after Wyeth filed the '006 provisional application and years before the earliest of the three patents ('171) issued (August 2001 – July

2002). This disclosure makes an extended release formulation of venlafaxine not at all surprising, especially not to Wyeth.

236. The Upton patent qualifies as prior art under 35 U.S.C. § 102(e) and (f).

e. Alza's '589 PCT Application Disclosed Extended Release Venlafaxine

237. The collaboration agreement required Alza and Wyeth to exchange information about their respective efforts to develop extended release venlafaxine. The parties' Scientific Steering Committee, comprised of Alza and Wyeth employees, held one or more meetings that discussed the progress of the collaboration and other confidential information about the project, including the status of patent application filings and patent prosecution.

238. On May 27, 1993, Alza filed patent application U.S. Serial No. 08/068,480, listing inventors Edgren, *et al.* (the "Edgren application"). The Edgren application disclosed venlafaxine hydrochloride. The status of the prosecution of the Edgren application was discussed at multiple Scientific Steering Committee meetings between Wyeth and Alza, pursuant to the collaboration agreement. The Edgren application eventually matured into U.S. Patent No. 6, 440,457 on August 27, 2002 (the "Edgren Patent").

239. On December 8, 1994, the World Intellectual Property Organization in Geneva, Switzerland published WO 94/27589, assigned to Alza (the '589 PCT application). The '589 PCT application claims priority to the Edgren application. The '589 PCT application discloses once-a-day venlafaxine extended release formulations, methods for the administration of venlafaxine extended release formulations, and the hours required for *in vitro* dissolution. Once again, there was nothing surprising about the ability to extend the release of venlafaxine.

240. Upon information and belief, Alza conducted a clinical study regarding a venlafaxine extended release formulation during the period January-February 1994, identified as study No. 600B-134-US (the "134 Study"). The '134 Study constituted prior invention of

another that was not abandoned, suppressed, or concealed, and thus constituted prior art to the '171, '958, and '120 patents under 35 U.S.C. § 102(g).

241. The Alza '134 Study was material information and was not cumulative to the '589 PCT application because the 134 Study discloses that the subject Alza venlafaxine extended release formulation produced a peak blood plasma level in patients in about six hours, which the '589 PCT application does not disclose. Thus, the Alza formulation anticipates at least Claims 21, 24, and 25 of the '171 patent and Claim 2 of the '958 patent; such claims would not have issued had the Alza formulation been disclosed to the PTO.

242. The Alza 134 Study also reported a decreased incidence of nausea in patients receiving Alza's venlafaxine extended release formulation as compared with the conventional formulation. As such, that formulation anticipates at least Claim 20 of the '171 patent, Claim 1 of the '958 patent, and Claim 1 of the '120 patent.

243. Both the Edgren patent and the '589 PCT application qualify as prior art to the '171, '120, and '958 patents. The earliest date of invention for Wyeth's extended release formulations is March 25, 1996, the filing date of the '006 provisional application.

244. The '589 PCT application was published on December 8, 1994, over a year before Wyeth filed the '006 application. The '589 PCT application qualifies as prior art against the '171, '120, and '958 patents as a printed publication published in a foreign country before Wyeth invented venlafaxine hydrochloride extended release. 35 U.S.C. § 102(a). The '589 PCT application further qualifies as prior art against the '171, '120, and '958 patents as printed publications published more than one year before Wyeth filed the '006 provisional application. 35 U.S.C. § 102(b).

245. The Edgren application was filed with the PTO on May 27, 1993, roughly three years before Wyeth claimed it invented extended release venlafaxine hydrochloride (as claimed

in the '006 provisional application). The Edgren inventors disclosed an extended release venlafaxine hydrochloride formulation that maintained a constant level of venlafaxine in a patient's plasma over a twenty-four hour period, which can reduce toxic effects. Because its business partner had already extended the release of venlafaxine (and claimed it in a patent), the Wyeth inventors could show nothing surprising about Wyeth's formulation efforts.

246. The Edgren patent qualifies as patent defeating prior art against Wyeth's '171, '120, and '958 patents as a patent application by another filed in the U.S. before Wyeth invented its controlled release formulation for venlafaxine hydrochloride. 35 U.S.C. § 102(e).

247. Upon information and belief, after a reasonable opportunity for further investigation or discovery, Plaintiffs are likely to have evidentiary support establishing that one or more of the Wyeth applicants had actual knowledge of the Edgren patent and the Alza 134 Study and the materiality of same, and withheld such material information with the intent to deceive the PTO.

f. Wyeth's Own Experience With Inderal LA Belies Wyeth's Assertion Of "Unexpected" Results

248. The fact that propranolol and venlafaxine have similar solubility in water would have been of particular importance to the patent examiner because of the statements Wyeth makes in the method of use patents. Specifically, Wyeth claims that: "It was completely unexpected that an extended release formulation containing venlafaxine hydrochloride could be obtained because the hydrochloride of venlafaxine proved to be extremely water soluble." (*See e.g.*, '171 patent col.4 ll.57-60 (emphasis added).) At the time Wyeth made this statement, Wyeth was commercially selling an ER formulation of a highly water soluble active ingredient – Inderal LA. Therefore, the result was not "completely unexpected", or unexpected at all.

249. What the Wyeth inventors did was essentially to substitute venlafaxine in place of the propranolol in the Inderal LA formulation. Wyeth's knowledge that this formulation worked to make an ER formulation of propranolol directly contradicts Wyeth's assertion that it was "completely unexpected" to think a similarly water soluble product – venlafaxine – would also work as an ER product. Since unexpected results can be used to overcome prior art rejections under 35 U.S.C. § 103, but for the withholding, an examiner would have found the Inderal LA substitution and product label to be the basis for an additional obviousness rejection, since they demonstrate that the Inderal LA formulation provided a possible solution to a solubility problem. As such, this information was highly material and should have been disclosed to the patent examiner by Wyeth.

250. Upon information and belief, after a reasonable opportunity for further investigation or discovery, Plaintiffs are likely to have evidentiary support establishing that one or more of the Wyeth applicants had actual knowledge of the Inderal LA formula and product label, and the materiality of same, and withheld such material information with the intent to deceive the PTO.

g. Wyeth Intentionally Deceived the PTO by Fraudulently Claiming It Was the First to Discover, "Unexpectedly," Extended Release Venlafaxine

251. The Wyeth applicants withheld highly material information from the PTO with the intent to deceive the PTO. The Wyeth applicants had a duty to present all information that was known to be material to the patentability of the claims to the examiner. Information that is non-public, but known to the applicant, can be material to patentability. The Wyeth applicants breached their duty of candor to the PTO by failing to properly disclose Wyeth's collaboration agreement with Alza, the '589 PCT application, and the Edgren application.

252. Wyeth knew about the Edgren application and the '589 PCT application – prior to applying for and prosecuting the '171, '120, and '958 patents – from its participation in the Scientific Steering Committee with Alza under the terms of their collaboration agreement.

253. The Wyeth applicants were aware that the '589 PCT application disclosed "controlled release dosage forms" of venlafaxine hydrochloride. The Wyeth applicants were similarly aware the '589 PCT application claimed priority back to May 27, 1993, well before Wyeth claimed to have invented its extended release venlafaxine.

254. Wyeth did disclose the existence of the '589 PCT Application to the PTO on an Informational Disclosure Statement ("IDS") sent to the PTO on August 13, 1998 during the prosecution of the '328 application. Even then, it merely listed the '589 PCT Application on an information disclosure statement, with other patents. Wyeth never told the PTO that another entity claimed to have invented extended release forms of venlafaxine three years before Wyeth claimed to have invented extended release venlafaxine. Wyeth did not disclose the '589 PCT Application during the prosecution of the earlier '137 application. The Wyeth applicants each continued to misrepresent to the PTO that "[i]t was completely unexpected that an extended release formulation containing venlafaxine hydrochloride could be obtained."

255. The collaboration agreement and the resulting '589 PCT application were material to patentability because they presented a *prima facie* case of invalidity as a prior invention of another. Wyeth inventors Sherman, Clark, Lamar and White were not the first to invent methods of (i) eliminating peaks and troughs of venlafaxine in a patient's blood plasma and (ii) reducing nausea and vomiting, via once daily dosing of venlafaxine: *Alza and its scientists, with the knowledge and collaboration of Wyeth, had developed technology and filed and prosecuted a patent application directed to those methods at least three years before Wyeth claimed its*

"unexpected" discovery. The Wyeth inventors derived at least part of their invention from the collaboration with Alza.

256. The '589 PCT application is separately material because, contrary to Wyeth's claims to discovery, it was not unexpected that one could make a controlled release venlafaxine product that eliminated the peaks and troughs of the drug in blood plasma or reduce the incidence of nausea and vomiting.

257. That the Wyeth applicants intended to deceive the PTO must be inferred from (1) their knowledge that Alza was developing an extended release version of venlafaxine; (2) Alza disclosed to Wyeth that it had filed the Edgren application and reported to Wyeth on the status of the Edgren application; (3) Wyeth was aware of the '589 PCT application (as evidenced by its late submission of the '589 PCT application to the PTO); and (4) Wyeth knew the '589 PCT application disclosed formulations of extended release venlafaxine that minimized the troughs and peaks of the amount of venlafaxine in patients' blood serum levels.

258. The Wyeth applicants' intent to deceive must also be inferred from Wyeth's financial motivation. Wyeth was aware of the impact that an Alza patent would have on Wyeth's exclusivity to sell Effexor XR. Wyeth knew that the collaborative agreement provided that Alza would own the rights to any patent that resulted from their collaboration. Alza was free to sell, use, or license the rights to the technology to a third party. Even a patent that named both Wyeth and Alza inventors would be at least co-owned, if not completely owned, by Alza. Wyeth knew that it needed its own patent to have a monopoly over extended release venlafaxine.

259. Wyeth's conspicuous withholding of the full scope of the Alza formulations, while repeatedly arguing through six patent applications that the Wyeth discovery was unexpected, shows a high level of intent to deceive the PTO.

260. Wyeth's unexpected discovery fraud directly affects at least Claims 20-25 of the '171 patent and all of the claims of the '958 and '120 patents. Further, in the stark light of later patent infringement litigation, all three patents would be rendered entirely invalid and unenforceable as a result of false statements concerning "surprising" findings in developing the spheroid formulation of extended release venlafaxine, or in purportedly discovering that extending the release of venlafaxine eliminates peaks in blood plasma concentration. Because Wyeth defrauded the PTO by affirmatively but falsely claiming it had achieved "unexpected" results, Wyeth is not entitled to immunity for any claimed petitioning activity in seeking or enforcing the '171, '958, and '120 patents.

261. Upon information and belief, after a reasonable opportunity for further investigation and discovery, Plaintiffs will likely have evidentiary support to establish that one or more of the Wyeth applicants knew that the PTO would rely on their misrepresentations about unexpected results in evaluating Wyeth's method of use claims because the Wyeth applicants did not provide any evidence of unexpected results, and they withheld from the PTO extensive evidence which belied Wyeth's affirmative misrepresentations.

262. Upon information and belief, the PTO did, in fact, justifiably rely on the Wyeth applicants' misrepresentations as to unexpected results. Such reliance may be inferred from the fact that PTO Examiner Amy Hulina was prepared to reject Wyeth's claims over the prior art Upton patent, but other PTO examiners subsequently allowed similar claims in the face of Wyeth's repeated representations of unexpected results.

D. Wyeth Engaged in Sham Litigation against Seventeen or More Generic Manufacturers

263. Wyeth wrongfully listed all three of the fraudulently obtained patents in the Orange Book. The listing of these patents was unlawful because (i) the patents were obtained

through fraud; (ii) the patents were obtained deceptively; (iii) Wyeth knew that listing the patents would trigger statutory and regulatory consequences to which it was not entitled; and (iv) Wyeth knew that any litigation that might be brought on the basis of these Orange Book listings would be objectively baseless.

264. One component of Wyeth's monopolization strategy was to enforce its fraudulently obtained patents through infringement litigation against generic manufacturers. Wyeth knew that it could not rely on the fraudulently obtained patents to delay generic entry unless it listed them in the Orange Book because of the high legal barriers it would have to surmount in order to receive a court-ordered injunction. Thus, by taking advantage of the FDA's ministerial role in listing patents in the Orange Book, Wyeth wrongfully listed all three of the fraudulently obtained patents in the Orange Book.

265. Wyeth's listing of the fraudulently obtained patents compelled generic manufacturers to file Paragraph IV certifications to these patents. Thus, by using these patents to manipulate the ANDA process, Wyeth was able to delay approval of the generics' ANDAs by filing patent infringement litigation, even though the alleged infringement claims were meritless.

266. At least fifteen generic manufacturers sent Wyeth Paragraph IV certifications informing Wyeth they intended to manufacture AB-rated generic equivalents to Effexor XR and claiming their product would not infringe Wyeth's patents. In each and every instance, Wyeth reflexively sued the generic for infringement of the '171, '958, and '120 patents. Wyeth even sued branded manufacturer Osmotica, whose product was in a different form altogether (tablet instead of capsule) and was not an AB-rated generic equivalent of Effexor XR.

267. These lawsuits were pursued without either a reasonable basis or reasonable expectation of success, and were initiated solely for the purpose of illegally extending Wyeth's monopoly by delaying the entrance of generic manufacturers into the relevant market.

268. Wyeth knew that all the method-of-use claims were invalid and/or unenforceable. It knew that the clinical evidence did not support its comparative statements between Effexor XR and instant release Effexor. It knew its peaks and troughs claims, broadly construed beyond the specific spheroid formulation, were simple pharmacologic tautologies. It knew that prior art existed for the formulation and method-of-use claims made in the patents. Wyeth also knew that in the context of patent infringement litigation, where sophisticated parties who will not unwittingly rely on Wyeth's deceptive statements and nondisclosures can acquire the true information about the circumstances of the acquisition of a patent, it had no reasonable likelihood of succeeding on the merits of its sixteen infringement litigations – that is, if a federal court were ever given an opportunity to reach the merits.

269. Upon information and belief, none of the generic competitors sued by Wyeth employed the formulation disclosed and claimed in Wyeth's method of use patents.

270. Upon information and belief, at no time did Wyeth assert any of the formulation claims of its method of use patents; namely, Claims 1-19 of the '171 Patent, against any of the generic competitors.

271. Wyeth procured overly broad and invalid method claims in the Wyeth method of use patents. By filing suit against each generic competitor which filed an ANDA in connection with Effexor XR, Wyeth procured a 30-month delay of FDA approval as to those generic competitors, under circumstances where Wyeth had no legitimate basis to file suit against any of them, such that the Wyeth method of use patents should not have caused any delay in the approval of the ANDAs of the several generic competitors.

272. Wyeth also knew that its broad claim constructions failed to meet either the written description or the enablement requirements. In prosecuting the method claims before the PTO, Wyeth argued that they were entitled to a broad patent for the extended release

formulation. The patents' specification, however, lacked any evidence that, as of the March 1996 filing date, the named inventors possessed any extended release venlafaxine formulations other than the encapsulated coated spheroid formulation described. Wyeth could not demonstrate that the inventors possessed any other possible extended release formulations covered by the patents' broad claims, thereby rendering the patents invalid for failure to satisfy the written description requirement.

273. Moreover, Wyeth knew that its overly broad claim construction rendered the patents invalid for failure to satisfy the separate enablement requirement. The broadly asserted method claims, which encompass any extended release formulation of venlafaxine, were not enabled because a person of ordinary skill in the art would have to do undue experimentation in order to use the invention. The patents' specification provided no guidance or working examples for formulations other than one coated spheroid formulation.

274. The goal, purpose and/or effect of Wyeth's fraudulent procurement, wrongful listing, and sham patent suits was to prevent, delay, and/or minimize the success of the entry of generic competitors, which would have sold generic equivalents of Effexor XR in the United States at prices significantly below Wyeth's prices for Effexor XR, and therefore would have taken most of Wyeth's market share. Such generic competition would have effectively caused the average market price of Effexor XR to decline dramatically.

275. In short, for each of the seventeen lawsuits referenced below, no reasonable pharmaceutical manufacturer would believe there to be a realistic likelihood of success on the merits. In fact, because Wyeth knew that the patents were invalid and unenforceable and that each of these cases would (if permitted to go the distance) result in a Wyeth loss, Wyeth has, so far, settled sixteen of the seventeen infringement lawsuits before a court issued a final decision on the merits.

1. Teva

276. On December 10, 2002, Teva filed an ANDA seeking approval of a generic version of Effexor XR. Teva USA's ANDA included Paragraph IV certifications that Wyeth's '171, '120, and '958 patents were invalid, unenforceable, and would not be infringed by its generic extended release venlafaxine capsules.

277. As the first ANDA applicant to submit a substantially complete ANDA, Teva USA was entitled to be the only non-authorized generic on the market for 6 months. Typically, once a drug goes generic, the branded manufacturer sells both the branded version and an "authorized" generic version, usually selling the same exact pills in different bottles. During the first filer's exclusivity period, the branded manufacturer is the *only* firm (besides the first filer) able to market and sell a competing generic version of the drug because it is permitted to do so under the authority of its approved NDA rather than under an ANDA. Launching an authorized generic permits the branded company to capture some of the revenues and profits being earned on the sales of generics.

278. On March 24, 2003, Wyeth brought suit against Teva in the District of New Jersey for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Teva with infringement of Claims 20-25 of the '171 patent, Claims 1, 2, 13, and 14 of the '120, and Claims 1-6 of the '958 patent. All are method-of-use claims for either reducing the incidence of nausea and vomiting or smoothing out the troughs and peaks in the blood serum. Wyeth did not assert Teva infringed any of the formulation claims. Wyeth did not claim Teva infringed any other patents.

279. Teva answered, denying the allegations and claiming that all the patents were invalid and not infringed. On April 1, 2005, Teva filed a motion for leave to amend its answer to assert an inequitable conduct defense based on the "nausea" fraud. Wyeth opposed that motion

and convinced a magistrate judge to deny the motion on May 9, 2005, based on Teva's lack of diligence in presenting it. On August 3, 2005, the district judge held that the magistrate judge's findings as to Teva's lack of diligence were not clearly erroneous. Accordingly Teva's allegations of inequitable conduct were never adjudicated on the merits.

280. During the *Teva* litigation, the parties disputed the term "extended release formulation" – the critical term that defines the method-of-use claims broadly, or limited to the spheroid formulation developed by Wyeth. The *Teva* court concluded that when the term "extended release formulation" is "looked at in its proper context in the specification . . . one of ordinary skill in the art would construe the term to include [the] specific ingredients" mentioned in the specification.

281. Wyeth knew this ruling meant that loss of the litigation was right around the corner. Further, Wyeth knew that if this ruling were permitted to stand, other generic companies could use this ruling as an already-decided issue. Wyeth could have let the Hatch-Waxman process unfold, leading to the (correct) result that a federal court would have determined the truth of Wyeth's patent coverage. It did not.

282. Instead, in late 2005 Wyeth and Teva entered into a pact, forming a conspiracy with Teva to initiate the next phase of the anticompetitive scheme.

283. On January 20, 2006, the case was closed after the parties filed under seal a Joint Settlement and Release Agreement on November 2, 2005 ("the Settlement Agreement"). On information and belief, all of the entities named as defendants in this complaint were signatories to that Settlement Agreement.

284. As part of the Settlement Agreement, Teva and Wyeth agreed that the prior *Markman* ruling of the *Teva* court would be vacated. Through the vacatur, later generic companies would need to relitigate the construction of "extended release formulation" as

appearing in the Wyeth patents; this would, of course, equip both Wyeth and Teva with the ability to stall later generics. The *Teva* court did, in fact, vacate its *Markman* opinion on September 6, 2005.

285. Also as part of the Settlement Agreement, Wyeth gave Teva an *exclusive* license to sell a generic version of (instant release) Effexor before the original compound patent for venlafaxine expired. Wyeth would both forgo marketing its own authorized generic during that period *and* allow Teva's generic Effexor to come to market early.

286. The Husbands' patent expired in June 2008; with Wyeth's permission, Teva obtained FDA approval and began selling generic instant release venlafaxine in October 2006 – over a year and a half before it otherwise could have.

287. Wyeth also agreed to refrain from selling an authorized generic version of (instant release) Effexor until the Husband's patent expired – giving Teva at least a year and a half of being the *only* instant release generic on the market.

288. Wyeth also gave Teva *an exclusive* license to sell a generic version of extended release Effexor XR beginning on July 1, 2010, with the possibility of an earlier launch if another generic entered or was successful in invalidating the '171, '120 and '958 patents. Wyeth, again, agreed to not market an authorized generic for a set period of time. This date was more than two years after the expiration of the Husbands patent. Except in certain limited circumstances (that did not come to pass), the period of exclusivity under the license expired eleven months later, on June 1, 2011. Thus, the agreement between Wyeth and Teva contemplated that Teva would have eleven months as the exclusive generic seller on the market rather than the six months provided by the Hatch-Waxman Act.

289. By entering into the settlement agreement, Teva agreed to delay the launch of generic Effexor XR until two years after the expiration of the only Wyeth patent actually capable

of blocking generic competition to Effexor XR. Teva began selling generic extended release venlafaxine capsules on July 1, 2010 and was the only seller of generic Effexor XR until June 1, 2011.

290. Importantly, from Teva's point of view, Wyeth agreed to refrain from selling an authorized generic version of Effexor XR during the term of Teva's license. By agreeing not to launch an authorized generic, Wyeth in effect agreed not to compete on price with Teva's generic product – *i.e.*, it agreed to sell Effexor XR only at the higher branded price and not at the lower generic price. This allowed Teva to maintain a relatively high generic price as the only generic manufacturer on the market and to earn higher profits than it otherwise would have earned, all at the expense of Plaintiffs and other generic purchasers. It also ensured that every Effexor XR prescription filled with a generic during that time period was filled with Teva's product.

291. The agreement between Wyeth and Teva was structured to encourage Wyeth to resolve all subsequent challenges to the '171, '120, and '958 patents prior to a court finding of invalidity, non-infringement, or unenforceability. The vacatur of the *Teva* court's *Markman* ruling enabled later relitigation of the critical patent construction issue. Any final ruling on the merits would trigger the need for Teva to launch its generic product, and thus (on information and belief) Wyeth's license to Teva allowed Teva to enter the market earlier than June 2010 if any subsequent generic manufacturer succeeded in establishing invalidity, non-infringement, or unenforceability of Wyeth's three patents. Because such a result would have subjected Wyeth to generic competition from Teva earlier than July 2010, the agreement, by design, motivated Wyeth to resolve subsequent generic cases without a court finding of invalidity, non-infringement, or unenforceability. In fact, Wyeth resolved all of the next fifteen infringement litigations prior to any final ruling on the merits by a court.

292. Teva launched its immediate release generic Effexor tablets in August 2006. By the end of 2007, approximately 96% of Wyeth's sales of immediate release Effexor tablets worth over $900 million had converted to Teva generic immediate release venlafaxine tablets. The availability of generic immediate release venlafaxine tablets from Teva did not significantly impact Wyeth's sales of Effexor XR.

293. On or about July 1, 2010, Teva launched its generic Effexor XR capsules. The launch of generic Effexor XR capsules caused Wyeth's sales of branded Effexor XR capsules to significantly decrease.

294. Had Wyeth not fraudulently obtained the '171, '120, and '958 patents, and/or not listed those patents in the Orange Book, and/or not brought a sham infringement lawsuit based on these patents, and/or not colluded with Teva to delay generic competition, Teva would have come to market with generic Effexor XR capsules at least by June 2008 and Wyeth would have launched an authorized generic at the same time.

2. Impax

295. Wyeth was displeased with the New Jersey *Teva* court's *Markman* ruling, so it conspired with Teva to "undo" the ruling and devised a plan to litigate infringement actions in multiple different federal courts across the country.

296. On April 5, 2006, Wyeth brought suit against Impax Laboratories, Inc. ("Impax") in the District of Delaware for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Impax with infringement of Claims 20-25 of the '171 patent, Claims 1-6 of the '958 patent, and Claims 1, 2, 13, and 14 of the '120 patent.

297. Impax answered, denying the allegations and claiming that all the patents were invalid, not infringed, and unenforceable.

298. On or about September 26, 2007, Impax served on Wyeth a 49-page expert report expressing the opinion that the Wyeth applicants failed to disclose material information to the PTO during the prosecution of the ‘171, ‘958, and ‘120 patents. In response to a motion by Wyeth arguing that the expert report opined on issues of patent law, on January 11, 2008, the court struck Impax's expert report.

299. Wyeth and Impax relitigated construction of the term "extended release formulation" as used in the patents. In a different court and with a different judge than it had in *Teva*, on December 13, 2007 the *Impax* court issued a decision in Wyeth's favor on that issue. However, Wyeth did not then continue to prosecute (to an eventual ruling on the merits) whether its patent claims, as so construed, would be valid and enforceable (because any reasonable pharmaceutical manufacturer, including Wyeth, knew it would lose).

300. On May 13, 2008, an order was entered at the joint request of the parties to have the court defer ruling on pending motions for summary judgment. The parties avoided a ruling on the merits and Impax's allegations of inequitable conduct were never adjudicated on the merits.

301. The case was closed per a consent judgment on July 15, 2008, after the parties filed under seal a Joint Settlement and Release Agreement on June 9, 2008. Under the order, the parties purported to stipulate that the patents were valid, enforceable, and infringed upon. Impax agreed not to enter the market until expiration of the ‘171 patent, the ‘120 patent, and the ‘958 patent.

302. As part of the settlement, Wyeth granted Impax a license to market its generic version of Effexor XR on June 1, 2011, (because Wyeth had promised Teva it would be the only generic Effexor XR on the market until that date) subject to earlier launch in limited circumstances, but in no event earlier than January 1, 2011.

3. Anchen

303. On April 12, 2006, Wyeth brought suit against Anchen Pharmaceuticals, Inc.("Anchen") in the Central District of California for infringement of the '171 patent, the '120 patent, and the '958 patent. Wyeth charged Anchen with infringement of undefined claims.

304. Anchen answered, denying the allegations and claiming that all thee patents were invalid, not infringed, and unenforceable.

305. Wyeth and Anchen relitigated construction of the term "extended release formulation" as used in the patents. On December 20, 2007 the *Anchen* court issued an unpublished, in-chambers decision. Wyeth did not prosecute to an eventual ruling on the merits whether its patent claims, as so construed, would be valid and enforceable (they would not). The case was closed per an order on November 3, 2008 after the parties filed under seal a Joint Settlement and Release Agreement on September 26, 2008. Under the order, the parties purported to stipulate that the patents were valid, enforceable, and infringed. Anchen agreed not to enter the market until expiration of the '171 patent, the '120 patent, and the '958 patent; however, the agreement provides a license to Anchen on undisclosed terms.

4. Lupin

306. On March 12, 2007, Wyeth brought suit against Lupin Ltd. ("Lupin") in the District of Maryland for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Lupin with infringement of Claims 20-25 of the '171 patent, Claims 1-6 of the '958 patent, and Claims 1 and 2 of the '120 patent.

307. Lupin answered, denying the allegations and claiming that all three patents were invalid and not infringed.

308. Wyeth and Lupin relitigated construction of the term "extended release formulation" as used in the patents. On September 29, 2008 the *Lupin* court issued a decision in

Wyeth's favor on that issue. However, Wyeth did not then prosecute (to an eventual ruling on the merits) whether its patent claims, as so construed, would be valid and enforceable (they would not).

309. The case was closed per an order on April 23, 2009, after the parties filed a Joint Settlement and Release Motion under seal on March 6, 2009. Under the order, the parties purported to stipulate that the patents were both valid and infringed. Lupin agreed not to enter the market until expiration of the '171 patent, the '120 patent, and the '958 patent; however, the agreement provides a license to Lupin on undisclosed terms.

5. Osmotica

310. On April 20, 2007, Wyeth brought suit against Osmotica Pharmaceuticals Corporation ("Osmotica") in the Eastern District of North Carolina for infringement of the '171 patent, the '120 patent, and the '958 patent. Wyeth charged Osmotica with infringement of the "asserted claims" which include Claims 1-6 of the '958 patent and Claim 1 of the '120 patent. The parties disputed the term "extended release formulations."

311. Osmotica sought to market a *tablet* form of extended release venlafaxine, not an generic version of Wyeth's Effexor XR. Osmotica's NDA sought approval under the hybrid provisions of 505(b)(2) of the FDCA. Osmotica's product, by definition, was not an AB-rated generic equivalent of Effexor XR.

312. Osmotica answered, denying the allegations and claiming that all three patents were invalid, non-infringed, and unenforceable.

313. The case was closed per an order on March 19, 2008 after the parties filed under seal a Joint Settlement and Release Agreement on March 17, 2008. Under the order, Osmotica agreed not to enter the market until expiration of the '171 patent, the '120 patent, and the '958 patent; however, the agreement provides a license to Osmotica on undisclosed terms.

6. Sandoz

314. On June 22, 2007, Wyeth brought suit against Sandoz, Inc. ("Sandoz") in the Eastern District of North Carolina for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Sandoz with direct infringement, active inducement of infringement, and contributory infringement of Claims 20-25 of the '171 patent, Claims 1-6 of the '958 patent, and Claims 1, 2, 13, and 14 of the '120 patent.

315. Sandoz answered, denying the allegations and claiming that all three patents were invalid, not infringed, and unenforceable.

316. Wyeth and Sandoz relitigated construction of the term "extended release formulation" as used in the patents. On July 3, 2008, the *Sandoz* court issued a decision in Wyeth's favor on that issue. However, Wyeth did not prosecute to an eventual ruling on the merits whether its patent claims, as so construed, would be valid and enforceable (they would not).

317. The case was closed per an order on August 8, 2011 after the parties filed a stipulation of dismissal and a consent order. Under the order, Sandoz agreed not to enter the market until expiration of the '171 patent, the '120 patent, and the '958 patent except to the extent permitted under agreements between Wyeth and Sandoz (that were not reflected as having been filed with the court).

7. Mylan

318. On July 6, 2007, Wyeth brought suit against Mylan Pharmaceuticals Inc. ("Mylan") in the Northern District of West Virginia for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Mylan with direct infringement, active inducement of infringement, and contributory infringement of Claims 20-25 of the '171 patent, Claims 1-6 of the '958 patent, and Claims 1, 2, 13, and 14 of the '120 patent.

319. Mylan answered, denying the allegations and claiming that all three patents were invalid and not infringed and the parties filed cross-motions for summary judgment.

320. Wyeth and Mylan relitigated construction of the term "extended release formulation" as used in the patents. On May 22, 2009 the *Mylan* court issued a decision in Wyeth's favor on that issue.

321. The *Mylan* case proceeded to some summary judgment determinations, none of which would resolve the case. As part of its summary judgment briefing, Wyeth found itself in a conundrum; Wyeth argued that its broad method-of-use claims were enabled because anyone in the art could make the broad range of "extended release formulations" of venlafaxine, but that this enablement did not contradict its representations to the PTO that its formulation of slowing the release of venlafaxine was "completely unexpected".

322. On October 14, 2009 an order denied, in part, and granted, in part, Mylan's motions for summary judgment. Judge Keeley denied Mylan's motions regarding infringement and enablement, and granted Wyeth's motion regarding inventorship. Wyeth did not seek summary judgment on other bases. Mylan's other defenses, including its invalidity defenses, remained unresolved.

323. Wyeth did not then prosecute to an eventual ruling on the merits whether its patent claims, as so construed, would be valid and enforceable (they would not).

324. The case was closed per a dismissal order on December 21, 2009 after the parties filed under seal a Joint Settlement and Release Motion on November 30, 2009. Under the order, Mylan agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent; however, the agreement provides a license to Mylan on undisclosed terms.

8. Wockhardt

325. On August 8, 2007, Wyeth brought suit against Wockhardt Limited ("Wockhardt") in the Central District of California for infringement of the '171 patent, the '120 patent, and the '958 patent.

326. Wockhardt answered and asserted a counterclaim alleging inequitable conduct based on the "prior rejection" fraud. Wyeth filed a motion to dismiss Wockhardt's counterclaim, which Wockhardt opposed.

327. On May 29, 2008, the court denied Wyeth's motion, holding that Wockhardt had plead a claim that was plausible on its face.

328. The case was closed per an order entered on May 19, 2009, entering a consent judgment stipulating to the validity and enforceability of the patents and licensing Wockhardt on undisclosed terms.

9. Biovail

329. On June 26, 2008, Wyeth brought suit against Biovail Corporation ("Biovail") in the District of Delaware for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Biovail with infringement of undefined claims.

330. Biovail answered, denying the allegations and claiming that all three patents were invalid and not infringed.

331. The *Biovail* case only lasted nine months. The case was closed per an order on March 19, 2010 after the parties filed under seal a Joint Motion to Enter Consent Judgment and to Enter Stipulated Order on November 12, 2009. Under the order, the parties purported to stipulate that the patents were both valid and infringed. Biovail agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent; however, the agreement provides a license to Biovail on undisclosed terms.

10. Apotex

332. On August 18, 2008, Wyeth brought suit against Apotex Inc. and Apotex Corp. ("Apotex") in the Southern District of Florida for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Apotex with infringement of Claims 2-20 of the '171 patent, Claims 1-6 of the '958 patent, and Claims 1, 2, 13, and 14 of the '120 patent.

333. Apotex answered, denying the allegations and claiming that all three patents were invalid, not infringed and unenforceable for inequitable conduct.

334. Wyeth and Apotex relitigated construction of the term "extended release formulation" as used in the patents. On August 13, 2009, the *Apotex* court issued a decision in Wyeth's favor on that issue. However, Wyeth did not prosecute to an eventual ruling on the merits whether its patent claims, as so construed, would be valid and enforceable (they would not).

335. The case was closed per an order on September 15, 2010 after the parties filed under seal a Joint Settlement and Release Agreement on August 11, 2010. Under the order, the parties purported to stipulate that the patents were valid, enforceable, and infringed. Apotex agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent; however, the agreement provides a license to Apotex on undisclosed terms.

11. Torrent

336. On January 8, 2009, Wyeth brought suit against Torrent Pharmaceuticals Limited and Torrent Pharma Inc. ("Torrent") in the District of Delaware for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Torrent with infringement of claims undefined.

337. Torrent answered, denying the allegations and claiming that all three patents were invalid and not infringed.

338. The case was closed per an order on June 30, 2010 after the parties filed under seal a Joint Settlement and Release Agreement on May 6, 2010. Under the order, the parties purported to stipulate that the patents were both valid and infringed. Torrent agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent; however, the agreement provides a license to Torrent on undisclosed terms.

12. Cadila

339. On April 9, 2009, Wyeth brought suit against Cadila Healthcare Limited and Zydus Pharmaceuticals (USA) ("Cadila") in the District of Delaware for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Cadila with infringement of claims undefined.

340. Cadila answered, denying the allegations and claiming that all three patents were invalid and not infringed.

341. The case was closed per an order on March 30, 2010 after the parties filed under seal a Joint Settlement and Release Agreement on January 28, 2010. Under the order, the parties purported to stipulate that the patents were valid and infringed. Cadila agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent; however, the agreement provides a license to Cadila on undisclosed terms.

13. Aurobindo

342. On April 22, 2010, Wyeth brought suit against Aurobindo Pharma Limited ("Aurobindo") in the District of New Jersey for the infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Aurobindo with infringement of undefined claims.

343. Aurobindo answered, denying the allegations and claiming that all three patents were invalid and not infringed.

344. The case was closed per an order on January 6, 2011. The parties purported to stipulate that the patents were valid and infringed upon. Aurobindo agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent; however, the agreement between Wyeth and Aurobindo provides a license to Aurobindo on undisclosed terms.

14. Orgenus and Orchid

345. On July 2, 2009, Wyeth brought suit against Orgenus Pharma Inc. and Orchid Chemicals and Pharmaceuticals (collectively, "Orchid") in the District of New Jersey for the infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Orchid with infringement of claims undefined.

346. Orchid answered, denying the allegations and claiming that all three patents were invalid, unenforceable, and not infringed.

347. A consent order of final judgment was entered on April 14, 2011. The parties purported to stipulate that the patents were valid and infringed. Orchid agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent; however, the agreement between Wyeth and Orchid provides a license to Orchid on undisclosed terms.

15. Intellipharmaceutics

348. On June 30, 2010, Wyeth brought suit against Intellipharmaceutics International Inc., Intellipharmaceutics Corporation, and Intellipharmaceutics LTD (collectively, "Intellipharmaceutics") in the District of Delaware for the infringement of the '171 Patent, the '120 Patent, and the '958 Patent. The next day, July 1, 2010, Wyeth filed a second suit against Intellipharmaceutics for infringement of the '171 Patent, the '120 Patent, and the '958 Patent in the Southern District of New York.

349. Intellipharmaceutics answered in the New York action, denying the allegations, and claiming that all three patents were invalid, unenforceable, and not infringed.

350. A consent order of final judgment was entered on June 20, 2011 in the New York action. The parties purported to stipulate that the patents were valid and infringed. Intellipharmaceutics agreed not to enter the market until expiration of the '171 Patent, the '120 Patent, and the '958 Patent; however, the agreement between Wyeth and Intellipharmaceutics provides a license to Intellipharmaceutics on undisclosed terms. On September 1, 2011, Wyeth voluntarily dismissed the Delaware action without prejudice.

16. Dr. Reddy's

351. On September 3, 2010, Wyeth brought suit against Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's") in the District of New Jersey for infringement of the '171 patent, the '120 patent, and the '958 patent.

352. Dr. Reddy's answered, denying the allegations and claiming that all three patents were invalid and not infringed.

353. The case was closed by an order dated April 28, 2011, after the parties entered into a Stipulation and Order of dismissal on April 25, 2011.

354. As part of the settlement, Wyeth agreed that Dr. Reddy's could enter the market with its generic version of Effexor XR on June 1, 2011, subject to earlier launch in limited circumstances, but in no event earlier than January 1, 2011.

17. Nostrum

355. On April 21, 2011, Wyeth brought suit against Nostrum Laboratories, Inc., Nostrum Pharmaceuticals, LLC, and Enem Nostrum Remedies Pvt. Ltd. in the District of New Jersey for infringement of the '171 patent, the '120 patent, and the '958 patent.

356. This suit is pending before this Court. The parties have twice filed stipulations extending Nostrum's time to respond to the complaint (the most recent of which was filed on December 12, 2011). Nostrum is currently scheduled to respond on January 10, 2011.

E. Earlier Allegations and Evidence of the Invalidity and Unenforceability of Wyeth's '171, '120, and '958 Patents

357. In patent infringement litigation against generic manufacturers, allegations about validity or enforceability, or rulings on the merits against a patent holder, are the kind of developments that taint the patent with an issue regarding its validity or enforceability.

358. Here, Wyeth asserted sixteen different generic manufacturers infringed the method-of-use claims. Simply by filing suit, Wyeth kept each of the seventeen generic equivalents of Effexor XR off the market for the shorter of 30 months or a decision on the merits. In answering Wyeth's claim of infringement, each of the generic companies claimed that the patents were invalid. Several of the generic companies also alleged the patents were unenforceable due to inequitable conduct. The validity and enforceability was to be actively litigated between Wyeth and the generic manufacturers.

359. However, Wyeth settled each and every Effexor XR infringement suit before a federal court could render an opinion on the validity or enforceability of Wyeth's patents. Wyeth orchestrated settlements with the generics in order to bring an end to the litigation it started before a court could find the asserted method-of-use claims invalid or unenforceable.

360. Despite Wyeth's instituting numerous infringement lawsuits, and despite would-be generic competitors' allegations and evidence of invalidity and unenforceability, no court entered an order determining the invalidity or enforceability of the fraudulently obtained method-of-use claims. The only court to issue a substantive decision on the merits denied Wyeth's motion for summary judgment regarding infringement but did not determine whether or not the patents themselves were valid and/or enforceable. In the rare instances where litigation with the generics approached either a summary judgment decision addressing invalidity/enforceability or a trial date, Wyeth settled with the generics.

361. Wyeth cannot insulate itself from liability for the anticompetitive effects of its fraudulent procurement of the method-of-use claims by bringing lawsuits it knew it would lose and settling with the alleged infringing generic companies before the merits can be adjudicated. If the terms are favorable, generic manufacturers have a significant incentive to accept Wyeth's offer. However, prescription drug purchasers are still harmed by Wyeth's anticompetitive scheme and sham litigation.

362. Settlement by the parties to the infringement actions cannot preclude those harmed by the anticompetitive effects of Wyeth's wrongful actions (in both obtaining the patents and filing infringement suits) from seeking recovery for their damages.

363. Wyeth's conduct in procuring the illegal listing of the fraudulently obtained '171, '120, and '958 patents in the Orange Book is not entitled to immunity under the *Noerr-Pennington* doctrine because: (i) the FDA's listing of the fraudulently-obtained patents was a purely ministerial act, and thus Wyeth's conduct before the FDA does not constitute legally protected petitioning activity; (ii) the Noerr-Pennington doctrine does not immunize or protect the act of deceiving the FDA; (iii) no immunity applies to Wyeth's anticompetitive acts in structuring arrangements with Teva that delayed generic entry and allocated markets; and (iv) no immunity applies to this overall scheme.

364. Likewise, the *Noerr-Pennington* doctrine does not immunize Wyeth's patent infringement suits from antitrust liability, because each of the patent litigation actions brought by Wyeth was an objectively baseless "sham," which no litigant could reasonably have expected to win, and was prosecuted solely for the purpose of delaying entry of generic competition into the relevant market for extended release venlafaxine.

365. Wyeth's overarching scheme to improperly use its patents to manipulate the ANDA process and wrongfully delay generic competition is not immunized because Wyeth's

scheme was intended to, and did, unlawfully maintain its monopoly over the relevant market for extended release venlafaxine capsules.

VI. MONOPOLY POWER AND MARKET DEFINITION

366. At all relevant times, Wyeth had monopoly power over Effexor XR and its generic equivalents because it had the power to maintain the price of the drug it sold as Effexor XR at supra-competitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Effexor XR, with the exception of generic extended-release venlafaxine capsules.

367. A small but significant non-transitory price increase by Wyeth for Effexor XR would not have caused a significant loss of sales to other products prescribed and/or used for the same purposes as Effexor XR, with the exception of generic extended-release venlafaxine capsules.

368. Because of, among other reasons, psychotropic drugs' heterogeneous responses in different patient populations, Effexor XR is differentiated from all products other than AB-rated generic versions of Effexor XR.

369. Wyeth needed to control only Effexor XR and its AB-rated generic equivalents, and no other products, in order to maintain the price of Effexor XR profitably at supracompetitive prices while preserving all or virtually all of its sales. Only the market entry of a competing, AB-rated generic version of Effexor XR would render Wyeth unable to profitably maintain its current prices of Effexor XR without losing substantial sales.

370. Wyeth also sold Effexor XR at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins.

371. Wyeth has had, and exercised, the power to exclude competition to Effexor XR.

372. To the extent that Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant market is all extended release venlafaxine capsules, *i.e.*, Effexor XR (in all its forms and dosage strengths) and AB-rated bioequivalent extended release venlafaxine capsules. During the period relevant to this case, Wyeth has been able to profitably maintain the price of Effexor XR well above competitive levels.

373. Wyeth, at all relevant times, enjoyed high barriers to entry with respect to competition to the above defined relevant market due to patent and other regulatory protections, and high costs of entry and expansion.

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

375. Wyeth's market share in the relevant market was 100% until June of 2010, implying a substantial amount of monopoly power.

VII. MARKET EFFECTS

376. Wyeth, acting alone and/or in concert with Teva, willfully and unlawfully maintained its monopoly power by engaging in an overarching scheme to exclude competition that discouraged rather than encouraged competition on the merits. This scheme was designed for the anticompetitive purpose of forestalling generic competition and carried out with the anticompetitive effect of maintaining supracompetitive prices for the relevant product. Wyeth implemented its scheme by, *inter alia*, improperly listing patents in the Orange Book, manipulating the prosecution of the '171, '958, and '120 patents, prosecuting multiple sham patent infringement lawsuits, and abusing the Hatch-Waxman framework, in concert with Teva, to serve its anticompetitive goals. These acts in combination were anticompetitive.

377. Wyeth's acts and practices, including its conspiracy with Teva, had the purpose and effect of unreasonably restraining competition and injuring competition by protecting

Effexor XR from generic competition. Wyeth's actions, including its conspiracy with Teva, allowed it to maintain a monopoly and exclude competition in the market for extended release venlafaxine capsules, *i.e.*, Effexor XR and its AB-rated generic equivalents, to the detriment of Plaintiffs and all other members of the Indirect Purchaser Class.

378. Wyeth's exclusionary conduct, including its conspiracy with Teva, has delayed generic competition and unlawfully enabled it to sell Effexor XR without generic competition. But for the illegal conduct of Wyeth and/or Teva, one or more generic competitors would have begun marketing AB-rated generic versions of Effexor XR much sooner than they actually were marketed, and, in any event, would have been on the market no later than June 14, 2008. By way of examples and not limitation: (i) if there had been no fraud upon the PTO, the '171, '958, and '120 patents would not have issued, the patents would never have been listed in the Orange Book, and thus the patents would never have been the subject of infringement litigation that led to the 30-month Hatch-Waxman stay; (ii) if there had been no patents, there would have been no lawsuits, and with no lawsuits there would have been no settlements, all of which acted to further delay FDA approval and the timing of generic launch; (iii) if the lawsuits had not been brought, the 30-month Hatch-Waxman stay would never have been triggered, no settlements would have been necessary, and FDA approval would have been forthcoming by June of 2008 with generic manufacturers ready, willing, and able to launch at that time; and (iv) if the settlement agreement had not occurred Teva would have earlier entered the market and/or the patents would easily have been invalidated, thus permitting generic entry much earlier.

379. The generic manufacturers seeking to sell generic versions of Effexor XR had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, and at least several of these generic

manufacturers would have been ready, willing and able to launch their generic versions of Effexor XR by June, 2008 were it not for Wyeth's illegal acts and conspiracies with Teva.

380. Wyeth's illegal acts and conspiracy with Teva, to delay the introduction into the U.S. marketplace of any generic version of Effexor XR, caused Plaintiffs and the Class to pay more than they would have paid for extended release venlafaxine capsules, absent this illegal conduct.

381. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding reference listed drug ("RLD") branded counterpart to which they are AB-rated. As a result, upon generic entry, purchases of brand drugs by indirect purchasers are rapidly replaced by purchases of generic versions of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generics. This price competition enables all indirect purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price; and/or (b) purchase the brand name drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

382. If generic competitors had not been unlawfully prevented from entering the market earlier and competing with Wyeth, end payors, such as Plaintiffs and members of the Class, would have paid less for extended release venlafaxine capsules by (a) substituting purchases of less-expensive AB-rated generic versions of Effexor XR for their purchases of more-expensive branded Effexor XR, (b) receiving discounts on their remaining branded Effexor XR purchases, and/or (c) purchasing generic Effexor XR at lower prices sooner.

383. Thus, the unlawful conduct of Defendants, and each of them, deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

384. Defendants' unlawful conduct had substantial and significant intrastate effects in each state, including but not limited to Kansas, Massachusetts, Mississippi, Nevada, New York, Tennessee, and Wisconsin, because, *inter alia*, Effexor XR was sold to consumers and third-party payors at higher prices than would have existed absent the unlawful conduct in each state and Defendants entered into an unlawful agreement which affected commerce in each state.

385. Defendant Wyeth's unlawful conduct also had substantial and significant intrastate affects in California (Anchen and Wockhardt), Florida (Apotex), New York (Intellipharmaceutics), North Carolina (Osmotica and Sandoz) and West Virginia (Mylan) where it brought sham patent infringement lawsuits against one or more generic companies.

VIII. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

386. During the relevant period, Plaintiffs and members of the Indirect Purchaser Class purchased substantial amounts of Effexor XR indirectly from Wyeth and/or purchased substantial amounts of generic Effexor XR indirectly from Teva and/or others. As a result of Defendants' illegal conduct, members of the Indirect Purchaser Class were compelled to pay, and did pay, artificially inflated prices for extended release venlafaxine capsules Those prices were substantially greater than the prices that members of the Indirect Purchaser Class would have paid absent the illegal conduct alleged herein, because: (1) the price of extended release venlafaxine capsules were artificially inflated by Defendants' illegal conduct; (2) Indirect Purchaser Class members were deprived of the opportunity to purchase lower-priced generic versions of extended release venlafaxine capsules sooner; and/or (3) the price of extended release venlafaxine capsules was artificially inflated by Defendants' illegal conduct.

387. As a consequence, Plaintiffs and members of the Indirect Purchaser 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.

388. Wyeth's efforts to monopolize and restrain competition in the market for extended release venlafaxine capsules have substantially affected interstate and foreign commerce.

389. At all material times, Wyeth manufactured, promoted, distributed, and sold substantial amounts of extended release venlafaxine capsules and extended release venlafaxine capsules in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

390. At all material times, Wyeth 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 Effexor XR.

391. In furtherance of their efforts to monopolize and restrain competition in the market for extended release venlafaxine capsules, Wyeth employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Wyeth's activities were within the flow of and have substantially affected interstate commerce.

392. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Hovencamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624. Prof. Hovencamp goes on to state that "Every 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."

393. Wyeth's anticompetitive actions enabled it to indirectly charge consumers and third-party payors prices in excess of what it otherwise would have been able to charge absent its unlawful actions individually and with Teva.

394. Wholesalers and retailers passed on the inflated prices of extended release venlafaxine capsules and generic extended release venlafaxine capsules to the Indirect Purchasers defined herein.

395. These prices were inflated as a direct and foreseeable result of Wyeth's anticompetitive conduct individually and with Teva.

396. The inflated prices the Indirect Purchaser Plaintiffs paid are traceable to, and the foreseeable result, of the overcharges by Wyeth.

IX. CLASS ACTION ALLEGATIONS

397. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a), (b)(2) and (b)(3), as representatives of a Indirect Purchaser Class defined as follows:

> All persons or entities throughout the United States and its territories who purchased and/or paid for Effexor XR or its AB-rated generic versions of Effexor XR for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class"), during the period of June 14, 2008, through and until the date when the effects of the Defendants' unlawful conduct ceases (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Effexor XR or its generic versions if they paid or reimbursed some or all of the purchase price.

398. The following persons or entities are excluded from the proposed class:

(a) Defendants and their respective subsidiaries and affiliates;

(b) all governmental entities (except for government funded employee benefit plans);

(c) all persons or entities who purchased Effexor XR or its generic equivalent for purposes of resale or directly from Defendants or their affiliates;

(d) fully insured health plans *i.e.* Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members;

(e) any "flat co-pay" consumers whose purchases were paid in part by a third party payor and whose co-payment share of the purchase price did not vary between brand-name and generic drug purchases;

(f) any "brand loyalist" consumers or third party payors who purchased Effexor XR and who did not purchase any AB-rated generic version after such generic versions became available;

(g) the judges in this case and any members of their immediate families.

399. Members of the Indirect Purchaser Class are so numerous that joinder is impracticable. Plaintiffs believe that the Class includes hundreds of thousands, if not millions of consumers, and thousands of third-party payors.

400. Plaintiffs' claims are typical of the claims of the members of the Indirect Purchaser Class. Plaintiffs and all members of the Indirect Purchaser Class were damaged by the same wrongful conduct of the Defendants, *i.e.*, they paid artificially inflated prices for extended release venlafaxine capsules and were deprived of earlier and more robust competition from cheaper generic versions of Effexor XR as a result of Defendants' wrongful conduct.

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

402. 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.

403. Questions of law and fact common to the members of the Indirect Purchaser Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Indirect Purchaser Class thereby making overcharge damages with respect to the Indirect Purchaser Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

404. Questions of law and fact common to the Indirect Purchaser Class include:

a. whether Wyeth willfully obtained and/or maintained monopoly power over Effexor XR and its generic equivalents;

b. whether Wyeth improperly listed the method of use patents in the Orange Book;

c. whether Wyeth and Teva unlawfully excluded competitors and potential competitors from the market for Effexor XR and its AB-rated generic bioequivalents;

d. whether Wyeth and Teva entered into an unlawful agreement in restraint of trade;

e. whether Wyeth unlawfully delayed or prevented generic manufacturers from coming to market in the United States;

f. whether Wyeth maintained monopoly power by delaying generic entry;

g. 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;

h. whether Wyeth's activities as alleged herein have substantially affected interstate commerce; and

i. whether, and if so to what extent, Wyeth's conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiff and the members of the Class.

405. 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.

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

COUNT ONE
(Monopolization Under State Law)
(Asserted Against Wyeth)

407. Plaintiffs repeat the allegations contained in the preceding paragraphs as if fully set forth herein.

408. As described above, from October 1997 until at least June 2010, Wyeth possessed monopoly power in the market for extended release venlafaxine capsules. No other manufacturer sold a competing version of extended release venlafaxine, whether branded or generic, before June 2010.

409. Wyeth willfully and unlawfully acquired and maintained its monopoly power in the extended release venlafaxine capsule market from June 2008 through at least June 2010 by engaging in an anticompetitive scheme to keep generic equivalents from the market – not as a result of providing a superior product, business acumen, or historical accident.

410. Wyeth knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of AB-rated generic versions of Effexor XR to maintain their monopoly power. This scheme included:

a. obtaining the ‘171, ‘958, and ‘120 patents by misleading the PTO and failing to exercise the duty of good faith;

b. improperly listing the '171, '958, and '120 patents in the Orange Book;

c. engaging in sham litigation;

d. prolonging the impact of their serial sham litigation through settlement arrangements that further delayed generic entry; and

e. negotiating settlements with subsequent generic applicants to preserve and protect its monopoly and the market-division agreement negotiated with Teva.

411. By means of this scheme, Wyeth intentionally and wrongfully maintained monopoly power with respect to Effexor XR and AB-rated bioequivalents in violation of state monopolization laws. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for their extended release venlafaxine capsules.

412. Plaintiffs and members of the Class have been injured in their business or property by Wyeth's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for extended release venlafaxine capsules than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that antitrust laws were designed to prevent, and flows from that which makes Wyeth's conduct unlawful. Plaintiffs and the Class are the proper entities to bring a case concerning this conduct.

413. Wyeth's anticompetitive conduct is not entitled to qualified *Noerr-Pennington* immunity.

414. Wyeth knowingly and intentionally engaged in sham litigation against manufacturers of AB-rated generic equivalents of Effexor XR. Wyeth repeatedly asserted that the extended release venlafaxine formulations of potential generic competitors infringed its method of use patents, thereby automatically keeping each potential generic competitor off the market for at least 30 months. Wyeth intentionally and deceptively alleged the generic manufactures' products infringed its method of use patents.

415. For each infringement suit, Wyeth knew at the time it filed that it had no realistic likelihood of success; that is, no realistic likelihood that a court would enforce the '171, '958, and '120 patents against a generic company. Wyeth knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a reasonable chance of succeeding on the merits of these infringement lawsuits. Wyeth filed these sham lawsuits for the purposes of using a governmental process (including the automatic 30-month stay of FDA approval) as an anticompetitive weapon to keep generics off the market.

416. Wyeth engaged in serial sham lawsuits as part of a pattern or practice of successive filing undertaken for the purposes of harassment, injuring market rivals, and unreasonably delaying generic entry. Wyeth filed seventeen different lawsuits as of the date hereof, all asserting unenforceable patents, for purposes of harassing generic manufacturers, keeping generics off the market, and preserving its monopoly over Effexor XR and AB-rated bioequivalents. Wyeth settled each lawsuit before a court could find the patents unenforceable and negotiated deals with the generic companies that kept the first generic off the market until June 2010 and the rest off the market until June 2011.

417. Wyeth engaged in distinct *Walker Process* frauds.

418. First, Wyeth obtained method of use claims for extended release venlafaxine by fraudulently claiming clinical data showed Effexor XR reduced the incidence of nausea and vomiting associated with instant release Effexor. Wyeth knew that its clinical data did not show a decreased incidence of nausea. Wyeth knew that this information would be material to the patent examiner. Wyeth intentionally withheld the truth about the clinical data in order to defraud the PTO into issuing patents that included method of use claims for the reduction in the incidence of vomiting.

419. Second, Wyeth obtained method of use claims for extended release venlafaxine by, first, failing to reveal that its own Upton patent disclosed extended release venlafaxine and, later, failing to disclose that a patent examiner had found all method of use claims unpatentable in light of the Upton patent. Wyeth knew that both the Upton patent and the examiner's rejection of the method of use claims in light of the Upton patent would be material to the later patent examiner. Wyeth intentionally withheld the Upton patent and the related examiner's rejection in order to defraud the PTO into issuing patents that included method of use claims.

420. Third, Wyeth fraudulently claimed that an extended release version of Effexor was unexpected, despite knowing the Upton patent and the '589 PCT application previously disclosed extended release versions of Effexor. Wyeth intentionally failed to inform the examiner about the prior disclosures of extended release venlafaxine and further failed to correct its fraudulent representation that an extended release version of venlafaxine was surprising in order to defraud the PTO into issuing patents that pertained to Effexor XR.

421. Fourth, Wyeth obtained patent claims for extended release venlafaxine by misrepresenting that it was "completely unexpected" that an extended release venlafaxine formulation could be obtained despite knowing and failing to disclose to the examiner that it developed the Effexor XR formulation by substituting venlafaxine for propranolol in the extended release formulation for its pre-existing Inderal LA product. Contrary to the representation to the PTO, Wyeth expected this formulation to work because venlafaxine and propranolol have similar solubilities in water and peak blood levels that occur in about six hours.

422. By engaging in the foregoing conduct, Wyeth has violated the following state antitrust laws:

a. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Arizona Revised Stat. §§ 44-1401, *et seq.*, with

respect to purchases of Effexor XR and AB-rated bioequivalents in Arizona by members of the Class.

b. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and Cal. Bus. & Prof. Code §§ 17200, *et seq.* with respect to purchases of Effexor XR and AB-rated bioequivalents in California by members of the Class.

c. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Florida by members of the Class and this conduct constitutes a predicate act under the Florida Unfair Deceptive Trade Practices Act.

d. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Kansas by members of the Class.

e. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Maine by members of the Class.

f. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Massachusetts by members of the Class in that the actions and transactions alleged herein occurred

primarily and substantially within Massachusetts, with thousands of End-payors paying substantially higher prices for Effexor XR and AB-rated bioequivalents.

g. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Michigan by members of the Class.

h. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.* with respect to purchases of Effexor XR and AB-rated bioequivalents in Minnesota by members of the Class.

i. Wyeth has intentionally and wrongfully maintained its monopoly over the relevant market in violation of Miss. Code Ann. §§75-21-1 *et seq.*, in that Wyeth accomplished its monopolistic goals in part through transactions lying wholly within the state, with thousands of Mississippi end-payors paying substantially higher retail prices for Effexor XR and AB-rated bioequivalents at Mississippi pharmacies.

j. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Nev. Rev. Stat. Ann. § 598A., *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Nevada by members of the Class, in that thousands of sales of Effexor XR and AB-rated bioequivalents took place at Nevada pharmacies, purchased by Nevada End-payors at supracompetitive prices caused by Defendants' conduct.

k. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-1 *et seq.*, with respect

to purchases of Effexor XR and AB-rated bioequivalents in New Mexico by members of the Class.

l. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of New York General Business Law § 340, *et seq*., with respect to purchases of Effexor XR and AB-rated bioequivalents in New York by members of the Class, and, to the extent New York law so requires, Plaintiffs hereby forgo any minimum or punitive damages in order to preserve the right of New York Class members to recover by way of a class action.

m. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of N.C. Gen. Stat. §§ 75-1, *et seq*., with respect to purchases of Effexor XR and AB-rated bioequivalents in North Carolina by members of the Class.

n. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of S.D. Codified Laws Ann. § 37-1, *et seq*., with respect to purchases of Effexor XR and AB-rated bioequivalents in South Dakota by members of the Class.

o. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq*., with respect to purchases of Effexor XR and AB-rated bioequivalents in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of End-payors in Tennessee paying substantially higher prices for Effexor XR and AB-rated bioequivalents at Tennessee pharmacies.

p. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Utah Code Ann. §§ 76-10-911, *et seq*., with respect to purchases of Effexor XR and AB-rated bioequivalents in Utah by members of the Class.

q. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in West Virginia by members of the Class.

r. Wyeth has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Wis. Stat. § 133.01, *et seq*., with respect to purchases of Effexor XR and AB-rated bioequivalents in Wisconsin by members of the Class in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of End-payors in Wisconsin paying substantially higher prices for Effexor XR and AB-rated bioequivalents at Wisconsin pharmacies.

423. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. Their injury consists of paying higher prices for extended release venlafaxine than they would have paid in the absence of those violations. This injury is of the type the antitrust and consumer protection laws of the above States and the District of Columbia were designed to prevent and flows from that which makes Defendants' conduct unlawful.

424. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT TWO
(Conspiracy To Monopolize)
(Asserted Against all Defendants)

425. Plaintiffs repeat the allegations contained in the foregoing paragraphs as if fully set forth herein.

426. Beginning in or about 2005, Wyeth and Teva engaged in a continuing illegal conspiracy to monopolize, the purpose and effect of which was to (i) prevent the sale of generic versions of extended release venlafaxine in the United States for a period of about two years, thereby protecting Effexor XR from any generic competition during that time, (ii) allocate all sales of extended release venlafaxine in the United States, (iii) elongate the 6 month Hatch-Waxman exclusivity period for the first generic ANDA filer, (iv) delay the introduction of an authorized generic of extended release of venlafaxine which otherwise would have appeared on the market at a significantly earlier time, and (v) effectively fix the price of which the Plaintiffs and the other members of the Indirect purchaser class would need to pay for venlafaxine.

427. By entering into this unlawful conspiracy, Wyeth has unlawfully conspired to monopolize the market for Effexor XR and AB-rated equivalents. The agreements between Wyeth and Teva are overt acts between separate economic entities, actual or potential competitors, and are illegal *per se* under state antitrust laws. Alternatively, this Complaint alleges that the agreements are a violation of state antitrust laws when viewed under a "quick look" or "rule of reason" mode of analysis.

428. Plaintiffs and all members of the Indirect Purchaser Class have been injured in their business and property by reason of the unlawful contracts, combinations and/or more conspiracies. Plaintiffs and members of Indirect Purchaser Class have paid more on their purchases of extended release venlafaxine then they would otherwise had paid, and/or were

prevented from substituting a less expensive, generic alternative for their purchases of the more expensive Effexor XR and/or Teva's more expensive generic Effexor XR.

429. There was a dangerous probability that Defendants' efforts to monopolize the extended release venlafaxine market would be successful.

430. By engaging in the foregoing conduct, Defendants have violated the following state antitrust laws:.

a. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of Arizona Revised Stat. §§ 44-1401, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Arizona by members of the Class.

b. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and Cal. Bus. & Prof. Code §§ 17200, *et seq.* with respect to purchases of Effexor XR and AB-rated bioequivalents in California by members of the Class.

c. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Florida by members of the Class and this conduct constitutes a predicate act under the Florida Unfair Deceptive Trade Practices Act.

d. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Kansas by members of the Class.

e. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Maine by members of the Class.

f. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Massachusetts by members of the Class, in that the actions and transactions alleged herein occurred primarily and substantially within Massachusetts, with thousands of End-payors paying substantially higher prices for Effexor XR and AB-rated bioequivalents

g. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of Mich. CompLaws Ann. §§ 445.771, *et seq.*, with respect to purchases of Effexor XR and AB-rated in Michigan by members of the Class.

h. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of Minn. Stat. §§ 325D.52, *et seq*. with respect to purchases of Effexor XR and AB-rated bioequivalents in Minnesota by members of the Class.

i. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of the Mississippi antitrust statute, Miss. Code Ann. §§75-21-1 *et seq.*, in that Defendant accomplished its monopolistic goals in part through transactions lying wholly within the state, with thousands of Mississippi End-payors paying substantially higher retail prices for Effexor XR and AB-rated bioequivalents at Mississippi pharmacies.

j. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of Nev. Rev. Stat. Ann. § 598A., *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Nevada by members of the Class, in that thousands of sales of Effexor XR and AB-rated bioequivalents took place at Nevada pharmacies, purchased by Nevada End-payors at supracompetitive prices caused by Defendants' conduct.

k. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of N.M. Stat. Ann. §§ 57-1-1 *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in New Mexico by members of the Class.

l. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of New York General Business Law § 340, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in New York by members of the Class, and, to the extent New York law so requires, Plaintiffs hereby forgo any minimum or punitive damages in order to preserve the right of New York Class members to recover by way of a class action.

m. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in North Carolina by members of the Class.

n. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in South Dakota by members of the Class.

o. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of Tenn. Code Ann. §§ 47-25-101, *et seq*., with respect to purchases of Effexor XR and AB-rated bioequivalents in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of End-payors in Tennessee paying substantially higher prices for Effexor XR and AB-rated bioequivalents at Tennessee pharmacies.

p. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of Utah Code Ann. §§ 76-10-911, *et seq*., with respect to purchases of Effexor XR and AB-rated bioequivalents in Utah by members of the Class.

q. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in West Virginia by members of the Class.

r. Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize in violation of Wis. Stat. § 133.01, *et seq*., with respect to purchases of Effexor XR and AB-rated bioequivalents in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of End-payors in Wisconsin paying substantially higher prices for Effexor XR and AB-rated bioequivalents at Wisconsin pharmacies.

431. As a result of Defendants' illegal conduct, Plaintiffs and the Class paid more than they would have paid for extended release venlafaxine, absent Defendants' illegal conduct. But

for Defendants' illegal conduct, competitors would have begun marketing generic versions of extended release venlafaxine well before June of 2010, and/or would have been able to market such versions more successfully.

432. If manufacturers of generic extended release venlafaxine entered the market and competed with Effexor XR in a full and timely fashion, Plaintiff and other Class members would have substituted lower-priced generic extended release venlafaxine for the higher-priced brand name Effexor XR for some or all of their extended release venlafaxine requirements, and/or would have paid lower prices on some or all of their remaining Effexor XR purchases.

433. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of extended release venlafaxine indirectly from a Defendant. As a result of Defendants' illegal conduct, alleged herein, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their extended release venlafaxine requirements. Plaintiff and the other Class members paid prices for extended release venlafaxine that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic extended release venlafaxine; (2) Class members were forced to pay artificially inflated prices for extended release venlafaxine; and/or (3) the price of extended release venlafaxine was artificially inflated by Defendants' illegal conduct.

COUNT THREE
(Conspiracy and Combination in Restraint of Trade)
(Asserted Against All Defendants)

434. Plaintiffs repeat the allegations contained in the foregoing paragraphs as if fully set forth herein.

435. Beginning in or about 2005, Wyeth and Teva engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade, the purpose and effect of which was

to (i) prevent the sale of generic versions of extended release venlafaxine in the United States for a period of about two years, thereby protecting Effexor XR from any generic competition during that time, (ii) allocate all sales of extended release venlafaxine in the United States, (iii) elongate the 6 month Hatch-Waxman exclusivity period for the first generic ANDA filer, (iv) delay the introduction of an authorized generic of extended release of venlafaxine which otherwise would have appeared on the market at a significantly earlier time, and (v) effectively fix the price of which the Plaintiffs and the other members of the Indirect purchaser class would need to pay for venlafaxine.

436. By entering into this unlawful conspiracy and combination, Wyeth and Teva have unlawfully conspired and combined in restraint of trade. The agreements between Wyeth and Teva are horizontal market allocation and price fixing agreements between actual or potential competitors and are illegal *per se* under state antitrust laws. Alternatively, this Complaint alleges that the agreements are an unreasonable restraint of trade when viewed under a "quick look" or "rule of reason" mode of analysis.

437. Plaintiffs and all members of the Indirect Purchaser Class have been injured in their business and property by reason of the unlawful contracts, combinations and/or more conspiracies. Plaintiffs and members of Indirect Purchaser Class have paid more on their purchases of extended release venlafaxine then they would otherwise had paid, and/or were prevented from substituting a less expensive, generic alternative for their purchases of the more expensive Effexor XR and/or Teva's more expensive generic Effexor XR.

438. By engaging in the foregoing conduct, Defendants have violated the following state antitrust laws:

a. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Arizona Revised Stat. §§ 44-

1401, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Arizona by members of the Class.

b. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and Cal. Bus. & Prof. Code §§ 17200, *et seq.* with respect to purchases of Effexor XR and AB-rated bioequivalents in California by members of the Class.

c. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Florida by members of the Class and this conduct constitutes a predicate act under the Florida Unfair Deceptive Trade Practices Act.

d. Defendants have intentionally and wrongfully 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 Effexor XR and AB-rated bioequivalents in Kansas by members of the Class.

e. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Maine by members of the Class.

f. Defendants have intentionally and wrongfully 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 Effexor XR and AB-rated bioequivalents in Massachusetts by members of the Class in that the actions and transactions

alleged herein occurred primarily and substantially within Massachusetts, with thousands of End-payors paying substantially higher prices for Effexor XR and AB-rated bioequivalents.

g. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mich. CompLaws Ann. §§ 445.771, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Michigan by members of the Class.

h. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.52, *et seq*. with respect to purchases of Effexor XR and AB-rated bioequivalents in Minnesota by members of the Class.

i. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of the Mississippi antitrust statute, Miss. Code Ann. §§75-21-1 *et seq.*, in that Defendant accomplished its monopolistic goals in part through transactions lying wholly within the state, with thousands of Mississippi End-payors paying substantially higher retail prices for Effexor XR and AB-rated bioequivalents at Mississippi pharmacies;

j. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. § 598A., *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in Nevada by members of the Class, in that thousands of sales of Effexor XR and AB-rated bioequivalents took place at Nevada pharmacies, purchased by Nevada End-payors at supracompetitive prices caused by Defendants' conduct.

k. Defendants have intentionally and wrongfully 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 Effexor XR and AB-rated bioequivalents in New Mexico by members of the Class.

l. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of New York General Business Law § 340, *et seq*., with respect to purchases of Effexor XR and AB-rated bioequivalents in New York by members of the Class, and, to the extent New York law so requires, Plaintiffs hereby forgo any minimum or punitive damages in order to preserve the right of New York Class members to recover by way of a class action.

m. Defendants have intentionally and wrongfully 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 Effexor XR and AB-rated bioequivalents in North Carolina by members of the Class.

n. 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, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in South Dakota by members of the Class.

o. 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 of Effexor XR and AB-rated bioequivalents in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of End-payors in

Tennessee paying substantially higher prices for Effexor XR and AB-rated bioequivalents at Tennessee pharmacies.

p. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Utah Code Ann. §§ 76-10-911, *et seq*., with respect to purchases of Effexor XR and AB-rated bioequivalents in Utah by members of the Class.

q. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Effexor XR and AB-rated bioequivalents in West Virginia by members of the Class.

r. 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 Effexor XR and AB-rated bioequivalents in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of End-payors in Wisconsin paying substantially higher prices for Effexor XR and AB-rated bioequivalents at Wisconsin pharmacies.

439. As a result of Defendants' illegal conduct, Plaintiffs and the Class paid more than they would have paid for extended release venlafaxine, absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of extended release venlafaxine well before June of 2010, and/or would have been able to market such versions more successfully.

440. If manufacturers of generic extended release venlafaxine entered the market and competed with Effexor XR in a full and timely fashion, Plaintiff and other Class members would

have substituted lower-priced generic extended release venlafaxine for the higher-priced brand name Effexor XR for some or all of their extended release venlafaxine requirements, and/or would have paid lower prices on some or all of their remaining Effexor XR purchases.

441. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of extended release venlafaxine indirectly from a Defendant. As a result of Defendants' illegal conduct, alleged herein, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their extended release venlafaxine requirements. Plaintiff and the other Class members paid prices for extended release venlafaxine that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic extended release venlafaxine; (2) Class members were forced to pay artificially inflated prices for extended release venlafaxine; and/or (3) the price of extended release venlafaxine was artificially inflated by Defendants' illegal conduct

COUNT FOUR
(Unfair And Deceptive Trade Practices Under State Law)
(Asserted Against All Defendants)

442. Plaintiffs repeat the allegations contained in the foregoing paragraphs as if fully set forth herein.

443. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and class members were deprived of the opportunity to purchase a less expensive AB-rated bioequivalents and forced to pay higher prices.

444. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq*.

445. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq*.

446. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq*.

447. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq*.

448. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq*.

449. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq*.

450. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq*., in that the actions and transactions alleged herein occurred primarily and substantially within Massachusetts, with thousands of End-payors paying substantially higher prices for Effexor XR and AB-rated bioevquivalents;

451. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq*.

452. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, *et seq*.

453. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq*.

454. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq*.

455. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq*.

456. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349 *et seq*.

457. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq*.

458. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq*.

459. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq*.

460. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code § 13-11-1, *et seq*.

461. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et seq*.

462. Plaintiffs and members of the class members have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Count. Their injury consists of paying higher prices for Effexor XR and/or AB-rated generic bioequivalents than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

COUNT FIVE
DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTIONS 1 AND 2 OF THE SHERMAN ACT
(Asserted Against All Defendants)

463. Plaintiffs repeat the allegations contained in the foregoing paragraphs as if fully set forth herein.

464. Wyeth, Teva, and others conspired to monopolize, and conspired and combined together to restrain trade, in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, in the manner described at length in this Complaint.

465. Wyeth intentionally and wrongfully created and maintained a monopoly in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, in the manner described at length in this Complaint.

466. Plaintiffs and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Complaint. Their injury consists of being deprived of the ability to purchase less expensive, generic versions of Effexor XR, and paying higher prices for such products than they would have paid in the absence of the antitrust violations.

467. Although some generic versions of Effexor have entered the market pursuant to licenses, the terms of which have not been publicly revealed, Plaintiffs continue to suffer and will continue suffer in the future from paying higher prices for Effexor XR and/or AB-rated generic versions than there would be if Defendants were not engaging in anticompetitive conduct.

468. In addition, Wyeth continues to insist on the validity of the '171, the '120 and the '958 patents which, as described above, are invalid and were procured by fraud, and shows no signs of ending its long string of patent infringement actions against would-be competitors. As a result, Plaintiffs and the Class continue to be threatened with loss or damage by violation of the anti-trust laws.

469. The injury to Plaintiffs and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct.

470. Plaintiffs and the Class, pursuant to Fed. R. Civ. P. 57 and 18 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.

471. 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 anti-competitive market effects caused by the unlawful conduct of Defendants and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

COUNT SIX
UNJUST ENRICHMENT UNDER STATE LAW
(All Defendants)

472. Plaintiffs repeat the allegations contained in the foregoing paragraphs as if fully set forth herein.

473. Defendants have benefited from the unlawful and inequitable acts alleged in this Complaint.

474. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for extended release venlafaxine by Plaintiffs and members of the Class.

475. Plaintiffs and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the Class.

476. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supra-competitive and artificially inflated prices for extended release venlafaxine is a direct and proximate result of Defendants' unlawful practices.

477. The financial benefits derived by Defendants rightfully belongs to Plaintiffs and the Class, as Plaintiffs and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

478. It would be inequitable under the laws of all states and jurisdictions within the United States for the Defendants to retain any of the overcharges for extended release venlafaxine derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

479. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the Class all unlawful or inequitable proceeds received by them.

480. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and the Class.

481. For those states with an exhaustion of remedies requirement, it would be futile for Plaintiffs to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Effexor XR or its generic equivalent as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Defendants.

482. Plaintiffs and the Class have no adequate remedy at law.

WHEREFORE, Plaintiffs demand judgment for the following relief:

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

B. Declaring that the conduct alleged herein to be in violation of Sections 1 and 2 of the Sherman Act, of the statutes of the States set forth above, and the common law of unjust enrichment under the laws of all states and jurisdictions within the United States;

C. Enjoining Defendants from continuing the illegal activities alleged herein;

D. Granting Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

E. Awarding Plaintiffs and the Class damages as permitted by law, including disgorgement;

F. Awarding the Indirect Purchaser Class damages (including treble or multiple damages where offered by law);

G. Awarding Plaintiffs and the Indirect Purchaser Class their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Granting such other relief as the Court may deem just.

CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.
Chair, Indirect Purchaser Plaintiffs'
Executive Committee

By: /s/ James E. Cecchi
JAMES E. CECCHI

Dated: January 9, 2012

Michael M. Buchman
Adam G. Kurtz
POMERANTZ HAUDEK GROSSMAN &
GROSS LLP
100 Park Avenue, 26th Floor
New York, New York 10017
(212) 661-1100

Richard J. Burke
Jeff A. Leon
COMPLEX LITIGATION GROUP LLC
1010 Market Street, Suite 660
St. Louis, Missouri 63101
(314) 880-7000

James R. Dugan, II
Douglas R. Plymale
David Franco
Kevin Oufnac
DUGAN LAW FIRM, PLC
One Canal Place
365 Canal Street, Suite 1000
New Orleans, LA 70130
(504) 648-0180

Kenneth A. Wexler
Mark R. Miller
Justin N. Boley
WEXLER WALLACE LLP
55 W. Monroe Street, Suite 3300
Chicago, Illinois 60603
(312) 346-2222

Jeffrey L. Kodroff
Theodore M. Lieverman
John Macoretta
SPECTOR, ROSEMAN, KODROFF &
WILLIS, P.C.
1818 Market Street, Suite 2500
Philadelphia, Pennsylvania 19103
(215) 496-0300

Plaintiffs Executive Committee

Lisa J. Rodruguez
Nicole M. Acchione
TRUJILLO RODRIGUEZ
& RICHARDS, LLC
258 Kings Highway East
Haddonfield, New Jersey 08033
(215) 795-9002

Liaison Counsel

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demands trial by jury of all issues so triable.

CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.
Chair, Indirect Purchaser Plaintiffs'
Executive Committee

By: /s/ James E. Cecchi
JAMES E. CECCHI

Dated: January 9, 2012

Michael M. Buchman
Adam G. Kurtz
POMERANTZ HAUDEK GROSSMAN &
GROSS LLP
100 Park Avenue, 26th Floor
New York, New York 10017
(212) 661-1100

Richard J. Burke
Jeff A. Leon
COMPLEX LITIGATION GROUP LLC
1010 Market Street, Suite 660
St. Louis, Missouri 63101
(314) 880-7000

James R. Dugan, II
Douglas R. Plymale
David Franco
Kevin Oufnac
DUGAN LAW FIRM, PLC
One Canal Place
365 Canal Street, Suite 1000
New Orleans, LA 70130
(504) 648-0180

Kenneth A. Wexler
Mark R. Miller
Justin N. Boley
WEXLER WALLACE LLP
55 W. Monroe Street, Suite 3300
Chicago, Illinois 60603
(312) 346-2222

Jeffrey L. Kodroff
Theodore M. Lieverman
John Macoretta
SPECTOR, ROSEMAN, KODROFF &
WILLIS, P.C.
1818 Market Street, Suite 2500
Philadelphia, Pennsylvania 19103
(215) 496-0300

Plaintiffs Executive Committee

Lisa J. Rodruguez
Nicole M. Acchione
TRUJILLO RODRIGUEZ
& RICHARDS, LLC
258 Kings Highway East
Haddonfield, New Jersey 08033
(215) 795-9002

Liaison Counsel