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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re: LIPITOR ANTITRUST LITIGATION	**MDL No. 2332**
THIS DOCUMENT RELATES TO: **All Direct Purchaser Class Actions**	**Master Docket No.: 3:12-cv-2389 (PGS/DEA)** **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT AND JURY DEMAND**

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INTRODUCTION

1. This is a federal antitrust action on behalf of a class of direct purchasers seeking recovery of overcharges arising from the delayed entry of generic versions of the brand name prescription drug Lipitor (atorvastatin calcium).

2. On September 5, 2013, this Court issued a memorandum and order (i) dismissing the claims to the extent based "on anything but the Pfizer/Ranbaxy settlement agreement" (*e.g.*, *Walker Process* and sham citizen petition theories of a prior complaint), (ii) declining to dismiss the claims based on the Pfizer/Ranbaxy agreement (*e.g.*, the reverse payment theory of the prior complaint), and (iii) granting leave to amend. This complaint follows. Solely to preserve the issues for appeal, this complaint re-alleges (in Count III) the prior claims to the extent based on allegations other than "the Pfizer/Ranbaxy settlement agreement."

3. Although the original compound patent for Lipitor provided defendants Pfizer with exclusivity until March 24, 2010, generics were foreclosed from entering the market until November 30, 2011 by the scheme of Defendants Pfizer and its would-be generic competitor defendant Ranbaxy's scheme to delay generic competition. The scheme included (i) entering into, around June of 2008, an anticompetitive and unlawful "reverse payment" patent settlement agreement under which Ranbaxy received a large and unexplained payment from Pfizer in exchange for Ranbaxy's agreement to delay its launch of generic atorvastatin calcium, and (ii) using the Ranbaxy agreement to thwart other generic companies' efforts to enter the market for atorvastatin calcium.

4. The scheme worked as planned. Generic Lipitor was not sold until on or about November 30, 2011, later than it would have been sold absent the defendants' illegal, anticompetitive conduct.

5. The defendants' scheme to delay generic Lipitor competition caused the direct purchasers and the members of the proposed Direct Purchaser Class to pay billions of dollars more for atorvastatin calcium than they would have paid absent such conduct.

A. The Unlawful Ranbaxy Reverse Payment Agreement

6. In or about June of 2008, Pfizer and Ranbaxy entered into a reverse payment agreement (the "Ranbaxy Delay Agreement" or "Agreement"). The Ranbaxy Delay Agreement constituted an unlawful contract, combination and conspiracy to allocate the entire United States market for atorvastatin calcium to Pfizer until November 30, 2011.

7. Under the Agreement, Pfizer gave substantial financial inducements to Ranbaxy to secure the delay of Ranbaxy's generic atorvastatin calcium, including: (a) Pfizer's sweetheart agreement to release claims worth hundreds of millions of dollars in likely damages against Ranbaxy for a pretextual payment of $1 million, claims stemming from Ranbaxy's "at risk" launch of a separate generic product (quinapril hydrochloride) in violation of patents Pfizer held on the drug (sold under the brand name "Accupril"), and (b) the right to market generic Lipitor in at least eleven *foreign* markets. These financial inducements were extraneous to any possible results that Ranbaxy might achieve in any U.S. Lipitor patent disputes that were, or ever could, exist between Ranbaxy and Pfizer.

8. In exchange for the payments by Pfizer, Ranbaxy agreed that it would not: (a) enter the market or compete with Pfizer in the atorvastatin calcium market in the United States until November 30, 2011; (b) relinquish or selectively waive its first-to-file 180-day marketing exclusivity in a manner that would permit any other ANDA filer to market a generic version of Lipitor in the United States before November 30, 2011 (which had the effect of creating a "bottleneck" that blocked FDA approval of later would-be generics); (c) contest the validity of process patents that Pfizer was misusing to delay the efforts of other would-be generic entrants; nor (d) further protest Pfizer's

application for reissuance of an enantiomer patent that had been declared invalid, in part, by the Federal Circuit.

B. The Obstruction of Later Generic Entrants

9. The Ranbaxy Delay Agreement created a regulatory bottleneck which delayed other, would-be generic entrants from entering the market for atorvastatin calcium. The bottleneck forced other generic ANDA filers to seek judicial determinations regarding all patents allegedly covering atorvastatin. Ranbaxy could be forced to launch its generic product or lose its 180-day exclusivity only if other ANDA filers could obtain appellate determination that all such patents were invalid and/or not infringed. If other ANDA filers could have accomplished that, generic Lipitor would have entered the market much earlier than November of 2011.

10. But such court determinations take time and money, and Pfizer used tactics to prevent later ANDA filers from breaking through the bottleneck. Pfizer opposed early court rulings, delayed proceedings, provided covenants not to sue on unasserted Orange Book-listed patents, and ultimately settled lawsuits brought by other ANDA filers to avoid determinations of invalidity and/or non-infringement. Consequently, despite efforts to do so, no ANDA filer was able to circumvent the Ranbaxy Delay Agreement by triggering Ranbaxy's 180-day marketing exclusivity prior to November 30, 2011.

C. The Harm to Direct Purchasers

11. Were it not for the conduct of Pfizer and Ranbaxy, generic Lipitor (atorvastatin calcium) would have been available in the United States earlier than November 30, 2011. Were it not for the defendants' illegal conduct, the direct purchasers and the members of the proposed Direct Purchaser Class would have begun to pay less for their atorvastatin calcium requirements earlier than November 30, 2011. The defendants injured the plaintiffs and members of the proposed Direct

Purchaser Class by causing them to pay substantial overcharges – potentially in the billions of dollars – on their purchases of atorvastatin calcium.

JURISDICTION AND VENUE

12. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover threefold damages, costs of suit and reasonable attorneys' fees for the injuries sustained by the direct purchasers and members of the Direct Purchaser Class resulting from the defendants' unlawfully preventing the entry of generic atorvastatin calcium into the United States market. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

13. The defendants transact business within this district, and they carry out interstate trade and commerce, in substantial part, in this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §1391(b) and (c).

THE PARTIES

14. The plaintiff Stephen L. LaFrance Holdings, Inc. is a corporation organized under the laws of Delaware and located in Pine Bluff, Arkansas. The plaintiff Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors (collectively with Stephen L. LaFrance Holdings, Inc., "SAJ") is a wholly owned subsidiary of Stephen L. LaFrance Holdings, Inc. organized under the laws of Arkansas and located in Pine Bluff, Arkansas. During the class period, McKesson Corp., SAJ's assignor, purchased Lipitor directly from Pfizer and was injured as a result of all of the defendants' unlawful conduct. McKesson Corp. resold, and will continue to resell, some of that Lipitor to SAJ. SAJ is the assignee of the claims of McKesson Corp. to the extent of those direct purchases from Pfizer.

15. The plaintiff Burlington Drug Co., Inc. is a corporation organized under the laws of the State of Vermont and located at 91 Catamount Drive, Milton, Vermont, 05468. During the class period, Burlington Drug Co. purchased Lipitor directly from Pfizer, and purchased generic Lipitor directly from Ranbaxy, and was injured as a result of all of the defendants' unlawful conduct.

16. The plaintiff Value Drug Company is a corporation organized under the laws of the Commonwealth of Pennsylvania and located at One Golf View Drive, Altoona, Pennsylvania 16601. During the class period, Value Drug Company purchased Lipitor directly from Pfizer, and purchased generic Lipitor directly from Ranbaxy, and was injured as a result of all of the defendants' unlawful conduct.

17. The plaintiff Professional Drug Company, Inc. is a corporation organized under the laws of the State of Mississippi with its principal place of business in Biloxi, Mississippi. During the class period, Professional Drug Company, Inc. purchased Lipitor directly from Pfizer, and was injured as a result of all of the defendants' unlawful conduct.

18. The plaintiff Rochester Drug Co-Operative, Inc. ("RDC") is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business located at 50 Jet View Drive, Rochester, New York 14624. During the class period, RDC purchased branded Lipitor directly from Pfizer, and purchased generic Lipitor directly from Ranbaxy, and was injured as a result of all the defendants' unlawful conduct.

19. The plaintiff American Sales Company LLC is a Delaware corporation with its principal place of business located in Lancaster, New York. During the class period, Cardinal Health, Inc., American Sales Company's assignor, purchased Lipitor directly from Pfizer and was injured as a result of all of the defendants' unlawful conduct. Cardinal Health, Inc. resold, and will continue to resell, some of that Lipitor to American Sales Company. American Sales Company is

the assignee of the claims of Cardinal Health, Inc., to the extent of those direct purchases from Pfizer.

20. These six plaintiffs are referred to collectively as the "direct purchasers."

21. The defendant Pfizer, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business at 235 East 42nd Street, New York, New York 10017. At all relevant times, Pfizer, Inc. sold branded Lipitor directly to the direct purchasers and/or their assignors, and to the other members of the Direct Purchaser Class, and engaged in the conduct challenged in this case and attributed to Pfizer, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

22. The defendant Pfizer Manufacturing Ireland, formerly known as Pfizer Ireland Pharmaceuticals, formerly known as Warner Lambert Export, Ltd., is a partnership organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals, a wholly-owned indirect subsidiary of defendant Pfizer, Inc., was the exclusive licensee of the '995 patent and other patents. At all relevant times, defendant Pfizer Manufacturing Ireland engaged in the conduct challenged in this case and attributed to Pfizer, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

23. The defendant Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. In 1997, Warner-Lambert and Pfizer began co-promotion of Lipitor. On June 19, 2000, Pfizer completed its merger with Warner-Lambert whereby Pfizer purchased all outstanding shares of Warner-Lambert common stock. Each share of Warner-Lambert stock was

converted into 2.75 shares of Pfizer common stock. The merger qualified as a tax-free reorganization and was accounted for as a pooling of interests. Warner-Lambert Company became a wholly-owned subsidiary of Pfizer Inc. At the end of 2002, Warner-Lambert Company became a Delaware limited liability company and changed its name to Warner-Lambert Company LLC. Warner-Lambert Company knowingly controlled all activities of the applicant before the PTO in connection with the prosecution of the '995 patent and other patents.

24. Warner-Lambert Company and Warner-Lambert Company LLC are collectively referred to as "Warner-Lambert." "Warner-Lambert" includes, but is not limited to, Warner-Lambert employee Bruce D. Roth.

25. The defendants referenced in the preceding four paragraphs are referred to collectively as "Pfizer."

26. The defendant Ranbaxy, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540.

27. The defendant Ranbaxy Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540.

28. The defendant Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, with a principal place of business located at Plot 90, Sector 32, Gurgaon - 122001 (Haryana), India.

29. At all relevant times, the defendants Ranbaxy, Inc. and Ranbaxy Pharmaceuticals, Inc. acted in their own right and as agents of defendant Ranbaxy Laboratories Limited. The defendants referenced in the preceding three paragraphs are referred to collectively as "Ranbaxy."

30. The term "defendants" refers to all the defendants.

31. All of the defendants' actions described in this complaint are part of, and were in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, or done by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs, within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of defendants.

LEGAL BACKGROUND

A. The regulatory structure for approval of generic drugs and substitution of generics for brand name drugs.

32. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 ("FDCA"), a manufacturer of a new drug must obtain FDA approval to sell a new drug. The manufacturer must file a New Drug Application ("NDA") that includes data showing the drug is safe and effective as well as information about applicable patents.

33. Generic manufacturers may file Abbreviated New Drug Applications, or "ANDAs," that (i) rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, and (ii) show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug (or, in other words, is bioequivalent to the brand name drug). Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

34. After approval of an NDA, the brand manufacturer may list any patents that it 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 patents in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The FDA

relies on the brand name manufacturer for information concerning the validity and applicability of the patents to the brand name drug. The FDA performs a ministerial function only in listing patents in the Orange Book.

35. Patents issued after the FDA approves an NDA may be listed in the Orange Book as related to the NDA if the manufacturer certifies, *inter alia*, that the new patents claim either the approved drug (for compound patents) or approved methods of using the new drug (for method-of-use patents). The NDA holder must list any new patents within 30 days of issuance. 21 U.S.C. §§ 355 (b)(1) & (c)(2). Process patents, by contrast, are ineligible for Orange Book listing.

36. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. An ANDA must contain one of four certifications. A "Paragraph IV" certification must state "that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product."

37. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer may delay final FDA approval of the ANDA merely by suing the generic manufacturer for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of 30 months (two-and-a-half years), 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" while the 30-month stay is pending but cannot authorize the generic manufacturer to go to market.

38. As an incentive to spur generic companies to provide less expensive alternatives to branded drugs, the first generic manufacturer to file a substantially complete ANDA containing a

Paragraph IV certification gets a 180-day period of protection from competition with other ANDA filers.[1]

39. The statutory rules in effect for ANDAs filed (and Paragraph IV certifications submitted) before December of 2003 created an opportunity for branded drug companies and first-filed ANDA applicants to collude to delay generic drug competition. Because the running of the first-filer's 180-day exclusivity is not triggered except after (a) the first-filer commercially markets its product, or (b) an appellate court determination that all Orange Book-listed patents for the branded drug are invalid or not infringed, the first-filer can, in concert with the branded drug company, create a "bottleneck" which keeps later-filed ANDA applicants from entering the market simply by deferring commercial launch of (or "parking") its product. The FTC has observed this potential and the anticompetitive effects that can result. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration, An FTC Study, at vi-xi (FTC July 2002).

40. Absent a payment from the branded company, it is generally not in a first-filed ANDA applicant's unilateral economic interests to park its 180-day exclusivity and delay the return on its investment in connection with the filing of its ANDA.

41. By contrast, brand name manufacturers have large financial incentives to (a) delay the first-filer from triggering its 180-day exclusivity and (b) impede subsequent ANDA filers from obtaining a court decision that all Orange Book-listed patents are invalid and or non-infringed, in order to delay generic entry.

[1] However, the brand name manufacture or its licensee may sell an "authorized generic" during the first-filer's exclusivity period.

B. The benefits of generic drugs.

42. Once the generic ANDA filer demonstrates therapeutic equivalence (*i.e.*, the generic drug delivers the same amount of active ingredient as the brand) and pharmaceutical equivalence (*i.e.,* the generic comes in the same dosage form, milligram strength and route of administration) to the corresponding branded drug, the FDA assigns an "AB" rating to the generic drug, permitting it to be sold and also substituted for the brand name drug at the pharmacy counter. Typically, AB-rated generics (referred to here as "generics") are priced significantly below their branded counterparts. Upon the entry of additional generics, drug prices generally fall even more. A recent study by the FTC found that on average, generics capture 90% of a brand's prescriptions within a year, and generic prices are 85% below the pre-generic brand price. *See* Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (January 2010), p. 8.

43. Generic competition enables purchasers to (a) purchase generic versions of the brand name drug at a substantially lower price than the brand name price, and (b) purchase the brand name drug at a reduced net price. Generic competition to a single branded drug product can result in billions of dollars in savings to consumers, direct purchasers, insurers, and all drug purchasers.

44. All states permit (and some states require) pharmacists to automatically substitute a generic drug for the corresponding brand name drug unless the doctor has stated that the prescription for the brand name product must be dispensed as written. Until a generic manufacturer enters the market, no such substitution can occur and therefore, the brand name manufacturer can charge supra-competitive prices profitably without material loss of sales volume. Consequently, brand name drug manufacturers have a strong interest in seeking to delay the introduction of generic competition into the market.

45. Many third-party payers (such as health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded

counterparts. Many consumers routinely switch from a branded drug to an AB-rated generic drug once the generic becomes available. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterparts' sales, causing a significant reduction of the branded drug's unit and dollar sales.

FACTS

A. A primer on statins.

46. Lipitor belongs to a class of drugs called statins. Discovered in the 1970s, statins lower cholesterol by inhibiting the liver enzyme 3-hydroxy 3-methylglutrayl-coenzyme A reductase ("HMG-CoA reductase"). HMG-CoA reductase controls the rate of the metabolic production of cholesterol; inhibiting HMG-CoA reductase inhibits the production of cholesterol. Common thinking is that high cholesterol is associated with coronary heart disease and atherosclerosis in some populations.

47. Efforts to reduce cholesterol levels are a lucrative business: by 1997, five of the largest pharmaceutical companies marketed and sold six different brand name statins. In 2002, almost one in ten Americans aged 20 and older took a statin. In 2004, sales of statins topped $15.5 billion, comprising 6.6% of all prescription drug sales.

48. Branded statins cost between $2.50 and $5.00 for a single daily pill ($75 to $150 a month, $900-$1,800 a year); generic statins cost markedly less, sometimes less than $1 a day.

B. 1986-1987: Warner-Lambert obtains the original Lipitor patent, the '893 patent.

49. On May 30, 1986, Warner-Lambert filed a patent application for a group of compounds and pharmaceutical compositions useful as hypercholesterolemic and hypolipidemic

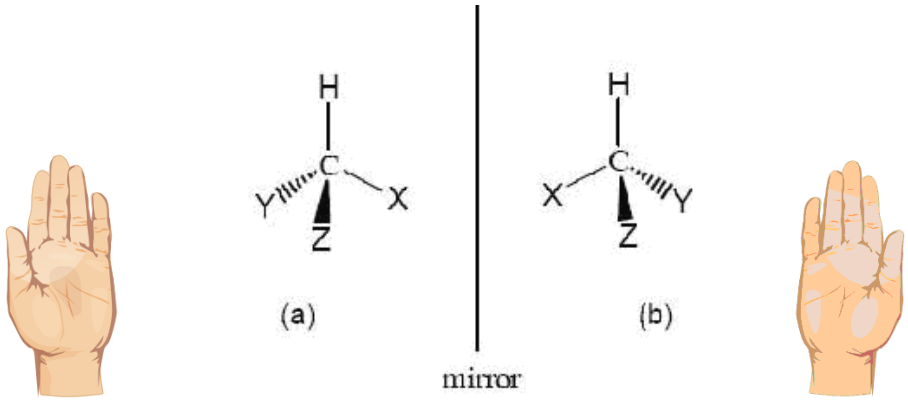
agents.[2] The patent application was entitled "*Trans-6-[2-(3- or 4-Carboxamido-Subsituted Pyrrol-1-yl)alkyl]-4-Hydroproxypyran-2-one Inhibitors Of Cholesterol Synthesis.*"

50. This application would eventually lead to the issuance of the basic compound patent for Lipitor, U.S. patent 4,681,893 (the "'893 patent").

51. To understand how the '893 patent covered compounds which included the isolated "R-trans enantiomer," and that it included the R-trans enantiomer in calcium form, some background of the chemistry of enantiomers is helpful.

52. *Enantiomers* are isomers that are mirror images of each other but cannot be superimposed. For example, a person's left hand and right hand are non-superimposable mirror images of each other. Images (a) and (b) in Figure 1 below are enantiomers (where the carbon atom is the chiral center around which a compound's structure is built).

Figure 1: Example of Pair of Enantiomers



53. Pairs of enantiomers share many chemical and physical properties, such as identical melting points, solubility, and colors. Other properties, such as biological properties, may differ.

[2] The application was in the name of Bruce D. Roth. Roth was, at all relevant times, a leader of the drug discovery team at Warner-Lambert that developed Lipitor. He is the named inventor of Patent Nos. 4,681,893 and 5,273,995; the patent applicant for Patent Nos. 4,681,893 and 5,273,995; and the patent applicant in connection with the re-issuance proceedings for Patent No. 5,273,995. Patent Nos. 4,681,893 and 5,273,995 issued to Roth and were assigned to his employer, Warner-Lambert. Roth is not individually named as a defendant in this action.

54. Enantiomers can be distinguished from one another by their effect on the rotation of polarized light, and are said to be *optically active*. Enantiomers reflect polarized light in either a clockwise direction (right, denoted "+") or a counter-clockwise direction (left, denoted "-"). When equal mixtures of two opposite enantiomers are present, called a *racemic mixture* or *racemate*, the mixture is not optically active because the optical rotations of the enantiomers cancel each other.

55. Consistent with this conventional thinking, Warner-Lambert's application for the '893 patent contemplated the trans-form of compounds in structural formula I, *i.e.*, racemic or enantiomeric forms of structural formula I. Furthermore, the application contemplated atorvastatin in a variety of formulations, including calcium salts.

56. On July 21, 1987, the United States Patent and Trademark Office ("PTO") issued the '893 original Lipitor patent. The '893 patent was assigned to Warner-Lambert. In the absence of an extension, the original Lipitor patent would have expired on May 30, 2006, twenty years from the date of the first application. The application of patent extensions and regulatory exclusivities lengthened the period of protection until March 24, 2010. (The extensions are discussed later.)

57. The '893 patent envisaged the ability to have just the R-trans or S-trans enantiomers of compounds of structural formula I. The '893 patent also recognized that these compounds could be in acid or salt form. While the '893 patent covered multiple formulations of compounds having structural formula I, Warner-Lambert focused on developing and commercializing the R-trans enantiomer of structural formula I in calcium salt form, which it called "atorvastatin." The '893 patent thus covered atorvastatin.

C. 1989-1993: Warner-Lambert obtains a follow-on enantiomer patent, the '995 patent.

58. In April of 1989, Warner-Lambert internally designated atorvastatin as a "lead compound" for further investigation. At this time, Warner-Lambert knew that the '893 patent covered atorvastatin, and that it would provide Warner-Lambert with many years of patent

protection and many years of exclusive sales of atorvastatin (later called Lipitor). Nevertheless, Warner-Lambert sought to extend *even further* the period for exclusive sales for its new statin.

59. In doing so, Warner-Lambert faced certain legal hurdles. Warner-Lambert knew that the R-trans enantiomer was the active enantiomer responsible for atorvastatin's ability to inhibit cholesterol. Warner-Lambert also knew the PTO would likely reject an application to patent an enantiomer covered by the '893 patent; after all, such an "invention" would be either anticipated by (that is, already covered by) the '893 patent, or be obvious in light of the '893 patent.

60. Anticipating an obviousness rejection, senior management at Warner-Lambert instructed the Warner-Lambert researchers to review the *pre-existing* biological data for the R-trans enantiomer to find data that supported both (i) a claim that the activity of the isolated R-trans enantiomer was surprising and (ii) the patentability of the isolated R-trans enantiomer. The researchers ignored internal memos reporting an expected two-fold increase for the R-trans enantiomer, instead electing to cobble together data points from a variety of flawed tests in order to support a (false) claim that the R-trans enantiomer supposedly showed *ten* times more activity.

61. Warner-Lambert presented this amalgamation of data to the PTO as support for the purportedly "surprising" and "unexpected" discovery of a tenfold increase in activity. At no time did Warner-Lambert disclose the mish-mash of data that purported to support that assertion.

62. Moreover, some of the data Warner-Lambert ultimately submitted to the PTO contained significant errors, including a data submission that was represented as complete and statistically significant but was in fact the partial results of a single selected test so methodologically flawed (*e.g.*, the drug wasn't even dissolved into a solution before testing as would be mandatory in any completed protocol) that no reasonable chemist would have relied on it to support the claimed ten-fold increase in activity. (After the issuance of the '995 patent, Pfizer acknowledged that the

data submission contained significant errors and informed the PTO that it was no longer relying on such data. *See infra* at ¶¶101-106.)

63. Nevertheless, on December 28, 1993, the R-trans enantiomer patent, U.S. patent 5,273,995 (the "'995 patent") issued.

64. The misconduct regarding the '995 patent has been detailed in the prior complaints filed in these actions. Apart from Count III that appears later for purposes of appeal, this complaint does not allege *Walker Process* fraud.[3] However, we briefly summarize these facts because the strengths and weaknesses of the parties' patent positions are relevant to understanding the circumstances under which Pfizer and Ranbaxy entered into the Ranbaxy Delay Agreement in 2008.

D. The '893 original Lipitor patent protected the Lipitor franchise for years.

65. Following issuance of the patents, under 21 U.S.C. § 355, Warner-Lambert listed both the '893 patent and the '995 patent in the FDA Orange Book. At the time of the FDA's approval of Lipitor in 1996, the '893 patent was scheduled to expire on May 30, 2006. The '995 patent, by contrast, was scheduled to expire on December 28, 2010.

66. Shortly after FDA approval**,** Warner-Lambert sought a patent term extension for the '893 patent under 35 U.S.C. § 156 to account for the time lag between the issuance of the patent and FDA approval.

67. Warner-Lambert's application informed the PTO that (i) the FDA had approved Lipitor, (ii) the active ingredient in Lipitor was atorvastatin calcium, and (iii) atorvastatin calcium is covered by the '893 patent. Warner-Lambert claimed that the '893 patent claimed atorvastatin calcium as a new chemical entity (Claims 1-4), as a pharmaceutical composition (Claim 8), and as a

[3] For appellate purposes, plaintiffs rely upon the factual allegations set forth in the Consolidated Class Action Complaint, detailing Warner-Lambert's fraud, filed as Doc. No. 435-3 and attached hereto as Exhibit A.

method to inhibit cholesterol biosynthesis (Claim 9). As a result, the PTO extended the term of the '893 patent term until September 24, 2009.

68. Thereafter, Warner-Lambert sought and obtained six additional months of marketing exclusivity from the FDA for pediatric testing. All exclusivities applicable to the '893 patent expired on March 24, 2010.

69. Warner-Lambert also obtained six months of pediatric exclusivity for the '995 patent. As a result, all exclusivities applicable to the '995 patent expired on June 28, 2011.

70. In total, the '893 patent provided more than thirteen years of exclusivity to market and sell branded Lipitor – from the 1997 launch until March of 2010. The '995 patent, if reissued, could tack on another 15 months of protection from generic Lipitor competition.

E. After launch, Warner-Lambert and Pfizer obtained and listed additional patents.

71. Subsequent to the 1997 launch of Lipitor, Warner-Lambert (and later Pfizer) procured additional patents covering particular (and narrow) processes or formulations ostensibly relating to versions of atorvastatin calcium.

72. First, in November of 1997, Warner-Lambert procured U.S. Patent No. 5,686,104 (the "'104 patent," expiry January 19, 2013), and in October of 2000 procured U.S. Patent No. 6,126,971 (the "'971 patent," expiry November 11, 2014). Both the '104 and '971 patents cover particular ways of formulating atorvastatin calcium with various excipients to stabilize the finished pharmaceutical product. These two patents are referred to as the "Unasserted Stabilization Formulation Patents;" "unasserted" because despite later efforts by generic companies to enter the market, Pfizer never asserted these two patents against any of them; "stabilization" because the composition mentioned in the patents contemplates a particular way of achieving stabilization in the final product; and "formulation" because the two patents only cover two narrow formulations of atorvastatin calcium products.

73. Second, in October of 1999, Warner-Lambert procured U.S. Patent No. 5,969,156 (the "'156 patent," expiry July 8, 2016). Generally speaking, the '156 patent covers crystalline atorvastatin calcium (not amorphous).

74. Third, in July 2000, Warner-Lambert procured U.S. Patent No. 6,274,740 (the "'740 patent," expiry July 16, 2016). In August of 2001, Warner-Lambert acquired U.S. Patent No. 6,087,511 (the "'511 patent," expiry July 16, 2016). Both the '740 and '511 patents are process patents, which claim a specific process for making amorphous atorvastatin calcium using crystalline Form I atorvastatin as a starting material. These two patents are called the "Process Patents."

75. Pfizer listed the Unasserted Stabilization Formulation Patents and the '156 patent in the FDA Orange Book as covering Lipitor. As a practical matter, however, Pfizer knew that would-be generic makers could design-around these narrow patents. The Process Patents were not listed in the Orange Book, because patents for a particular process to make a drug are ineligible to be listed there.

F. 2003: Pfizer files litigation against Ranbaxy based on the '893 and '995 patents.

76. Ranbaxy was the first to file an ANDA for generic Lipitor with a Paragraph IV certification. On August 19, 2002, Ranbaxy filed ANDA 76-477, seeking approval to sell a generic version of Lipitor in the 10 mg, 20 mg, 40 mg, and 80 mg tablet strengths.

77. As the first to file a substantially complete ANDA for generic atorvastatin calcium, Ranbaxy was entitled to 180 days of marketing exclusivity under the then-effective provisions of the FDCA. No other ANDA applicant for generic Lipitor could receive FDA approval until the expiration of Ranbaxy's period of marketing exclusivity, which would not commence running until the earlier of either the inception of Ranbaxy's actual commercial marketing or a non-appealable court decision finding all patents listed for Lipitor in the Orange Book invalid or not infringed.

78. Beginning in late 2002, Ranbaxy sent four Paragraph IV certifications to Pfizer with respect to all patents listed in the FDA Orange Book (*i.e.*, the '893, '995, '156, '971 and '104 patents). In its Paragraph IV certification, Ranbaxy asserted that no valid patent claims covering Lipitor would be infringed by the sale, marketing, or use of Ranbaxy's ANDA product.

79. In response, Pfizer filed an action in the United States District Court for the District of Delaware, alleging that Ranbaxy's ANDA product would infringe the '893 and '995 patents (the "*Ranbaxy* litigation"). Pfizer did not allege infringement of the Unasserted Stabilization Formulation Patents nor the '156 patent. By operation of Hatch-Waxman, Pfizer's filing suit within 45 days automatically blocked approval of Ranbaxy's ANDA for up to 30 months.

80. From 2003 to 2006, Pfizer's infringement litigation against Ranbaxy based upon the '893 and '995 patents progressed through discovery, a trial (in 2004), a district court decision (in 2005), and an eventual appeal and decision by the United States Court of Appeals for the Federal Circuit (in 2006).

G. 2003-2006: The District and Federal Circuit Court Rulings on the '893 and '995 Patents.

81. Two features of the district court *Ranbaxy* proceedings are noted here.

82. First, in pre-trial proceedings Pfizer attempted to amend its complaint to add new patent infringement claims based on the '511 and '470 Process Patents. However, process patents may not be listed in the FDA Orange Book and, therefore, could not serve as a basis for Pfizer's infringement action against Ranbaxy under Hatch-Waxman. Accordingly, the district court denied Pfizer's motion because claims under these two Process Patents would be "premature."

83. Second, while the issues regarding Warner-Lambert's inequitable misconduct were hotly contested, they were also buried during the *Ranbaxy* trial with numerous other challenges raised by Ranbaxy against both the '995 and the '893 patents.

84. Eventually, the district court, after trial, ruled that Warner-Lambert's PTO submissions regarding the alleged ten-fold biologic power of the R-trans enantiomer over the racemate were not made with intent to deceive. The district court rejected all challenges to the validity and enforceability of both the '893 and the '995 patents.

85. Ranbaxy challenged both rulings on multiple bases in an appeal to the Federal Circuit.

86. On November 2, 2006, the Federal Circuit affirmed the ruling that the '893 patent was valid and would be infringed by Ranbaxy's product. However, the Federal Circuit reversed the district court's ruling regarding the validity of the '995 patent, determining that claim 6 – the only claim that Pfizer alleged was infringed by Ranbaxy's ANDA product – was invalid under 35 U.S.C. § 112, ¶4 for improper dependent claim structure.[4] Because this ruling rendered moot the need to address other challenges to the '995 patent, the Federal Circuit declined to address Ranbaxy's challenge to the district court's rulings relating to unenforceability for inequitable misconduct relating to Pfizer's submission of erroneous enantiomer data to the PTO. Ranbaxy thereby retained the ability to make this challenge again should the need arise.

87. Based upon the Federal Circuit's mandate in late 2006, the district court amended its final judgment order to enjoin the effective date of any approval of Ranbaxy's ANDA for generic Lipitor until March 24, 2010 (when exclusivity applicable to the '893 patent expired) and to remove from its final judgment order any prohibition of effective FDA approval of Ranbaxy's ANDA based on the '995 patent. The district court's final judgment order, as amended, was sent to FDA.

[4] The Federal Circuit ruled that as a dependent claim, Claim 6 ostensibly narrowed Claim 2 by claiming "the hemi-calcium salt of the compound of Claim 2." However, Claim 2 itself was a dependent claim limited only to atorvastatin acid and did not include salts. Thus, Claim 2 and Claim 6 dealt with "non-overlapping subject matter," and the claims had been improperly constructed. As a result, the 2006 Federal Circuit ruling held Claim 6 invalid.

88. In summary, after the entry of final judgment in the *Ranbaxy* litigation in late 2006, (i) Ranbaxy would need to await until expiry of all exclusivities applicable to the '893 patent in March of 2010 before launching its generic atorvastatin calcium, (ii) there was *no '995 patent* blocking Ranbaxy as it had been declared invalid after a final judgment, and thus there was no preclusive effect from it, and (iii) if the issue arose, Ranbaxy could still contest enforceability of the '995 patent based on an attack that Warner-Lambert's submission erroneously purported to show surprising effects of the atorvastatin enantiomer over its racemate.

H. 2005: Pfizer files a "citizen petition" with FDA to hinder ANDA approvals

89. Pfizer also sought to use a citizen petition to delay generic atorvastatin.

90. During the 30-month period from early 2003 until about August of 2005, the *Ranbaxy* litigation had stayed final FDA approval of Ranbaxy's generic Lipitor ANDA.

91. As August of 2005 approached, Ranbaxy's ANDA was the only pending ANDA on file for generic Lipitor. Pfizer knew that after the end of the 30-month stay (in August 2005), FDA could issue final approval for Ranbaxy's generic Lipitor ANDA, which in turn would permit generic Lipitor competition to begin. Pfizer also knew that as a matter of procedure and practice, FDA did not issue tentative approvals to ANDA filers after an applicable 30-month stay had expired; it issued final approvals only. So once the 30-month stay against Ranbaxy's ANDA had expired in August 2005, Pfizer would have no warning of when the ANDA approval might occur.

92. Pfizer wanted to delay such final approval for as long as it could.

93. As a result, beginning in July of 2005, Pfizer sent a series of communications, including a "citizen petition," to FDA. Pfizer's letters and citizen petition were sent not for a proper purpose but as an attempt to slow down the FDA approval process for Ranbaxy's ANDA.

94. Pfizer's July 2005 letter to the FDA, entitled "Generic Versions of Atorvastatin," stated that Pfizer was "concerned" that ANDA applicants for generic Lipitor were using amorphous

atorvastatin calcium, which, Pfizer claimed, "may be susceptible to higher levels of impurities than are found in Lipitor and that may degrade more quickly and thus have inferior stability compared to Lipitor." Pfizer said that this "may raise questions about the approval of" ANDAs for generic Lipitor. Pfizer asked FDA to "carefully scrutinize" such "potential differences in quality . . . before the atorvastatin variants are approved under ANDAs." Pfizer said that "the risk of reduced quality in the generic product," due to the use of amorphous atorvastatin, was "clear," and that Ranbaxy's ANDA should be "reviewed with considerable skepticism." On November 7, 2005, Pfizer re-filed the July 2005 letter as a citizen petition.

95. In making these arguments to the FDA, Pfizer ignored more than a decade of FDA policy, the FDA's 2002 rejection of a similar argument in relation to the drug Ceftin, subsequent FDA pronouncements reinforcing that the polymorphic form of the drug (*i.e.,* crystalline versus amorphous) was immaterial to ANDA approval, and Pfizer's own clinical studies using amorphous atorvastatin to support the safety and efficacy of Lipitor.

96. Pfizer submitted no evidence to the FDA demonstrating that Ranbaxy's ANDA product, because it used amorphous atorvastatin calcium as the drug substance (i) would not be pharmaceutically equivalent or bioequivalent to branded Lipitor, (ii) would not demonstrate satisfaction of the conditions for approval under the FDCA, or (iii) would not be capable of being processed or manufactured under current good manufacturing practices ("cGMP").

97. Pfizer's citizen petition, which was ultimately denied on November 30, 2011, was still pending at the time Pfizer and Ranbaxy entered the Ranbaxy Delay Agreement in June 2008. The FDA has a practice of not finalizing a response to a citizen petition relating to bioequivalence of a drug product unless approval of an ANDA relating to that drug is otherwise imminent. Therefore,

if the Ranbaxy Delay Agreement had not been reached, the FDA, under its practices and procedures, would have denied the citizen petition earlier, when Ranbaxy's ANDA was otherwise approvable.

I. 2007-2008: Pfizer begins reissuance proceedings for the enantiomer patent.

98. In January 2007, and in the wake of the 2006 Federal Circuit ruling tossing the vital Claim 6 of the '995 patent, Pfizer sought reissuance of the enantiomer patent to, in Pfizer's words, "correct a technical defect in some of the patent claims." In so doing, Pfizer sought to limit the PTO's review to a determination of whether the newly proposed re-wording of the claims (to correctly construct dependent or independent claims) would satisfy 35 U.S.C. § 112, ¶4.

99. While at the outset Pfizer sought only to correct what it termed a technical defect, it knew that huge problems lurked behind the scenes for a re-issuance effort. The PTO or others might raise the far more substantive problem that an enantiomer patent was simply an obvious extension of the original '893 patent (and that the data to support a finding of surprising or unexpected activity of the enantiomer was false). By this time (early 2007), the enantiomer patent and its nearly identical foreign counterparts had been the subject of considerable litigation, not only in the *Ranbaxy* litigation (where the ruling regarding the enantiomer patent had not seen appellate scrutiny), but also in other countries throughout the world. Through these foreign proceedings, Pfizer learned it could no longer get away with relying upon the erroneous and false biological data to support a claim that the R-trans enantiomer of atorvastatin was ten times more active than racemic atorvastatin (or indeed that it was anything other than the expected double strength). As a result, Pfizer told the PTO that it had learned that the 1989-1993 biological data contained "significant errors," and was withdrawing reference to such data as a basis to reissue the '995 patent.

1. The re-issuance proceeding show that the biologic data could not support a basis to issue the '995 patent.

100. On January 16, 2007, Roth and Pfizer submitted the '995 reissue application. The applicants did not amend or modify the '995 patent specification as part of the reissue proceedings. Roth's remarks include a list of the "objective evidence" that "completely refutes any suggestion of obviousness." But now, the list did *not* include the purported surprising effectiveness of the R-trans enantiomer or a purported ten times greater activity of the R-trans enantiomer over the racemate.

101. An Informational Disclosure Statement of the same date states:

> Subsequent to the Federal Circuit's decision, while preparing for trial in Australia on a '995 counterpart, Pfizer first learned of *significant errors* in the COR results which neither Pfizer nor the parties adverse to it had discovered before. This discovery led Pfizer to advise the Federal Circuit that COR data could not be relied on to compare the relative activity of compounds — see Exhibit 9, page 10, fn 2. Thus *any earlier reference in Pfizer's findings, conclusions and brief to relative activity among compounds based on the COR test is withdrawn and is not relied on in these reissue proceedings. Pfizer does not at this point in the reissue rely for patentability on any comparisons based on CSI.* Neither CSI nor COR data were relied on by either U.S. court in reaching their decisions regarding the validity of '995 claim 6.

Elsewhere, Pfizer states "Pfizer does not now rely on any …data [comparing between and among calcium salts and other salts of atorvastatin and its racemates] in support of patentability."

102. In May 2007, Ranbaxy filed a protest with the PTO against Pfizer's reissue application. Ranbaxy would continue protesting for about another year until, pursuant to a comprehensive agreement to be discussed below (the Ranbaxy Delay Agreement), its silence was bought off.

103. On June 7, 2007, as part of the enantiomer reissue proceedings, Pfizer submitted a Second Informational Disclosure Statement that discusses "Foreign Proceedings on '995 Counterparts" and attached additional materials produced as part of certain non-U.S. proceedings.

Pfizer acknowledged that the biological data submitted in support of its patent applications — in the CSI Table, the Roth Declaration, and the foreign " '995 counterparts" — is inaccurate:

> [A]pplicant is submitting these documents to permit the Examiner to consider their potential materiality. Further, many of these documents … contain biological data or summaries of biological data, and *some of that biological data is now understood to be inaccurate* (due to transcription errors, calculation errors, experimental errors, etc.).

104. Elsewhere in the reissue proceedings, Pfizer referred to the biological data at issue in the Australian and Canadian patent litigation as "biologic data that Pfizer *then* argued showed that the atorvastatin enantiomer had unexpected and surprising inhibition of cholesterol biosynthesis in-vitro in comparison to the racemic form of atorvastatin," while reiterating that they *"are not relying on any of the biological data as a basis for the patentability of the pending claims at the present time."* Similarly, Roth and Pfizer stated, "[a]pplicant is not submitting *corrected* biological data at the present time because, as applicant has emphasized repeatedly in these reissue proceedings, applicant is not currently relying on the biological data for patentability."

105. At one point in the reissue proceedings, the examiner, seeing Roth's prior (mis)representations in the PTO record, relied on the biological data to overcome an obviousness rejection:

> Claims 6, 13 and 14 have not been rejected as being obvious as the declaration of Bruce D. Roth filed February 25, 1991 discloses unexpected properties which would overcome any 35 USC 103(a) rejection of claims 6, 13 and 14 as atorvastatin calcium was shown to have activity greater than fifty-fold more than that of the S-trans and at least ten-fold more than that of the racemate.

106. Pfizer knew it could no longer allow the PTO to use its erroneous biological data. As a result, it "reiterated [to the PTO] that they are not presently relying on any of the biological data (including the data contained in the Roth declaration) as support for the patentability of claims 6, 13 and 14." Pfizer stated:

> Although applicant believes that the evidence provided in the Roth Declaration is sound, and is in no way disclaiming this data, it does not believe that it is necessary to consider such evidence in view of the present record … applicant respectfully requests that the Examiner withdraw her reliance on the data in the Roth Declaration and focus instead on the overwhelming evidence of secondary considerations that are discussed above….

The referenced secondary considerations include the argument based on Lipitor's subsequent commercial success.

107. In August 2007, the PTO issued a First Office Action rejecting Pfizer's reissue application on grounds set forth in Ranbaxy's May 2007 protest — that certain claims in the '995 patent were anticipated, obvious, or constituted double-patenting.

108. On April 24, 2008, the PTO issued a non-final *rejection* of claims 6, 13, and 14. In so doing, the examiner stated, "[a]s the data contained in the Roth declaration has not been relied on by Applicant in the instant reissue and is not a comparison of the claimed subject matter (atorvastatin calcium) to the closest prior art, the examiner withdraws the reliance on the data in the Roth Declaration to overcome an obviousness rejection of reissue claims 6, 13 and 14."

2. Pfizer Faced the Real Risk that its Application to Reissue the '995 Patent Would Be Denied.

109. As Pfizer could no longer rely on the erroneous data that was submitted in connection with the '995 patent application, Pfizer faced the real risk that its application to reissue the '995 patent would be denied.

110. Pfizer's arguments for reissuance were extremely weak. Instead of addressing the pertinent question of whether the '995 R-trans enantiomer patent was obvious given the coverage for atorvastatin already in the original '893 compound patent – *i.e.* whether the enantiomer has some surprising and unexpected attributes beyond those of the racemic compound – Pfizer's reissue application repeatedly characterized the question before the PTO as whether "Lipitor" had

experienced commercial success warranting, as a secondary consideration, a conclusion that it was non-obvious. Pfizer's 2007 reissue application and its later support read more like promotional pieces to sell the PTO on Lipitor's marketing success, rather than support for Pfizer's position on the actual issues to be decided by the PTO.

111. The argument of looking generally at "Lipitor" (rather than distinguishing attributes of the enantiomer that were allegedly surprising and unexpected) was flawed because Lipitor was protected by the '893 patent from the initial launch of Lipitor through all of the re-issue proceedings. Thus, any showing of success of Lipitor generally would not in any way elucidate why the '995 patent (which *also* covered Lipitor) was not obvious over the original '893 compound patent.

112. Indeed, Warner-Lambert, and later Pfizer, repeatedly identified the '893 patent as the patent which would provide protection for Lipitor. Warner-Lambert listed the '893 patent in the Orange Book, thus forcing generic companies to serve a Paragraph IV certification if they wished to launch a generic before expiry of the '893 patent. Shortly after Lipitor was approved by the FDA in late 1996, Warner-Lambert sought, and obtained, a patent term extension on the '893 patent (not the '995 patent) to make up for years that it took to study Lipitor. And Pfizer later brought infringement cases against generic companies arguing that their proposed Lipitor products allegedly would infringe the '893 patent.

113. Put simply, from late 1996 to 2009, Pfizer's commercialization of Lipitor was actively protected by the original '893 Lipitor compound patent. The '995 patent, if valid, simply extended that period of time, *i.e.*, both patents covered the commercialized R-trans enantiomer calcium salt formulation. Thus, any arguments raised with the PTO at any time regarding the

commercial success of "Lipitor" could not, as a matter of fact or law, elucidate in any way whatsoever whether or not the '995 patent was non-obvious over the '893 patent.[5]

114. Outside of the '995 reissue proceedings, Pfizer has admitted that commercial success of Lipitor cannot be used as a basis to distinguish between the '893 and '995 patents. According to Pfizer it would not be appropriate "to infer the non-obviousness of *two* unrelated patents based on the success of a *single* commercial product." (Emphasis in original.)

115. By April of 2008, things looked bleak, as they should have, for reissuance of an enantiomer patent. The PTO had repeatedly rejected the application; since Pfizer was no longer relying upon the false biological data, the PTO had before it no scientific basis to conclude the enantiomer claims were anything other than obvious over the '893 patent; Pfizer had repeatedly argued "commercial success", but that basis for allowance was a logical impossibility, and Ranbaxy remained as an objector to re-issuance in the proceedings, effectively blocking any re-issuance.

J. The circumstances in early 2008 leading to the Ranbaxy Delay Agreement.

116. By 2008, Pfizer faced the real risk that generic entry could occur in or around March of 2010. After all, (i) the basic compound patent for Lipitor, the '893 patent, only afforded Pfizer protection until March of 2010; (ii) the '995 patent had been adjudicated, with finality, as invalid and therefore could not be used to extend exclusivity beyond March of 2010; (iii) its effort to gain re-issuance of an enantiomer patent had been met with protests by Ranbaxy, rejections by the PTO and

[5] While not needed for these claims, we note that Pfizer's re-issue efforts misleadingly led the examiner not to appreciate this point. For example, Pfizer's re-issue application stated that the re-wording of the '995 patent should be allowed so that the "active ingredient responsible for Lipitor's success [could] be restored and the active ingredient that makes Lipitor work will again be protected by species claims," falsely suggesting that without the allowance Lipitor would be without patent protection. This was a false suggestion because Lipitor's active ingredient was also covered by the original '893 patent. Similarly, Pfizer's reissue application misleadingly referred only to the portion of the 1993 ruling of the board of appeals decision which held the '995 patent not anticipated by the '893 patent; Pfizer completely ignored the portion of that same ruling which determined that an enantiomer patent under circumstances such as this case would be obvious over an original compound patent. Elsewhere, Pfizer stated that "one molecule - the molecule specifically claimed in Claim 6 of this re-issue application is responsible for the success."

the need for Pfizer to eschew any reliance on the erroneous and false scientific data originally used to get the patent; (iv) even if a re-issuance application were allowed, any re-issued enantiomer patent could still be challenged by Ranbaxy; (v) its two Process Patents could not apply to Ranbaxy's product (and would likely not apply to other generic versions of Lipitor either) and did not provide Pfizer with any regulatory exclusivities such as additional 30-month stays; (vi) its two Unasserted Stabilization Formulation Patents had never been, and could never be, asserted against Ranbaxy (nor likely against any other generic company); and (vii) the petition it had filed with FDA lacked all merit and would, in time, be rejected.

117. To set the stage for the allegations of Pfizer's conspiratorial unlawful activities in light of the risks Pfizer faced, this complaint sets out these circumstances in more detail.

1. The '893 patent could only bar generic entry until March of 2010, and Pfizer faced the risk that reissuance of the '995 would be denied.

118. As to the '893 patent, the *Ranbaxy* district court's entry of final judgment in the end of 2006 barred generic entry by Ranbaxy until March of 2010. As to the '995 patent, however, the final order adjudged claim 6 (the only '995 patent claim asserted against Ranbaxy) invalid for improper dependent claim structure. As a result, the '995 patent could not, as a matter of law, be enforced against Ranbaxy. When in early 2008 Pfizer looked at its strategic options, it could only expect the '893 patent to bar generic entry by Ranbaxy until March of 2010 (with the '995 having no preclusive effect). After March 2010, the FDA could have granted final approval of Ranbaxy's ANDA. Even if the '995 patent were re-issued, it would not automatically bar Ranbaxy. Pfizer would need to obtain a preliminary injunction or final court ruling of validity and infringement.

119. As to the '995 patent, during the re-issuance proceedings and given Ranbaxy's protest to it, Pfizer could no longer use the corrupt and rigged data (which misleadingly showed a ten-fold

increase in biologic activity of the enantiomer over the racemate), that it had used to obtain the '995 patent in the first place. Pfizer's arguments for re-issuance were also extremely weak.

2. The two Unasserted Stabilization Formulation Patents and the '156 patent could not bar Ranbaxy's entry.

120. In 2008 and when assessing strategic options, Pfizer could gain no solace from its two Unasserted Stabilization Formulation patents, nor the '156 patent, as methods to preclude Ranbaxy entry.

121. As to the two Unasserted Stabilization Formulation Patents (*i.e.*, the '971 and '104 patents), neither patent had yet been used as the basis for an infringement action against Ranbaxy, nor could they be. Both patents claimed narrow formulations to achieve stabilization for particular atorvastatin drug products, and thus did not apply to Ranbaxy's proposed product under its ANDA.

122. As to the '156 patent, it covered *crystalline* forms of atorvastatin, not amorphous ones. But Ranbaxy's product was amorphous. Pfizer did not and could not show that Ranbaxy's product would infringe the Unasserted Stabilization Formulation Patents or the '156 patent, and as of today, Ranbaxy's ANDA is presumed not to infringe these patents.

3. As to Lipitor, the two Process Patents would not apply to Ranbaxy's (nor likely to other generic companies') generic product

123. The two Process Patents also did not provide a vehicle to delay entry of Ranbaxy's generic version of Lipitor (nor could they delay entry of all or most other generic versions of Lipitor developed by other generic companies).

124. The '511 and '740 patents have patent applications that trace back to a common application and therefore the specifications for both are virtually identical. The Summary of the Invention sections of these two patents are identical and state:

> [T]he present invention is a novel process for the preparation of amorphous atorvastatin and hydrates thereof which *comprises* . . . (a)

> dissolving *crystalline Form I atorvastatin* in a non-hydroxylic solvent; and (b) removing the solvent to afford amorphous atorvastatin.

(emphasis added).

125. The Process Patents are narrow in scope. For a generic manufacturer's process to infringe either of these patents, the generic manufacturer must, *inter alia*, dissolve *crystalline Form I atorvastatin* in the specified solvent. If the manufacturing process dissolves any crystalline structure other than Form I in the specified solvent, or dissolves amorphous atorvastatin, the process does not and cannot infringe either of the Process Patents. To infringe, the manufacturing process used must also include each and every other limitation of the claimed processes of the Process Patents. For example, Claim 1 of the '740 patent further requires use of "a non-hydroxylic solvent at a concentration of about 25% to about 40%."

126. Because of the narrow scope of the Process Patents, and the ample number of both amorphous and crystalline forms of atorvastatin that were available, a very large number of non-infringing alternatives existed to the technology claimed in the Process Patents. Indeed, the prior art, including the '893 patent (covering the active ingredient of Lipitor, atorvastatin calcium), describes numerous processes for making atorvastatin calcium that are prior art to the Process Patents and would invalidate the claims of the Process Patents if those claims read on the processes described in the '893 patent.

127. During Pfizer's own development of Lipitor, Pfizer first produced (for years) amorphous atorvastatin in its manufacturing processes before developing (much later) crystalline formulations such as Form I. There is no need for someone seeking to produce amorphous atorvastatin calcium to first produce Form I crystalline atorvastatin calcium.

128. Pfizer knew that generic companies would design around process or formulation patents such as these, which is evident in its comment that "[t]he generic versions of atorvastatin will

differ in physical form from Lipitor solely to support an effort by the generic applicants to avoid the reach of patent protection of the innovator." It is common practice for experienced generic companies such as Ranbaxy to conduct patent searches during the drug development process, and to select drugs and approaches to formulating products that are allegedly covered by patents but which the generic companies can readily design around.

129. Process patents cannot be listed in the FDA's Orange Book because they are not patents claiming an approved drug or an approved use of a drug. The existence of the Process Patents did not, therefore, provide a vehicle for immediate patent litigation nor did it create a regulatory impediment to generic entry. (ANDA filers are not required to file Paragraph IV certifications, or any other certifications, with respect to non-listed patents. As a result, no subject matter jurisdiction for an infringement action based on non-listed patents exists prior to actual generic entry.)

130. Nor did the existence of the Process Patents create any significant design or legal impediment to generic entry even when litigation might be ripe. The Process Patents narrowly claim only one of many different ways to manufacture amorphous atorvastatin. Numerous non-infringing alternatives to the processes claimed in the Process Patents existed such that there was no reasonable likelihood that Pfizer would be able to use the Process Patents to obtain a court order enjoining ANDA filers, including Ranbaxy, from selling generic versions of Lipitor on the ground that they infringed the Process Patents. In fact, a later Pfizer patent summarized several other processes by which one could manufacture amorphous atorvastatin. *See* U.S. Patent No. 8,258,315. Indeed, in the '315 patent, Pfizer further noted a number of published U.S. and International Patent Applications and patents have disclosed processes for "preparing amorphous atorvastatin." For example, "WO 01/28999 discloses a process for forming amorphous atorvastatin by recrystallization of crude

atorvastatin from an organic solvent." Also, "WO 01/42209 discloses preparing amorphous atorvastatin by precipitating the atorvastatin using a solvent in which atorvastatin is insoluble or very slightly soluble, from a solution of atorvastatin which is provided with a solvent in which atorvastatin is freely soluble." Further, "U.S. Published Patent Application 2004/0024046 A1 discloses a process for forming amorphous atorvastatin by precipitating atorvastatin from a solution with a solvent in which atorvastatin is insoluble or very slightly soluble."

131. As a result, the Process Patents had no exclusionary power vis-à-vis potential generic competitors, including Ranbaxy. Pfizer did not (and could not) prove the facts necessary to meet its burden of establishing infringement of each element of the Process Patents. Therefore, even though the Process Patents were presumed to be valid and enforceable, they had no exclusionary power. Pfizer could not use the Process Patents to exclude Ranbaxy (or likely any would-be generic entrant) from the market.

4. Pfizer faced the risk that its citizen petition could be denied at any moment.

132. In early 2008, Pfizer's citizen petition related to amorphous atorvastatin calcium remained pending. While that petition would frustrate FDA processing of pending ANDAs for a period of time, Pfizer could not reasonably expect the petition to actually be granted because it lacked any credible scientific basis. Thus, its denial could come at any time.

133. However, in circumstances where the FDA had been advised of an agreed-upon generic entry date, it would be expected that once an ANDA was otherwise ready for approval, FDA would deny the petition simultaneously with allowance of an ANDA on the agreed-upon entry date (as a common course for the FDA is to leave a petition pending while an ANDA is not otherwise ready for approval).

5. Pfizer, however, had enormous leverage over Ranbaxy with respect to a completely different drug, Accupril.

134. In stark contrast to the dire circumstances Pfizer found itself in early 2008 with respect to efforts to extend Lipitor exclusivity beyond March of 2010, Pfizer was sitting in the cat bird seat with respect to a different blockbuster brand drug, Accupril. More detail will follow, but by early 2008 Pfizer had established, after appellate review, that Ranbaxy had infringed Pfizer's valid Accupril patents through what was likely willful infringement. And the court in that case had only a few months earlier ruled that Pfizer would be permitted to press damage claims dating back to the initial launch of the generic version of Accupril by Ranbaxy, damage claims in the hundreds of millions of dollars.

135. In early 2008 Pfizer found itself in two, quite different, positions with respect to Ranbaxy. Pfizer's ability to stop Lipitor, the largest selling drug of all time, from going generic sometime shortly after March of 2010 was slim. But as to Accupril, Pfizer had against Ranbaxy (its nemesis in Lipitor) damage claims worth hundreds of millions of dollars.

K. Pfizer created the illusion of litigation to create the appearance of patent life beyond March of 2010.

136. To stop generic competition for Lipitor, Pfizer needed to disguise a reverse payment to Ranbaxy to buy Ranbaxy's agreement to delay launching its generic version of Lipitor. Agreements between branded and generic companies can often create a vehicle to extend unlawfully branded market exclusivity. If there were a pending court case against Ranbaxy involving Lipitor, Pfizer could then settle with Ranbaxy through a reverse payment, and (unlawfully) extend its Lipitor market exclusivity and associated monopoly profits, and then later try to argue its settlement was lawful. But in early 2008, Pfizer had no litigation against Ranbaxy that it could settle.

137. So Pfizer needed to first create the illusion of litigation against Ranbaxy involving patents that applied to Lipitor. And since Pfizer wished to extend the purported patent life for

Lipitor past March 24, 2010 (expiry of all exclusivities applicable to the '893 patent), it needed the illusion of litigation involving patents with a life beyond March 24, 2010. And at this time the '995 patent was still hung up in re-issue proceedings that looked, in part from Ranbaxy's objections, increasingly dismal. So for a basis to bring suit, Pfizer turned to the two Process Patents, the '740 and '511 patents.

138. On or about March 24, 2008, Pfizer filed a complaint in the United States District Court for the District of Delaware alleging that Ranbaxy infringed the Process Patents ("*Ranbaxy II*"). Thus, nearly five years after it first attempted to sue Ranbaxy for allegedly infringing the Process Patents, and knowing that a court had already ruled that it lacked standing under 28 U.S.C. §§ 2201 and 2208 to do so, Pfizer again sued Ranbaxy for declaratory judgment of infringement of the very same Process Patents on the very same grounds that earlier resulted in dismissal.

139. A lawsuit based on the Process Patents was not justiciable years earlier. It was less so in *Ranbaxy II*. At the conclusion of the *Ranbaxy* litigation, the final judgment permanently enjoined Ranbaxy from engaging in the manufacture, use, offer to sell or sale of its generic version of Lipitor until all exclusivities applicable to the '893 patent expired in March 24, 2010. Thus, in *Ranbaxy II* Ranbaxy itself argued "any harm to Pfizer from alleged infringement of the [Process Patents is] much less imminent now than in the [*Ranbaxy*] case when the Court found no imminent threat of harm or injury." There was no jurisdiction for *Ranbaxy II*. Pfizer knew this.[6]

140. The *Ranbaxy II* complaint contained only the most conclusory of infringement allegations. The complaint included no factual allegations or support explaining, let alone establishing, how Ranbaxy's process satisfied the various elements of the claims of the Process

[6] Likewise, because process patents cannot be listed in the Orange Book, Pfizer could not (and did not) use the Process Patents to obtain the automatic 30-month stay of FDA approval of a pending ANDA.

Patents. The complaint did not even allege that Ranbaxy starts with the crystalline atorvastatin when making amorphous atorvastatin. Instead, it merely concludes:

> 30. Upon information and belief, Ranbaxy's Atorvastatin Product is made or is intended to be made by a process which if practiced in the United States would infringe the '511 patent.
>
> * * *
>
> 41. Upon information and belief, Ranbaxy's Atorvastatin Product is made or is intended to be made by a process which if practiced in the United States would infringe the '740 patent.

141. These allegations were not sustainable as a matter of fact and law. The Process Patents narrowly claim only one of many different ways to manufacture amorphous atorvastatin. In fact, a later Pfizer patent summarized several other processes by which one could manufacture amorphous atorvastatin. *See* U.S. Patent No. 8,258,315 (*supra* at ¶130).

142. There were numerous forms of atorvastatin, other than the crystalline Form I specified in the Process Patents, that Ranbaxy could have (and, upon information and belief, did) use at the start of its manufacturing process. And there was no need for Ranbaxy to first create a crystalline form of atorvastatin calcium before creating an amorphous form of atorvastatin calcium.

143. Moreover, Pfizer knew that Ranbaxy intended to use amorphous atorvastatin as a starting material in manufacturing its atorvastatin calcium. Pfizer had no basis to believe that Ranbaxy would use potentially infringing crystalline atorvastatin to achieve amorphous atorvastatin in its manufacturing. Nor did Pfizer have any reasonable expectation that during the discovery process it would learn information supporting a claim of infringement of the two Process Patents.

144. During the pendency of *Ranbaxy II*, Pfizer never produced any evidence to support its purely conclusory allegations that Ranbaxy infringed the Process Patents. Nor could it, since such allegations were false and baseless as a factual (and legal) matter.

L. In June of 2008, Pfizer and Ranbaxy Execute the Ranbaxy Delay Agreement.

145. On June 17, 2008 (*i.e.*, less than three months after Pfizer filed its pretextual declaratory judgment suit based on the Process Patents), Pfizer and Ranbaxy executed an agreement to delay generic entry for atorvastatin calcium (the "Ranbaxy Delay Agreement" or "Agreement")). The Agreement is an unlawful "pay-for-delay" agreement.

146. To disguise the Ranbaxy Delay Agreement's true anticompetitive purpose, Pfizer and Ranbaxy characterized the Agreement as, in part, settling the *Ranbaxy II* litigation. That was a pretext for its true anticompetitive goals and accomplishments.

147. The Ranbaxy Delay Agreement is a reverse payment agreement constituting an unlawful contract, combination and conspiracy to allocate the entire United States market for atorvastatin calcium to Pfizer until November 30, 2011.

1. Pfizer's Financial Inducements to Ranbaxy

148. In exchange for Ranbaxy's agreement to delay its launch of (and not to authorize another ANDA filer to launch) generic Lipitor until November 30, 2011, Pfizer gave substantial financial inducements to Ranbaxy, including: (a) Pfizer's dismissal of damages claims likely worth hundreds of millions of dollars (including claims for enhanced damages for Ranbaxy's willful infringement) stemming from Ranbaxy's "at risk" launch of a generic version of Accupril in exchange for a token payment of $1 million; and (b) the right to market generic Lipitor in at least eleven *foreign* markets outside the United States**.**

a. Release of the *Accupril* liability was worth hundreds of millions of dollars.

149. Years earlier in late 2004, Ranbaxy (acting in partnership with the first-filer Teva) had launched a generic version of Pfizer's branded drug product Accupril "at risk" – a product that had annual branded sales of over $500 million prior to the Ranbaxy/Teva launch. Under an agreement with Teva, Ranbaxy supplied its generic Accupril product to Teva, who was appointed

the exclusive distributor of the product. But events had not gone as apparently planned, and by 2008 Ranbaxy faced huge financial exposure. To understand the basis for, and magnitude of, this exposure, some background is necessary.

150. In January 1999, Teva filed the first ANDA seeking approval to market generic Accupril. In December 2002, Ranbaxy also filed an ANDA for Accupril. The ANDAs of both companies contained Paragraph IV certifications.

151. Within 45 days of receiving Teva's certification, on March 2, 1999, Pfizer filed a patent infringement suit against Teva ("*Accupril I*"). Pfizer did not respond to Ranbaxy's Paragraph IV certification letter, nor did it sue Ranbaxy within forty-five days of receiving the letter, which would have triggered a 30-month stay of approval of Ranbaxy's ANDA.

152. The *Accupril I* litigation continued and in October 2003, Pfizer established on summary judgment that Teva's generic Accupril product infringed claims 1, 4-10, 12, 16, and 17 of Pfizer's '450 patent covering Accupril. *See Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 289 F. Supp. 2d 515, 520 (D.N.J. 2003). While Teva later appealed certain aspects of this ruling, Teva never challenged the district court's determination that its generic Accupril product infringed claims 16 and 17 of the '450 patent.

153. During the course of the *Accupril I* proceedings, Pfizer and Teva had contested the meaning of the term "saccharide" as used in the '450 patent. Teva argued for a broad construction, Pfizer a narrow one. Eventually, the parties stipulated that as used in the '450 patent, the term "saccharide" means a "sugar" and includes only lower weight molecular carbohydrates, specifically mono- and disaccharides and their simple derivatives.

154. On June 29, 2004, Judge Debevoise issued an opinion in *Accupril I* rejecting Teva's obviousness and anticipation arguments as to claims 16 and 17 and its enablement argument, as well

as its allegations of inequitable conduct, thereby establishing the validity and enforceability of the '450 patent covering Accupril. On the same day, Judge Debevoise entered an injunction barring Teva from selling the generic quinapril product described in its ANDA.

155. Meanwhile, Ranbaxy was eager to launch its generic version of Accupril, but was prevented from obtaining FDA approval due to Teva's right to 180 days of marketing exclusivity as the first-filing generic (an exclusivity that had not yet been triggered). Because Teva was enjoined from launching its own product, on August 26, 2004, unbeknownst to Pfizer, Teva and Ranbaxy entered into a distribution and supply agreement pursuant to which Teva was appointed as the exclusive distributor of *Ranbaxy's* generic Accupril product. In exchange, Teva relinquished its 180-day exclusivity, thereby clearing the way for Ranbaxy to obtain final FDA approval.

156. Under the agreement, Ranbaxy would provide Teva with its FDA-approved product for sale, with the parties splitting the profits equally. The partnership also provided that *Ranbaxy would fully indemnify Teva for any liability related to Ranbaxy's launch*. Thus, Ranbaxy would be solely responsible for any damages to Pfizer flowing from the launch of generic quinapril.

157. Ranbaxy obtained final approval of its ANDA product in December 2004 and, pursuant to this agreement, Ranbaxy and Teva engaged in a surprise launch of Ranbaxy's generic Accupril product on December 16, 2004.

158. Ranbaxy's ANDA product contained microcrystalline cellulose ("mcc"), a polysaccharide. Ranbaxy's position was that, in light of the positions taken by Pfizer in *Accupril I* (Pfizer argued for a narrow claim construction) and the stipulation entered into by the parties in that case (defining saccharide as a sugar, limited to mono- and disaccharides), the mcc in its ANDA product did not constitute a "sugar" and therefore did not infringe the '450 patent.

159. In January 2005, Pfizer sued Ranbaxy and Teva for patent infringement, with Judge Debevoise again presiding ("*Accupril II*"). Pfizer sought treble damages for willful infringement pursuant to 28 U.S.C. § 284.[7] Pfizer moved for, and successfully obtained, a preliminary injunction against Ranbaxy and Teva which halted all generic sales. The order was granted on the basis that Pfizer had shown a strong likelihood that it would prevail on the merits. The Court of Appeals for the Federal Circuit unanimously affirmed the district court's preliminary injunction order.

160. Pfizer posted a $200 million bond in conjunction with the injunction going into effect, demonstrating that Pfizer placed great value on preserving its Accupril franchise, and informed the court that Ranbaxy and Teva's sale of "massive quantities" of generic product had "decimated" Pfizer's Accupril sales. Pfizer had sales in 2004 of approximately $525 million for branded Accupril. In 2005, the year after Ranbaxy/Teva launched generic Accupril, Pfizer's sales of branded Accupril had declined to approximately $71 million.

161. Teva, Ranbaxy's co-defendant, informed the court that because of the previous rulings on validity and enforceability rulings in *Accupril I*, Teva would not seek to re-litigate those issues. Judge Debevoise, in discussing discovery in *Accupril II*, remarked that "[t]he liability issues have been well reviewed…."

162. With respect to infringement of the '450 patent by its generic Accupril product, Ranbaxy conceded that if the court in *Accupril II* adopted the claim construction then being put forth by Pfizer – namely that as used in the '450 patent "saccharide" was *not* limited to "sugar" and encompassed polysaccharides – then it "absolutely" infringed. Judge Debevoise, in granting the

[7] *See Etna Products Co., Inc. v. Q Mktg. Group, Ltd.*, 2004 U.S. Dist. LEXIS 15323, *35, 40-41 (S.D.N.Y. Aug. 6, 2004) (Section 284 "imposes no limitation on the types of compensable harm resulting from infringement" and compensatory damages may be enhanced up to three times where an infringer has acted with deliberate intent to infringe and cause harm).

preliminary injunction in *Accupril II* adopted the claim construction put forth by Pfizer. In upholding the injunction, the Federal Circuit noted:

> The district court did not clearly err in determining that Warner-Lambert is likely to prevail in its charge that Ranbaxy literally infringes claim 16. Ranbaxy conceded in the preliminary injunction hearing that its formulation 'absolutely' literally infringes claim 16 if 'saccharides' is construed to include polysaccharides. *Given that concession and the fact that we have construed 'saccharides' to include polysaccharides, we cannot help but conclude that the district court was on solid ground in finding that it is likely that Ranbaxy literally infringes claim 16. . . .* Ranbaxy's challenges to the district court's finding are easily rejected.

163. With respect to invalidity and unenforceability, Pfizer took the position that the issues of invalidity and unenforceability "have been decided conclusively against Teva in the first lawsuit." Pfizer later described the invalidity and unenforceability defenses raised in the Teva litigation (*Accupril I*) as follows:

> Throughout years of hard fought litigation, Teva asserted *every conceivable challenge* in an effort to have the '450 patent declared invalid, unenforceable and not infringed. Teva asserted the '450 patent was unenforceable for 'inequitable conduct,' that the patent was invalid for lack of novelty, nonobviousness, non-enablement and improper inventorship.

All of Teva's invalidity and unenforceability arguments, however, were ultimately rejected by the district court and/or on appeal to the Federal Circuit.

164. In fact, Ranbaxy told the Court in *Accupril II* that it was relying entirely on its (rejected) non-infringement position, and did not have any invalidity or unenforceability theory prior to the preliminary injunction decision:

> Ranbaxy felt it had the silver bullet defense . . . Ranbaxy wanted to win on non-infringement. . . . Does Ranbaxy want the patent knocked out, invalidated? No, of course not. Ranbaxy doesn't care because it's got a non-infringement defense. And the preliminary injunction, your Honor, you'll recall Ranbaxy's sole argument was based on non-infringement. Do we want the patent knocked out? No.

165. Meanwhile, in August 2005, in *Accupril I*, the Federal Circuit affirmed the finding of enforceability and validity of the '450 patent, except as to the enablement issue, aspects of which

were remanded to the district court. On remand, the district court held in Pfizer's favor – *i.e.,* that all claims were enabled. Teva did not challenge on appeal the district court's grant of summary judgment for Pfizer regarding Teva's infringement of claims 16 and 17. Teva did, however, challenge certain aspects of the district court's grant of summary judgment on infringement for other claims (*i.e.*, claims 1, 4-10, and 12), which the Federal Circuit remanded to the district court. On remand, the district court granted Pfizer's motion for summary judgment on infringement of those claims as well.

166. In the *Accupril II* litigation, Ranbaxy asserted that it was entitled to present different variations of the same invalidity theories (including, *inter alia*, obviousness, anticipation, and non-enablement) on which Teva had lost in *Accupril I*. Ranbaxy had no reason to expect that re-litigating the same invalidity and unenforceability defenses that Teva had presented (which—unlike infringement—are not party specific) would result in a more favorable outcome. For all purposes, Ranbaxy was in the challenging position where the best invalidity and unenforceability theories already had been resolved in favor of Pfizer. Accordingly, as both the district court and Federal Circuit agreed, Pfizer had established a likelihood of success on the merits of the litigation against Ranbaxy.

167. After the grant of preliminary injunction, Pfizer knew that there was "a strong likelihood that Ranbaxy will lose the liability phase of this case."

168. Pfizer also described the case as "less complicated than the norm." In fact, Pfizer asserted "[w]ith the really difficult issues having been already decided during the preliminary injunction proceedings in this case, or during the seven-year pendency of the first [Teva] litigation, this case is about as simple as a patent case gets."

169. As of February 2008, most of the discovery in *Accupril II* was complete. The parties had served and responded to interrogatories, requests for the production of documents, and taken depositions. In fact, Ranbaxy had proposed that fact discovery conclude in February 2008.

170. Ranbaxy was likely liable for hundreds of millions of dollars in damages to Pfizer. In Pfizer's April 2005 Earnings Conference Call, Jeffrey Kindler (who later became Pfizer's CEO in 2006) told shareholders that:

> The court ordered Teva and Ranbaxy to immediately stop marketing the product, which Teva had launched last Dec. under its own label, but with an agreement for indemnification by Ranbaxy. The court held that we were likely to prevail in our infringement suit and ordered the injunction to prevent any further sales. We intend to proceed aggressively with that case. There has been no trial setting yet, but at trial, we intend to seek recovery for lost profits and sales that we incurred as a result of them having an infringing product on the market. We believe that is going to result in very substantial damages on our behalf and we intend to seek that form out. *...And as I said, we had very, very substantial damages in the way of lost profits that we intend to recover from Ranbaxy*.

(emphasis added). In other words, in line with its fiduciary responsibilities to its shareholders, Pfizer told its shareholders that it would aggressively seek very substantial damages from Ranbaxy for Accupril.

171. Ranbaxy itself conceded that "the stakes are high [is] reflected by the fact that Plaintiffs posted a $200 million bond to secure issuance of a preliminary injunction against Ranbaxy and Teva."

172. Not only was Ranbaxy (who was fully indemnifying Teva) potentially liable for lost profits, but Pfizer had requested that the district court enhance the damages based on a willful infringement theory.

173. In a patent case, if willful infringement is found, the court may, under 35 U.S.C. § 284, enhance damages up to three times the damages awarded. To prove willful infringement, Pfizer would have had to establish that (1) Teva and Ranbaxy acted despite an objectively high likelihood

that their actions constituted infringement of a valid patent, and (2) the objectively defined risk was either known or so obvious that it should have been known to Teva and Ranbaxy.

174. Given the prior litigation between Pfizer and Teva, and Ranbaxy's knowledge of that litigation, including the various district court rulings, Pfizer was likely to establish that the "at risk" launch of Ranbaxy's generic product constituted willful infringement. Specifically, Pfizer argued that conduct Teva and Ranbaxy undertook after the Court entered the preliminary injunction in *Accupril II* such as "stuff[ing] the distribution channels with infringing product until the injunction was formally entered two days later" and taking no "action to withdraw its enjoined product from the market . . . inform[ing] its distributors/customers that it would not accept any returns" constituted willful infringement of the'450 patent.

175. So by early 2008, as to Accupril, Pfizer had Ranbaxy over a very large barrel – exposed to hundreds of millions of dollars in damages from the *Accupril II* litigation. Escaping from that liability would be of enormous financial value to Ranbaxy.

b. Release of the *Accupril* liability for a token $1 million payment is a pretext to hide a large and unexplained reverse payment from Pfizer to Ranbaxy.

176. On its face, Ranbaxy's $1 million token payment to Pfizer to settle the *Accupril II* litigation was so far below fair value that it may fairly be characterized as a fig leaf to hide the true economic realities of the transaction. Ranbaxy's likely exposure for its "at risk" sales of Accupril was so high that Pfizer could leverage Ranbaxy to quit efforts to enter the Lipitor market in a timely manner. The $1 million payment was a pretext to hide *the economic reality that the transaction yielded a massive net payment worth hundreds of millions of dollars to Ranbaxy*.

177. The release of Ranbaxy from hundreds of millions of dollars in likely liability for *Accupril II* for $1 million was not fair value. Having represented to the Court, the public, and its shareholders that it held a claim likely valued at multi-hundred million dollars against Ranbaxy,

Pfizer could not, and would not, give up that large claim for a mere $1 million, *unless there were another component to the deal*. That component was Ranbaxy's agreement to delay launching Lipitor until November 30, 2011.

178. Pfizer also gave Ranbaxy the right to market generic Lipitor in at least eleven foreign markets outside the United States. These provisions provided no benefit to United States consumers or to competition in the United States. And these provisions added to the financial inducements provided by Pfizer to Ranbaxy, and were not of a kind that Ranbaxy could ever expect to achieve through success in any litigation of U.S. Lipitor patents.

179. The Ranbaxy Delay Agreement also ostensibly gave Ranbaxy protection from potential infringement liability in connection with the variety of patents that purportedly covered atorvastatin. However, this "consideration" was of little or no value because neither Ranbaxy or Pfizer believed that there was any such legitimate threat of infringement of such patents.

180. Pfizer's release of Ranbaxy from hundreds of millions of dollars in likely *Accupril II* liability far exceeded any litigation costs (in any or all cases) Pfizer avoided by settling.

2. In exchange for Pfizer's payment, Ranbaxy agreed to delay its launch of generic Lipitor and to bottleneck later would-be generics.

181. In exchange for the massive payments made by Pfizer to Ranbaxy, Ranbaxy agreed (i) to delay its generic entry of Lipitor until November 30, 2011, (ii) not to relinquish or selectively waive its first-to-file 180-day marketing exclusivity in a manner that would permit any other ANDA filer to market a generic version of Lipitor before November 30, 2011 (*i.e.* create a bottleneck blocking later-filed ANDAs), (iii) not contest the validity of the Process Patents, and (iv) cease protesting Pfizer's application for reissuance of the '995 patent.

182. First, Ranbaxy agreed to be enjoined from selling any atorvastatin product in the United States until the end of November, 2011. In other words, at the time of the June 2008

Ranbaxy Delay Agreement (when there were no patents that could stop Ranbaxy's entry after March of 2010), Ranbaxy agreed not to compete with a generic Lipitor until November of 2011. Pfizer granted Ranbaxy a license to all patents controlled by Pfizer that were purportedly necessary for making atorvastatin calcium effective only on and after November 30, 2011 for the life of each such Lipitor patent.

183. Second, to ensure that no other generics could enter the market and destroy Pfizer's Lipitor monopoly, Ranbaxy agreed to not relinquish or selectively waive its first-to-file 180-day marketing exclusivity in a manner that would permit any other ANDA filer to market a generic version of Lipitor in the United States before November 30, 2011. This aspect of the Ranbaxy Delay Agreement both bottlenecked regulatory approval for other would-be entrants and barred Ranbaxy from cutting a deal to enable selective entry by one or more a co-ventured generics prior to November 2011.

184. Third, Ranbaxy agreed to cease protesting Pfizer's application for reissuance of the enantiomer patent (the'995 patent).

3. Absent the reverse payment agreement, Ranbaxy would have received FDA ANDA approval for generic Lipitor earlier.

185. Ranbaxy's ANDA would have been approved, and Ranbaxy (either on its own, or with a generic partner) would have launched generic Lipitor earlier had there been no unlawful reverse payment (*i.e.*, but for the large reverse payment in the Ranbaxy Delay Agreement). Alternatively, absent Ranbaxy's ability to launch (either at all, or in sufficient commercial quantities to supply the market), Ranbaxy would have selectively waived, or forfeited entirely, its 180-day exclusivity rights in favor of other generic Lipitor ANDA filers.

186. Ranbaxy's atorvastatin calcium ANDA would have received final approval earlier absent the defendants' anticompetitive conduct. The FDA has policies and procedures in place to prioritize the review of ANDAs, *e.g.*, expediting the review of the first applications for which there

are no blocking patents or exclusivities. Regarding the FDA's review of applications for generic Lipitor, the Ranbaxy Delay Agreement blocked all generic applicants, including Ranbaxy, from marketing their products. The FDA was aware that the earliest date Ranbaxy could market generic Lipitor under its agreement with Pfizer was November 30, 2011, and thus the FDA's (and Ranbaxy's) approval efforts focused on that date (not earlier dates). As Ranbaxy maintained its 180-day exclusivity, all subsequent applicants were blocked from marketing generic Lipitor as well, until Ranbaxy's exclusivity was triggered and had elapsed.

187. Furthermore, the FDA was under tremendous pressure, including from Congress, to speed consumer access to generic Lipitor at the earliest possible moment. Ranbaxy was also under tremendous pressure to monetize its biggest asset, *i.e.*, its first-to-file ("FTF") atorvastatin ANDA, at the earliest possible moment, so much so that Ranbaxy paid Teva a large amount of money — in effect an insurance policy — in order to ensure that Ranbaxy was able to launch generic Lipitor at the earliest possible moment.

188. As it turned out, given the existence of the Ranbaxy Delay Agreement, FDA had no reason to grant final approval before November 30, 2011, and so it did not do so until then. But had the Ranbaxy Delay Agreement permitted an earlier entry date, or had there been no such agreement at all, generic Lipitor could have been, and would have been, marketed earlier than November 30, 2011, because the FDA would have granted final approval earlier and Ranbaxy would have launched earlier.

189. The FDA did not issue its formal written denial of Pfizer's baseless petition until November 30, 2011 for the same reason: FDA practice was to issue responses to citizen petitions with respect to bioequivalence issues for a product on the same date as the generic for that product was approved.

a. The longstanding FDA policy of prioritizing the review of ANDAs.

190. As a matter of procedure and practice, the FDA has long employed methods of prioritizing the review of pending ANDA applications. For example, in 1990 the Division of Generic Drugs within the FDA issued a policy and procedure guide establishing a "first-in, first-reviewed" policy for generic drug applicants. This policy, along with similar guidance for the pharmaceutical industry, has been updated and modified from time to time and is still in place today. One of the modifications which have been instituted over the years is to prioritize the review of the first ANDAs for which there is no blocking patent or exclusivity.

191. Similarly, the FDA has been experiencing a backlog of pending applications, such that prioritizing ANDA review is more important than ever. Furthermore, as a matter of procedure and practice, in a situation where an ANDA filer will not be able to market a drug until a time far into the future, such as Ranbaxy's generic Lipitor ANDA due to the Ranbaxy Delay Agreement, the FDA shifts assets to other priorities within the Office of Generic Drugs. FDA prioritizes the review of ANDAs in this way by keeping abreast of the current posture of any litigation that may impact the timing of approval of an ANDA. For instance, as a matter of procedure and practice, upon accepting an ANDA for filing, the FDA expressly requests that the applicant promptly submit a copy of any settlement agreement between the applicant and the patent holder.

b. The FDA's review of Ranbaxy's ANDA for atorvastatin calcium.

192. On June 18, 2008 Ranbaxy publicly announced its agreement with Pfizer, including the news that under the agreement Ranbaxy's launch date was delayed until November 30, 2011. Ranbaxy submitted this information to the FDA shortly thereafter. Ranbaxy also informed the FDA its proposed generic product was now crystalline atorvastatin calcium, pursuant to a license from Pfizer. As Ranbaxy no longer intended to market amorphous atorvastatin calcium, the citizen petition was moot at this point.

193. Thus, due to the FDA's longstanding policy of prioritizing the review of ANDAs and the recent pressure of the ANDA backlog, on information and belief, once FDA learned of the fact that the first generic for Lipitor, *i.e.*, Ranbaxy's, would not be marketed until November 30, 2011, FDA shifted assets away from Ranbaxy's ANDA and the Pfizer petition and toward other priorities within FDA until the November 2011 date drew closer.

c. The tremendous pressure on the FDA to approve generic Lipitor.

194. That the FDA was under immense pressure to approve a generic Lipitor product also shows that it would have earlier approved Ranbaxy's ANDA absent the agreed-to date for Ranbaxy's market entry contained in the Ranbaxy Delay Agreement. But, since the November 2011 date was set by the Ranbaxy Delay Agreement, the FDA could not speed up Ranbaxy's actual launch, regardless of what efforts FDA might make.

195. For example, on March 10, 2011, Senate Health, Education, Labor, and Pensions Committee Chairman Tom Harkin, along with Senators Jay Rockefeller, Charles Schumer, Debbie Stabenow, and Sherrod Brown sent a letter to FDA Commissioner Dr. Margaret Hamburg. In the letter the Senators stated, "Given the tremendous savings that access to generic atorvastatin will afford both consumers and the government, we urge you to act now to clarify the relevant regulatory issues in the matter so the public can receive access to a more affordable generic version of Lipitor on the earliest possible date." The "tremendous savings" to consumers and the government would be between "$3.97 billion to $6.7 billion a year upon generic entry, which equates to $10.9 million to $18.3 million a day." Likewise, the FDA recognized the importance and cost savings of having a generic Lipitor available to consumers

196. Absent the Ranbaxy Delay Agreement, Ranbaxy would have received ANDA approval earlier.

4. Absent the reverse payment agreement, Ranbaxy would have launched generic Lipitor earlier.

197. Not only would the FDA's approval of Ranbaxy's ANDA been forthcoming earlier, but absent the reverse payment in the Ranbaxy Delay Agreement, Ranbaxy would have made arrangements to launch an AB-rated generic atorvastatin calcium no later than June 28, 2011 (if not earlier).

198. Absent the large payment in the Ranbaxy Delay Agreement and given the enormous profit opportunity generic Lipitor presented, Ranbaxy would have been highly motivated to pursue generic entry much earlier than November 30, 2011. In early 2008 (the time when the Ranbaxy Delay Agreement was executed), at least three alternatives were available to Ranbaxy to effectuate generic entry earlier than November of 2011.

199. First, Ranbaxy and Pfizer could have settled pending and potential future Lipitor patent disputes with a negotiated entry date no later than June 28, 2011 (or likely earlier) but without the kind of large and unexplained reverse payment that occurred here.

200. Each party was motivated to reach some kind of resolution. Pfizer's suit over its Process Patents held no prospect for success. Its efforts to achieve re-issuance of an enantiomer patent were, to date, unsuccessful, in no small part due to Ranbaxy's opposition. Even if Pfizer did obtain a re-issued enantiomer patent, Ranbaxy was sure to challenge the patent in the courts. And Pfizer had only recently settled with generic maker Cobalt (which had been pursuing launch of an atorvastatin using a sodium rather than calcium salt) by appointing Cobalt as the future, exclusive (even as to Pfizer) seller of an authorized generic version of Lipitor, with a launch date to be timed to coincide with the launch of the first ANDA-approved Lipitor generic (but no later than November of 2011). (In short, if Ranbaxy launched generic Lipitor before November 2011, Pfizer had agreed that Cobalt could launch an authorized generic as well).

201. Pfizer was motivated to settle for additional reasons. In early 2008 there existed a

serious and real threat that Ranbaxy, or Ranbaxy working with one or more ANDA applicant, through a 180-day selective waiver or forfeiture collaboration, might ensure the launch of generic atorvastatin calcium once the '893 patent exclusivity expired in March of 2010. Ranbaxy has expressed its willingness to enter at risk with a generic product of other blockbuster drugs, telling one court that "Ranbaxy [] presently intends to manufacture, use, sell and offer to sell drug products for which the ANDA has been submitted once the FDA approves the ANDA" -- in other words, Ranbaxy would launch its generic "once the FDA approv[ed]" it and would not need to await final resolution of the patent case. And in other drug situations Ranbaxy had collaborated with other would-be generic entrants to effectuate "at risk" launches.

202. Ranbaxy, too, had strong motivations to settle, even if it could not have its huge *Accupril* liability paid off by Pfizer. The first-to-file status Ranbaxy held for Lipitor was the true pearl in its inventory of ANDA applications; the sooner it launched, the sooner it could monetize that opportunity. Certainly if Ranbaxy was willing to settle for a November 30, 2011 launch date it would have likewise been willing to enter into alternative agreements with earlier entry dates. In fact, absent a large payment from Pfizer, Ranbaxy would have insisted on an earlier launch date

203. A Lipitor patent settlement between Pfizer and Ranbaxy *sans* a large and extraneous financial payment to Ranbaxy would have focused discussions on the litigation positions (existing and future) of the parties. And the result would have achieved a negotiated generic entry date markedly earlier than November 2011, and certainly no later than June 2011. Without the large payoff to Ranbaxy, Ranbaxy's position would have been that an agreed entry date shortly after March of 2010 was in order (as there was no enantiomer patent blocking its entry at the time, and the prospect for re-issuance of the '995 patent was then dim). In response, Pfizer would have argued for a later entry date, but its weak position would not warrant entry dates into 2011. So absent Pfizer's payments to Ranbaxy, Ranbaxy

would not have agreed to delay its launch of generic Lipitor into late 2011. At a minimum, absent the payment to Ranbaxy, Ranbaxy would not have agreed to delay its launch (or to delay authorizing another ANDA filer to launch) for as long as it did, and would instead have agreed only to a substantially shorter period of time before which it would enter.

204. A second alternative available to Ranbaxy to effectuate generic entry earlier than November of 2011 was to litigate, win and then launch. Some of the Lipitor patents had never even been asserted against Ranbaxy, nor would they ever be. The'995 patent had been declared invalid, and could not be asserted. And Ranbaxy had dispositive arguments against the enantiomer re-issue application. If Ranbaxy continued its opposition, either the PTO would not have issued an enantiomer patent, or Ranbaxy would have prevailed in any legal effort to use a later-issued enantiomer patent as a basis to preclude marketing of a generic Lipitor. After all, Pfizer's re-issue request now eschewed any reliance on the falsified data, and its sole reliance on commercial success was fundamentally flawed. Finally, the process patent litigation was baseless and had only been conjured up as a vehicle to house a reverse payment settlement.

205. Pfizer has acknowledged the lack of lawful exclusionary power for a significant portion of this time, *viz.*, from June of 2011. In 2005, before the Ranbaxy Delay Agreement existed and before the '995 patent was declared invalid, Pfizer's former Chairman and CEO stated:

> There are dozens of generic drug manufacturing companies with a red circle around June 28, 2011. That's the day the patent for our anti-cholesterol medication Lipitor expires. . . . Shortly thereafter a number of generic alternatives to Lipitor will be introduced and consumers will have a choice of generic tablets containing atorvastatin calcium[.]

206. Of course, at the time of this statement only the '995 patent expired in June of 2011. Other patents purportedly covering Lipitor -- namely the Unasserted Stablization Formulation Patents, the '156 patent, and the Process Patents -- would expire between 2013 and 2017. If the

Unasserted Stabilization Formulation Patents, the Process Patents, and/or the '156 patent had any hope of legitimately keeping generics off the market, Pfizer's CEO would not have ignored them and the literally tens of billions of dollars they would have conferred on Pfizer. His statement that June 28, 2011 is the key date only makes sense if one recognizes — as Pfizer did — that the Unasserted Stabilization Formulation Patents, the Process Patents, and the '156 patent could not block generics from entering.

207. As to the petition filed by Pfizer in 2005, it would not have delayed final approval of Ranbaxy's ANDA under any of the scenarios outlined above. In light of the Ranbaxy Delay Agreement with Pfizer, Ranbaxy switched to a non-amorphous form of atorvastatin. As a result, the FDA concluded that "the issues raised in the [petition] are not pertinent to the Ranbaxy ANDA, as amended, and that this petition need not be responded to prior to the approval of Ranbaxy's ANDA…." *See* Comment of Robert L. West, Deputy Director of the Office of Generic Drugs, in the Approval Routing Sheet for Ranbaxy's atorvastatin calcium ANDA, at p. 5. A settlement between Pfizer and Ranbaxy eliminating only the illegal inducements for delayed entry would have given rise to this same situation. Second, in light of the agreed upon November 30, 2011 entry date, the FDA was not incentivized to rule on the petition any earlier than that, as the potential effects of such a ruling could only affect other ANDA filers – not Ranbaxy. Those later ANDA filers would expect the FDA to deny the petition given the FDA's consistent position on the use of amorphous API.

208. In short, an infringement case against Ranbaxy (or any other ANDA filer), based upon any legitimately obtained Lipitor patent that expired after March 24, 2010, would have been (and was, with respect to, for example, Pfizer's suit claiming infringement of Pfizer's Process Patents) a failure. As a result, the Ranbaxy Delay Agreement gave Pfizer protection from generic Lipitor competition beyond the lawful limits of its exclusionary power under any Lipitor-related

patent. Nor did Pfizer or Ranbaxy subjectively believe there was any such legitimate threat of infringement from such patents.

209. A third alternative available to Ranbaxy in early 2008 to effectuate generic entry earlier than November of 2011 was to continue to litigate, but launch its generic Lipitor after March of 2010 without awaiting its likely litigation victories. In 2008, Pfizer's then-existing Lipitor patent portfolio did not put Ranbaxy (or likely any other relevant ANDA filer) in danger of liability for infringement of any legitimately obtained patent past March of 2010 (the expiry of the '893 patent). No legitimately obtained patent posed a reasonable or realistic threat of infringement liability to Ranbaxy (or likely any other relevant ANDA filer) for making or selling generic Lipitor, other than the '893 patent. And as of the date of the Ranbaxy Delay Agreement, the only means by which Pfizer could have prevented a launch by Ranbaxy of generic Lipitor on or after March 24, 2010 was by obtaining an injunction. But as Pfizer knew in 2008, obtaining such an injunction would have been impossible, because it would have required a showing that Pfizer was likely to succeed on the merits of process patent infringement claims that it could not win.

210. In sum, there were multiple ways and avenues by which Ranbaxy would have launched generic Lipitor before November 2011 but for the Ranbaxy Delay Agreement. Ranbaxy was motivated to monetize its first-to-file 180-day marketing exclusivity, and would have more rapidly pursued its atorvastatin calcium ANDA absent the agreed-to delayed date for Ranbaxy's market entry contained in the reverse payment agreement with Pfizer.

211. The first-to-file generic Lipitor was a tremendous opportunity for Ranbaxy. Despite only being on the market with a generic Lipitor for one month of 2011, atorvastatin calcium was Ranbaxy's largest selling product in 2011. Ranbaxy also achieved sales growth of 17% over the previous year, "mainly on account of revenues from First to File product, Atorvastatin, in the US

market in December 2011." These are significant economic benefits that Ranbaxy could have, and would have, realized long earlier had it not accepted the large payment from Pfizer to delay its launch.

212. Following execution of the Ranbaxy Delay Agreement in 2008, Ranbaxy geared its launch activities to achieve a November 2011 launch time frame. There was no need for it to rush to make preparations for an immediate Lipitor generic launch. After all, it would not be doing so for three and a half years. Eventually, however, Ranbaxy did make its preparations and timely launched on November 30, 2011. These activities would have occurred much earlier had Ranbaxy not promised to delay its launch until the end of 2011.

213. For example, Ranbaxy eventually took steps to ensure issues related its "good manufacturing practices" at its facilities in India did not prevent it from being able to market generic Lipitor. In December 2009 Ranbaxy effectuated a manufacturing site transfer of atorvastatin calcium from its facility in India to Ranbaxy's wholly-owned subsidiary, Ohm Laboratories in New Jersey which was not experiencing any such issues. This way, whatever issues Ranbaxy may have been having with FDA regulatory compliance at one or more of its facilities in India would not negatively impact the timing of the its launch of generic Lipitor. This is borne out by the facts that (a) Ranbaxy ultimately received approval to market generic Lipitor in the U.S. from the Ohm facility in New Jersey, and (b) FDA worked with Ranbaxy to ensure that its ANDA was reviewed and approved on November 30, 2011, allowing for an immediate launch.

214. Absent the defendants' anticompetitive scheme, Ranbaxy could and would have proceeded with a manufacturing site transfer earlier, either to Ohm or to another facility, and FDA would have been willing to work with Ranbaxy, just as it actually did, to ensure launch during

earlier periods. The Ohm facility had been operational for Ranbaxy for quite some time and was available for a site transfer in the relevant time period at issue here.

215. In fact, at or around the same time Ranbaxy filed its ANDA for atorvastatin calcium, Ranbaxy also filed the first ANDA to market a dosage strength of a drug in the same "statin" family as atorvastatin calcium, simvastatin. As with atorvastatin, Ranbaxy effectuated a manufacturing site transfer for simvastatin from India to the Ohm facility in New Jersey. Ranbaxy received final approval for its simvastatin ANDA on June 23, 2006 and began marketing its first-to-file generic shortly after.

216. Similarly, in the same time period as the atorvastatin calcium filing, Ranbaxy filed the first ANDA with FDA to market donepezil hydrochloride, the active ingredient in the brand drug Aricept. Aricept had approximately $2.6 billion in sales in 2010. Around the time of the atorvastatin calcium site transfer in December 2009, Ranbaxy effectuated a site transfer of donepezil hydrochloride from India to the Ohm facility in New Jersey. On the first day a generic version of Aricept could be marketed, November 26, 2010, Ranbaxy received approval with first-to-file exclusivity to market donepezil hydrochloride. In 2011, donepezil was the second best performing product after atorvastatin calcium.

217. Finally, Ranbaxy could have, and eventually did, co-venture its generic Lipitor efforts in order to facilitate generic entry for Lipitor. [redacted]

[redacted] Ranbaxy and Teva signed an agreement regarding generic Lipitor [redacted] containing some or all of these options and/or other options.

218. Once Ranbaxy made the decision to partner with another company in order to monetize generic Lipitor, it is hardly surprising Ranbaxy chose Teva. It is well known in the industry that Teva looks to partner with 180-day exclusivity holders given the profit opportunity such exclusivities present. Since Ranbaxy gained approval to market generic Lipitor from its Ohm facility in New Jersey, it never needed the insurance policy the deal with Teva effectively provided. However, Ranbaxy still paid Teva a substantial amount of money in order to be able to monetize its first-to-file atorvastatin calcium ANDA at the earliest possible moment under the Ranbaxy Delay Agreement.

5. Absent the reverse payment agreement, Pfizer or a co-venture partner would have entered the Lipitor market with an authorized generic earlier.

219. Not only would Ranbaxy have entered the market for atorvastatin calcium earlier had there been no large payoff to it as part of the Ranbaxy Delay Agreement, but an authorized generic version of Lipitor would also have entered at or close to the time of Ranbaxy's earlier launch as well.

220. An earlier launch of an authorized generic timed to coincide with Ranbaxy's earlier launch would have occurred either through Pfizer's co-venture arrangements with Cobalt, or through Pfizer's captive generic subsidiary, Greenstone.

221. In April 2008, Cobalt (a generic maker seeking to market a sodium salt version of atorvastatin) and Pfizer agreed to settle patent infringement litigation between them. Cobalt agreed

to abandon its challenge to the Lipitor patents, and not to launch its atorvastatin sodium product until at least the expiration date of all patent and regulatory exclusivities related to the '995 patent on June 28, 2011. In exchange, Pfizer appointed Cobalt as its exclusive (even as to Pfizer) authorized distributor of Pfizer's NDA approved atorvastatin product in generic form, which is identical to Pfizer's branded Lipitor, but labeled and packaged for distribution into generic drug channels in the U.S. from the earlier of November 30, 2011 or the date any ANDA filer makes generic Lipitor available for sale in the U.S.

222. By appointing Cobalt to be the exclusive distributor of generic Lipitor (under Pfizer's NDA) *with exclusive rights even as to Pfizer*, Pfizer was agreeing to cede all authorized generic sales of Lipitor to Cobalt (*i.e.* Pfizer was agreeing not to sell an authorized generic version of Lipitor in competition with Cobalt) for five years.

223. As a result, Cobalt and Pfizer were ready, willing and able to launch an authorized generic immediately upon the launch of Ranbaxy's ANDA-approved generic. By delaying the Ranbaxy launch the Ranbaxy Delay Agreement also had the effect of delaying the entry of Pfizer's authorized generic to be launched through Cobalt.

224. And even if the Cobalt agreement did not exist or was not performed, Pfizer nevertheless would have launched an authorized generic immediately upon Ranbaxy's entry. Greenstone is a subsidiary of Pfizer, specializing in the marketing and sale of generic versions of Pfizer's brand-name drugs. Greenstone's business model depends upon Pfizer's drug pipeline, more precisely the time at which Pfizer's drugs will lose exclusivity. For any major brand-name Pfizer drug approaching the end of its exclusivity, the distribution of an authorized generic through Greenstone is likely.

225. Greenstone, however, will not launch any generic product unless and until another company enters the market with its own generic version. Since Greenstone's authorized generic is priced at, or near, the same level as other generics there is no benefit to Pfizer in having Greenstone be the first generic to launch. All of Greenstone's sales would cannibalize the otherwise exclusive branded sales. Once generic entry does occur, usually by a first-to-file ANDA generic company, Greenstone wants to immediately launch its (meaning Pfizer's) authorized generic.

226. Greenstone itself has no manufacturing capabilities (Pfizer produces the authorized generic versions of its drugs on the same production line as its branded versions). As the end of patent exclusivities approach, and Greenstone's market analysis shows the likelihood of a generic entrant in the market, Greenstone takes steps to have Pfizer manufacture generic versions of the drug.

227. As a result, even if the Cobalt arrangements did not exist, Greenstone would have been ready, willing and able to launch an authorized generic immediately upon the launch of Ranbaxy's ANDA-approved generic. By delaying the Ranbaxy launch the Ranbaxy Delay Agreement also had the effect of delaying the entry of a Greenstone authorized generic.

M. The Operation of the Ranbaxy Delay Agreement

228. Pursuant to the Ranbaxy Delay Agreement, Ranbaxy agreed not to sell its generic version of Lipitor in the United States until November 30, 2011 -- twenty (20) months after the '893 patent (and any associated marketing exclusivities) was scheduled to expire, and five (5) months after any re-issued enantiomer patent (the '995 patent) would expire, if in fact such an enantiomer patent was issued and survived patent challenges. Pfizer and Ranbaxy performed under the Ranbaxy Delay Agreement, and successfully delayed multiple efforts by other generics to launch competing products.

1. Ranbaxy withdraws its challenges to the re-issuance of an enantiomer patent.

229. As part of the Ranbaxy Delay Agreement, Ranbaxy agreed not to challenge the validity of any Lipitor patent, including the '995 patent, which was then the subject of reissuance proceedings. Pursuant to the Ranbaxy Delay Agreement, Ranbaxy dropped its challenge to the reissuance of the '995 patent — a challenge which had been successful prior to the date of the Agreement.

230. With Ranbaxy out of Pfizer's way, Pfizer renewed its effort to obtain re-issuance of the enantiomer patent. Pfizer continued to barrage the PTO with information about the commercial success of "Lipitor," treating it as if that were the correct and only relevant issue.

231. Eventually, the PTO relented to Pfizer's barrage of Lipitor materials regarding commercial success.

232. On April 6, 2009, the PTO reissued claims 6, 13, and 14 of the '995 patent as the RE '667 patent. The PTO based its ruling to grant the re-issuance of an enantiomer patent not on the basis of the biological studies and representations made by Warner-Lambert (even though a version of the CSI assay data remains in the specification for the patent), but instead on the basis of Pfizer's arguments that the commercial success of Lipitor shows that the '995 patent could not have been obvious.

233. All exclusivities applicable to the '667 patent, like its predecessor the '995 patent, would expire (and did expire) on June 28, 2011. (Pursuant to the Ranbaxy Delay Agreement, Ranbaxy could not sell its generic version of Lipitor until November 30, 2011, a full five months after the '667 patent expired).

234. The reissue proceedings do, however, confirm what Pfizer had long known: the biologic data submitted as part of the application for the '995 patent was false, inaccurate, incorrect, and riddled with errors. And by buying off Ranbaxy's opposition to the reissuance of '995 claims,

along with a sleight-of-hand with respect in its submissions to the PTO, Pfizer got the PTO to finally allow, albeit incorrectly, several claims of the '995 patent as the RE '667 patent.

2. The Ranbaxy Delay Agreement created a bottleneck preventing later ANDA filers from entering the market with generic Lipitor.

235. The Ranbaxy Delay Agreement also had the purpose and effect of preventing other ANDA filers from launching their own generic versions of Lipitor before Ranbaxy did.

236. As of the 2008 Ranbaxy Delay Agreement, there were only two ways that Ranbaxy's 180-day exclusivity could be triggered. The first trigger event would be when Ranbaxy began selling its generic product – but Pfizer and Ranbaxy had collusively delayed the start of Ranbaxy's generic Lipitor sales, and thus they had delayed this trigger date, and hence other generics would remain blocked.

237. The second trigger event would be if other generic companies obtained appellate court decisions that all of the unexpired patents Pfizer had listed in the Orange Book for Lipitor (*i.e.,* the '893, '995, '104, '971 and '156 patents) were invalid or not infringed. If another ANDA filer were to obtain such court decisions, Ranbaxy's 180-day first-to-file marketing exclusivity would commence running, even if Ranbaxy had not yet begun commercial marketing of its ANDA product by that time, and even if Ranbaxy did not want its exclusivity to commence running.

238. Pfizer did not want generic Lipitor competition before the November 30, 2011 date provided in the Ranbaxy Delay Agreement, and Ranbaxy did not want any involuntary triggering or forfeiture of its anticipated, and enormously valuable, 180-day first-to-file marketing exclusivity.

239. To prevent the involuntary triggering of Ranbaxy's 180-day exclusivity prior to November 30, 2011, Pfizer thwarted the efforts of other generic manufacturers to obtain judgments of invalidity or non-infringement with respect to the '104, '971 and '156 patents. To effectuate this campaign, Pfizer sued subsequent ANDA filers on some (but not all) of its Orange Book-listed

patents, provided covenants not to sue on some of the unasserted patents in order to avoid ultimate court rulings of invalidity or non-infringement, and/or settled cases prior to judgments on the merits, vigorously opposed the efforts of ANDA applicants to obtain declarations that the remaining patents were invalid and/or not infringed, and otherwise engaged in a pattern of dilatory conduct designed to forestall, prior to Ranbaxy's agreed-upon November 30, 2011 entry date, judicial decisions that any of the remaining patents were invalid and/or not infringed.

a. Apotex.

240. For instance, after it received a Paragraph IV certification in December of 2008 from Apotex, Inc. and Apotex Corporation ("Apotex") as to the '995 patent, the Unasserted Stabilization Formulation Patents, and the '156 patent, Pfizer sued Apotex for infringement of only the '995 patent. Apotex's answer included counterclaims, pursuant to 21 U.S.C. § 355(j)(5)(C), asserting non-infringement and invalidity of the both the '995 patent (and '667 reissue patent), the Unasserted Stabilization Formulation Patents, and the '156 patent.

241. As the Apotex trial court recognized: "Apotex's hope is to obtain a decision from this Court that the Unasserted Patents are invalid or are not infringed by Apotex's product, thereby triggering Ranbaxy's exclusivity period. Absent such a court ruling (either in this case or in litigation involving another subsequent ANDA filer), Apotex will not be able to market its generic atorvastatin drug until 180 days after Ranbaxy begins marketing its drug, which, as a result of the settlement agreement between Pfizer and Ranbaxy, will not occur until November 2011 at the earliest."

242. In furtherance of the Ranbaxy Delay Agreement, Pfizer sought dismissal of Apotex's counterclaims, arguing that they were nonjusticiable.

243. Although the Apotex court denied Pfizer's motion to dismiss, the motion had its intended effect: it delayed discovery and litigation for well over a year and, combined with

subsequent litigation delay tactics surrounding discovery and summary judgment motions, prevented Apotex from obtaining a judgment of non-infringement and invalidity of the Unasserted Stabilization Formulation Patents and the '156 patent before November 30, 2011.

b. Mylan.

244. On May 1, 2009, Mylan sent Pfizer a letter providing notice of Mylan's ANDA submission and intent to market a generic version of Lipitor, supplying a Paragraph IV certification as to the Unasserted Stabilization Formulation Patents and the '156 patent, and offering confidential access to certain portions of Mylan's ANDA. By June 15, 2009, Pfizer had filed an action against Mylan alleging infringement of only the '156 patent, and seeking a declaratory judgment of infringement of the Process Patents.

245. Mylan filed a motion for leave to file an amended answer containing counterclaims pertaining to the Unasserted Stabilization Formulation Patents, to obtain a declaration of noninfringement and/or invalidity with respect to them. In support of that effort, Mylan sought discovery regarding the Unasserted Stabilization Formulation Patents. Mylan's motion to compel discovery was granted by court order on August 25, 2010.

246. But Pfizer continued to refuse to supply Mylan with the discovery it required. Mylan was forced to file an emergency motion to enforce the court's discovery order.

247. To frustrate Mylan's continued efforts to obtain discovery and thus proceed with its counterclaims pertaining to the Unasserted Stabilization Formulation Patents, Pfizer, on August 30, 2010, hastily covenanted not to sue Mylan on them, hoping to moot Mylan's continued efforts to discover facts that would assist its counterclaims and the court's order of August 25, 2010 compelling that discovery.

248. The court expressed frustration with Pfizer's litigation tactics regarding the Unasserted Stabilization Formulation Patents, and enforced its order requiring Pfizer to supply discovery to Mylan pertaining to them:

> I'm granting Mylan's request. I'm very troubled by the conduct of Pfizer here with respect to this ongoing discovery dispute. The way I see it, if Pfizer wanted to provide a covenant not to sue, it was within its authority at any time to provide the covenant not to sue with respect to the formulation patents. For whatever reasoning only known to Pfizer, they waited until August 30th [2010] to give the covenants not to sue, which was perhaps not coincidently shortly after the issuance of the August 25th order granting the defendants' request for discovery * * * That's simply just not how this is supposed to work.

249. Pfizer continued to delay the progress of the case. In a November 20, 2010 letter to the court regarding Dr. Reddy's Laboratories Ltd.'s ("DRL") request to be heard at the *Markman* hearing in the Mylan patent litigation pertaining to the '156 patent, counsel for Mylan complained about Pfizer's continued dilatory tactics: "Pfizer uses DRL's request to be heard on the '156 patent as another opportunity to attempt to delay the Pfizer-Mylan cases."

250. Mylan also sought to remove Ranbaxy's blocking 180-day exclusivity period by way of a separate action against FDA seeking an order requiring FDA to determine whether or not Ranbaxy was entitled to a 180-day first-to-file marketing exclusivity.

c. Actavis.

251. In August of 2010, Pfizer sued Actavis Group hf, Actavis Inc., Actavis Elizabeth LLC and Actavis Pharma Manufacturing Private Ltd. (collectively "Actavis") after Actavis submitted to FDA an ANDA seeking approval to market generic Lipitor. Although Actavis had included the Unasserted Stabilization Formulation Patents in its Paragraph IV certification, Pfizer sued Actavis only for infringement of the '156 patent.

252. In September 2010, Actavis counterclaimed for declaratory judgment of invalidity and non-infringement of the Unasserted Stabilization Formulation Patents. Pfizer moved to dismiss

these counterclaims as unripe. In opposing that motion, Actavis argued that "Pfizer's listing of the [Unasserted Stabilization Formulation Patents] in the Orange Book and its refusal to litigate them creates patent uncertainty and indefinitely delays the approval of Actavis' ANDA," and noted that "[e]ven if Pfizer granted Actavis a covenant not to sue on the [Unasserted Stabilization Formulation Patents], however, it would not address the fact that Actavis is suffering from an indefinite delay in FDA approval of its ANDA and its concurrent inability to enter the market."

253. Actavis also argued that, by virtue of the Ranbaxy Delay Agreement and Pfizer's refusal to litigate the validity and infringement of its Unasserted Stabilization Formulation Patents, "Actavis is being restrained from the free exploitation of non-infringing goods, it is suffering exactly the type of injury-in-fact that is sufficient to establish Article III standing" (internal citations and quotations omitted).

254. Despite their efforts to do so, no ANDA filer was able to circumvent the Ranbaxy Delay Agreement between Pfizer and Ranbaxy by triggering Ranbaxy's 180-day marketing exclusivity prior to November 30, 2011.

3. The Ranbaxy Delay Agreement operated as an unlawful reverse payment agreement.

255. In summary, the Ranbaxy Delay Agreement was unlawful because it constituted an illegal reverse payment agreement pursuant to which Pfizer effectively paid substantial monies to its competitor, Ranbaxy, through a release of liability worth hundreds of millions of dollars (and disguised by a cynical $1 million payment from Ranbaxy back to Pfizer) which far exceeds any valuation of avoided litigation costs or fair value for goods or services, all in exchange for the delay of market entry for generic atorvastatin calcium by Ranbaxy. Ranbaxy could never have seen release of this *Accupril* liability through any judgment it might obtain in *Lipitor* litigation. The parties also violated antitrust law through the Ranbaxy Delay Agreement by conspiring to hinder and

frustrate the efforts of other would-be generic competitors in the market for generic atorvastatin calcium.

256. There was no cognizable, non-pretextual procompetitive justification for the Ranbaxy Delay Agreement, nor was there for the substantial financial inducement flowing to Ranbaxy under the Agreement. Even if there were some conceivable justification, the Ranbaxy Delay Agreement, and the payments flowing to Ranbaxy under the Agreement, was not reasonably necessary to achieve it.

257. The defendants did not need to resort to payments from Pfizer to Ranbaxy in order to resolve their patent litigation. According to FTC analyses, in 2004 and 2005, a majority of agreements between brand and generic manufactures settling patent disputes contained no anticompetitive payment from the brand to the generic manufacturer. Like the parties to such agreements identified by FTC, were it not for the anticompetitive payment from Pfizer to Ranbaxy, if defendants would have entered into an agreement at all, they would have entered into an agreement providing that Pfizer would not compensate Ranbaxy for delay, and that Ranbaxy would enter far earlier than the Ranbaxy Delay Agreement provided.

INTERSTATE COMMERCE

258. The defendants' efforts to monopolize and restrain competition in the market for atorvastatin calcium have substantially affected interstate and foreign commerce.

259. At all material times, Pfizer manufactured, promoted, distributed, and sold substantial amounts of branded Lipitor in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Beginning around November 30, 2011, Ranbaxy did the same with respect to generic Lipitor.

260. At all material times, Pfizer transmitted funds, 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 branded Lipitor. Beginning around November 30, 2011, Ranbaxy did the same with respect to generic Lipitor.

261. In furtherance of their efforts to monopolize and restrain competition in the market for atorvastatin calcium, the defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of the defendants were within the flow of and have substantially affected interstate commerce.

MONOPOLY POWER AND MARKET DEFINITION

262. At all relevant times, Pfizer had monopoly power over atorvastatin calcium because Pfizer had the power to maintain the price of atorvastatin calcium at supracompetitive levels without losing substantial sales.

263. A small but significant, non-transitory price increase by Pfizer to Lipitor would not have caused a significant loss of sales such that the price increase was not profitable.

264. Lipitor does not exhibit significant, positive cross-elasticity of demand with respect to price, with any product other than AB-rated generic versions of Lipitor (defined to include an authorized generic).

265. Due to the federal and state statutes and regulations governing the marketing of brand and generic drugs, industry practices and Lipitor's use and varying ability to inhibit the production of cholesterol, Lipitor is differentiated from all products other than AB-rated generic versions of Lipitor.

266. Pfizer needed to control only Lipitor and its AB-rated generic equivalents, and no other products, in order to maintain the price of Lipitor profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Lipitor would render Pfizer unable to profitably maintain its current prices of Lipitor without losing substantial sales.

267. Pfizer also sold branded Lipitor at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

268. The defendants have had, and exercised, the power to exclude generic competition to branded Lipitor.

269. The defendants, at all relevant times, enjoyed high barriers to entry with respect to branded and generic Lipitor.

270. To the extent that the direct purchasers are legally required to prove monopoly power circumstantially by first defining a relevant product market, they allege that the relevant market is all atorvastatin calcium products — *i.e.*, Lipitor (in all its forms and dosage strengths) and AB-rated bioequivalent atorvastatin calcium products. During the period relevant to this case, the defendants have been able to profitably maintain the price of Lipitor well above competitive levels.

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

272. Pfizer's market share in the relevant market was 100% at relevant times.

MARKET EFFECTS

273. Ranbaxy began to ship generic Lipitor to direct purchasers and other members of the proposed Direct Purchaser Class on or shortly before November 29, 2011, prior to receiving formal, written final approval of its ANDA from FDA. Ranbaxy informed the direct purchasers and other members of the Direct Purchaser Class that such shipments of generic Lipitor were subject to "quarantine," meaning that the generic Lipitor could not be resold until FDA's issuance to Ranbaxy of formal, written ANDA approval.

274. FDA delayed issuing written approval for Ranbaxy's ANDA until November 30, 2011, because FDA was informed that the Ranbaxy Delay Agreement prevented Ranbaxy from selling generic Lipitor until November 30, 2011. Ranbaxy's ANDA was in an approvable condition well before November 30, 2011 and, were it not for the Ranbaxy Delay Agreement, would have

received final FDA approval at a much earlier time. By practice FDA organizes its priorities around "rate limiters," and the Ranbaxy Delay Agreement was a rate limiter that caused FDA to wait until November 30, 2011 to issue formal, written approval to Ranbaxy's ANDA.

275. The acts and practices of Pfizer alone, and of Pfizer and Ranbaxy working together, had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Lipitor from generic competition for a substantial period of time until November 30, 2011 and such later time as the effects of suppressed generic competition will abate. The defendants' actions allowed Pfizer to maintain a monopoly and exclude competition in the market for atorvastatin calcium, to the detriment of the Direct Purchasers and all other members of the proposed Direct Purchaser Class.

276. But for defendants' overarching anticompetitive scheme, Ranbaxy, an authorized generic, and one or more other generic competitors would have begun selling AB-rated generic versions of Lipitor sooner than November 30, 2011, when Ranbaxy launched. As a direct and proximate result of the defendants' overarching anticompetitive scheme, in whole or in part, Ranbaxy or one or more generic competitors were delayed from launching generic Lipitor earlier than they did.

277. Ranbaxy and the other ANDA applicants seeking to market generic Lipitor had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, manufacturing commercial launch quantities adequate to meet market demand, marketing generic pharmaceutical products, and paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

278. As a result of the delay in generic Lipitor competition brought about by the defendants' overarching anticompetitive scheme, the Direct Purchasers and the members of the

proposed Direct Purchaser Class paid more for atorvastatin calcium than they would have paid absent the defendants' illegal conduct.

279. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, some or all of the direct purchases of branded drugs are rapidly substituted for 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.

280. This price competition enables all direct 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 or a lower price than they would have paid otherwise. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and direct purchasers experience substantial overcharges from that delay.

281. If generic Lipitor competitors had not been unlawfully prevented from earlier entering the market and competing with the defendants, the direct purchasers and members of the Direct Purchaser Class would have paid less for atorvastatin calcium by (a) substituting purchases of less-expensive AB-rated generic Lipitor for their purchases of more-expensive branded Lipitor, (b) paying less for their remaining branded Lipitor purchases, and (c) purchasing generic Lipitor at lower generic prices sooner.

282. Moreover, due to the defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic versions of Lipitor.

283. The defendants' unlawful conduct deprived the direct purchasers and the members of the Direct Purchaser Class of the benefits of competition that the antitrust laws were designed to ensure.

ANTITRUST IMPACT

284. During the relevant period, the direct purchasers and members of the proposed Direct Purchaser Class purchased substantial amounts of Lipitor from Pfizer, and substantial amounts of generic Lipitor from Ranbaxy. As a result of the defendants' illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for their atorvastatin calcium requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Lipitor was artificially inflated by defendants' illegal conduct and/or (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Lipitor sooner.

285. As a consequence, the direct purchasers and members of the Direct 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.

CLASS ACTION ALLEGATIONS

286. The direct purchasers, on behalf of themselves and all proposed Direct Purchaser Class members, seek damages, measured as overcharges, trebled, against the defendants based on allegations of anticompetitive conduct in the market for atorvastatin calcium, *i.e.*, branded Lipitor and its generic equivalents.

287. The direct purchasers bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a) and (b)(3), as representatives of a Direct Purchaser Class defined as follows:

> All persons or entities in the United States and its territories who purchased Lipitor or its AB-rated bioequivalent generic products directly from any of the defendants at any time during the period from no later than June 28, 2011, through and until the anticompetitive effects of defendants' conduct cease (the "Class Period").[8]

Excluded from the proposed Direct Purchaser Class are the defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

288. Members of the Direct Purchaser Class are so numerous that joinder is impracticable. The direct purchasers believe that there are numerous class members. Further, the Direct Purchaser Class is readily identifiable from information and records that are required by law to be maintained by the defendants.

289. The direct purchasers' claims are typical of the claims of the members of the Direct Purchaser Class. The direct purchasers and all members of the Class were damaged by the same wrongful conduct of the defendants, *i.e.*, they paid artificially inflated prices for atorvastatin calcium

[8] In defining the class as we have, the direct purchasers acknowledge that portion of this Court's order of September 2013 in which it cabined the available date on which damages may commence, i.e., June 28, 2011. That order related to this Court's dismissal of the *Walker Process* claim related to the '995 patent, a patent that (on its own or if re-issued) expired on June 28, 2011. The class definition in this revised complaint only starts the class period on that date.

However, the parties have not had an opportunity to brief or present argument to this Court on the consequences of the damages period in the event of a dismissal of some, but not all, claims from the prior complaint. The direct purchasers believe there is substantial evidence that "but for" Pfizer's illegal payment to Ranbaxy to delay entry of generic Lipitor, generic Lipitor could have become available earlier than June 28, 2011. When Pfizer and Ranbaxy negotiated the Ranbaxy Delay Agreement in June 2008, they could not have known with certainty whether the PTO would have reissued the '995 patent, and therefore, had they negotiated an agreement without the reverse payment, they likely would have settled for an entry date prior to June 28, 2011. The direct purchasers believe that an entry date prior to the expiration of a hotly disputed patent is also more consistent with *FTC v. Actavis*, *Inc.*, 133 S. Ct. 2223 (2013) -- entry on or about June 28, 2011 does not take into account all of the risk factors Pfizer faced that could have brought about entry earlier than that. *Id.* at 2231, 2235 ("Whether a particular restraint lies 'beyond the limits of the patent monopoly' is a *conclusion* that flows from that analysis and not, [], its starting point"; "the rationale behind a payment of this size cannot in every case be supported by traditional settlement considerations. The payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market"). The direct purchasers therefore reserve the right to raise this issue at the earliest possible time and amend the class definition if permitted by the Court.

and were deprived of the benefits of competition from cheaper generic versions of Lipitor as a result of defendants' wrongful conduct.

290. The direct purchasers will fairly and adequately protect and represent the interests of the Direct Purchaser Class. The interests of the direct purchasers are coincident with, and not antagonistic to, those of the Direct Purchaser Class.

291. The direct purchasers are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation. These lawyers have particular experience with class action antitrust litigation involving pharmaceutical products.

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

293. Questions of law and fact common to the Direct Purchaser Class include:

a. whether Pfizer willfully obtained and/or maintained monopoly power over Lipitor and its generic equivalents;

b. whether Ranbaxy entered into a contract, combination, and/or conspiracy with Pfizer to restrain trade and, if so, whether it should be evaluated under the "rule of reason" standard;

c. whether Pfizer and Ranbaxy, through their overarching anticompetitive scheme, unlawfully excluded competitors and/or potential competitors from the market for atorvastatin calcium, *i.e.*, Lipitor and its AB-rated generic bioequivalents (including an authorized generic);

d. whether the defendants unlawfully delayed or prevented generic manufacturers from coming to market in the United States with generic versions of Lipitor;

e. whether the defendants maintained monopoly power over atorvastatin calcium by delaying generic competition;

f. 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;

g. whether the activities of the defendants have substantially affected interstate commerce;

h. whether, and to what extent, the defendants' conduct caused antitrust injury (*i.e.*, overcharges) to the direct purchasers and the members of the proposed Direct Purchaser Class; and

i. the quantum of aggregate overcharge damages to the proposed Direct Purchaser Class.

294. 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, geographically dispersed persons or entities 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.

295. The direct purchasers know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

CLAIMS FOR RELIEF

COUNT I
VIOLATION OF 15 U.S.C. § 1
(Agreement in restraint of trade against all defendants)

296. The direct purchasers hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

297. This claim is pled against all defendants.

298. In 2008, Pfizer and Ranbaxy entered into the Ranbaxy Delay Agreement. Through that Agreement, Ranbaxy and Pfizer joined in an overarching anticompetitive scheme as co-conspirators. The Ranbaxy Delay Agreement is and was a contract, combination and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which were to: (a) allocate all sales of atorvastatin calcium in the United States to the Pfizer defendants until November 30, 2011; (b) prevent the sale of any generic version of atorvastatin calcium in the United States until November 30, 2011; and (c) fix the price at which the direct purchasers and all members of the proposed Direct Purchaser Class would pay for atorvastatin calcium.

299. Under the Ranbaxy Delay Agreement, Pfizer paid Ranbaxy financial inducements through large and unexplained payments that vastly exceed the cost of avoided litigation and are not otherwise explained by the value of any services provided by Ranbaxy to Pfizer (other than Ranbaxy's agreement to delay launching its generic Lipitor). There are no valid, procompetitive justifications for the Ranbaxy Delay Agreement. In exchange for these payments, Ranbaxy agreed to, and did, delay introduction of its generic Lipitor.

300. The Ranbaxy Delay Agreement harmed the direct purchasers and all members of the proposed Direct Purchaser Class.

301. The Ranbaxy Delay Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

302. Pfizer and Ranbaxy are each liable for the creation, maintenance, and enforcement of the Ranbaxy Delay Agreement, jointly and severally.

303. Pfizer and Ranbaxy are liable for the Ranbaxy Delay Agreement under the antitrust "rule of reason" standard.

304. There is and was no legitimate, non-pretextual, procompetitive business justification for the Ranbaxy Delay Agreement, nor for the compensation to Ranbaxy under the Agreement, that outweighs its harmful effect. Even if there were some conceivable and cognizable justification, the Ranbaxy Delay Agreement is and was broader than necessary to achieve such a purpose.

305. As a direct and proximate result of Pfizer's and Ranbaxy's anticompetitive conduct, the direct purchasers and all members of the proposed Direct Purchaser Class were harmed.

COUNT II
VIOLATION OF 15 U.S.C. § 2
(Conspiracy to monopolize against all defendants)

306. The direct purchasers hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

307. This claim is pled against all defendants.

308. Through the overarching anticompetitive scheme, including the Ranbaxy Delay Agreement and other misconduct as alleged herein, Pfizer and Ranbaxy conspired to maintain and enhance Pfizer's monopoly power in the relevant market.

309. Pfizer and Ranbaxy knowingly and intentionally conspired to maintain and enhance Pfizer's monopoly power in the relevant market.

310. Pfizer and Ranbaxy specifically intended that the overarching anticompetitive scheme would maintain Pfizer's monopoly power in the relevant market, and injured the Direct Purchasers and all member of the proposed Direct Purchaser Class.

311. Pfizer and Ranbaxy each committed at least one overt act in furtherance of the conspiracy.

312. As a direct and proximate result of Pfizer's and Ranbaxy's illegal and monopolistic conduct, the direct purchasers and all members of the proposed Direct Purchaser Class were harmed.

COUNT III
VIOLATION OF 15 U.S.C. §§ 1 and 2
(Against defendants as stated in prior complaint)

313. The claims of this count are re-stated for purposes of preserving appellate rights.

314. The direct purchasers hereby incorporate the allegations, paragraphs, claims, and demand for judgment of the prior Consolidated Direct Purchaser Complaint as if fully set forth herein. That prior complaint is attached as exhibit A.

315. The direct purchasers understand that this Court dismissed this count in its ruling of August of 2013. It is restated here for purposes of preserving appellate rights.

DEMAND FOR JUDGMENT

WHEREFORE, the direct purchasers, on behalf of themselves and the proposed Direct Purchaser Class, respectfully demand that the Court:

A. Determine 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 direct purchasers as the representatives of the Direct Purchaser Class;

B. Enter joint and several judgments against the defendants and in favor of the direct purchasers and the proposed Direct Purchaser Class;

C. Award the proposed Direct Purchaser Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and

D. Award the direct purchasers and the proposed Direct Purchaser Class their costs of suit, including reasonable attorneys' fees as provided by law.

JURY DEMAND

Pursuant to Fed. Civ. P. 38, the direct purchasers, on behalf of themselves and the proposed Direct Purchaser Class, demand a trial by jury on all issues so triable.

Dated: October 14, 2013

Respectfully submitted,

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