UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

SOUTHEAST LABORERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated,

Plaintiff,

v.

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC, RANBAXY LABORATORIES LIMITED, RANBAXY INC., AND RANBAXY PHARMACEUTICALS INC.,

Defendants.

Case No. _____

Jury Trial Demanded

CLASS ACTION COMPLAINT

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I. INTRODUCTION

1. In 1987, the U.S. Patent and Trademark Office (the "PTO") granted Warner-Lambert a patent (U.S. Patent No. 4,681,893, the "Original Lipitor Patent" or the "'893 Patent") for a racemic mixture[1] that inhibited the production of cholesterol. With subsequent extensions, this patent guaranteed over thirteen years of market exclusivity for Warner-Lambert's statin Lipitor.

2. But Warner-Lambert was not satisfied with the statutory norm. Two years after receiving the original Lipitor patent, Warner-Lambert tried to separately patent atorvastatin, the active ingredient in Lipitor and one of the enantiomers in the racemic mixture that Warner-Lambert had already patented.

3. Warner-Lambert knew that atorvastatin would be separately patentable only if it had a surprising quality. Data generated during Lipitor's development showed atorvastatin to be utterly ordinary, however, so Warner-Lambert defrauded the PTO in order to obtain the follow-on patent.

4. Warner-Lambert fraudulently claimed that the isolated enantiomer atorvastatin was, "surprisingly," ten times more active than the racemic mixture, when one skilled in the art would have expected only a two-fold difference in activity. To support its contention, Warner-Lambert submitted an unscientific conglomeration of data points that were cherry-picked from over a dozen separate tests performed in different formulations over several years. Oblivious to Warner-Lambert's deception, the PTO relied on the corrupted data and issued the duplicative follow-on patent (U.S. Patent Number 5,273,995, the "'995 Enantiomer Patent" or the "'995 Patent" or "follow-on patent") for the isolated enantiomer.

[1] A racemic mixture contains an equal amount of two enantiomers; enantiomers have the same chemical formula but are arranged as mirror images.

5. Armed with the duplicative follow-on patent, which it knew was invalid and/or unenforceable, and driven by the massive profits that Pfizer reaped each day that Lipitor maintained its market exclusivity, Pfizer prosecuted patent infringement litigation to keep generic Lipitor off the market for as long as possible. Pfizer used the fraudulently-obtained patent to delay the efforts of at least four generic manufacturers that sought approval to manufacture and sell generic Lipitor. Pfizer and Ranbaxy, one of the generic manufacturers that Pfizer sued, abandoned their adversarial positions and entered into an anticompetitive settlement to prolong Pfizer's monopoly on Lipitor and to allocate the market for the entrance of a generic bioequivalent.

6. This class action complaint seeks damages on behalf of all end-payors in the United States and its territories who indirectly purchased Lipitor and/or its generic bioequivalents during the period March 25, 2010 through and until the anticompetitive effects of Defendants' conduct cease, and who were injured by Defendants' anticompetitive actions. But for Warner-Lambert's fraud, the PTO would never have issued the follow-on patent—not at any time, not in any form. And but for the fraudulently-obtained follow-on patent and associated patent infringement litigation, generic Lipitor equivalents would have been available on or about March 24, 2010, the date on which the Original Lipitor Patent expired. Defendants' actions thus prevented the class from purchasing less-expensive generic Lipitor equivalents for at least twenty months, as it was not until November 30, 2011 that a generic bioequivalent was made available to consumers.

II. THE PARTIES

7. Plaintiff Southeast Laborers Health and Welfare Fund ("Southeast Laborers" or "Plaintiff") is a trust fund administered pursuant to the requirements of the Taft-Hartley Act, 29 U.S.C. § 186, by trustees appointed in equal numbers by labor representatives and union

representatives. Southeast Laborers is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. § 186(c)(5), and as defined by Sections 1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001, *et. seq*. As such, Southeast Laborers is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). Southeast Laborers' place of administration is located in Goodlettsville, Tennessee. During the class period, Southeast Laborers paid retail pharmacies for prescriptions filled by its members for Lipitor and/or its generic equivalents in Tennessee, Georgia, Alabama, Pennsylvania, and South Carolina, and was injured as a result of Defendants' misconduct.

8. Defendant Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware. Pfizer Inc. has a place of business at 235 East 42nd Street, New York, New York 10017.

9. Defendant Pfizer Ireland Pharmaceuticals is an Irish unlimited liability company with registered offices at Operations Support Group, Ringaskiddy, County Cork, Ireland. Pfizer Ireland Pharmaceuticals is a wholly-owned, indirect subsidiary of Pfizer Inc.

10. 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 Company and Pfizer began co-promotion of Lipitor, and in mid-2000, 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.

11. Throughout this complaint, Warner-Lambert Company and Warner-Lambert Company LLC are collectively referred to as "Warner-Lambert." The phrase "Warner-Lambert"

includes, but is not limited to, Warner-Lambert employees Bruce D. Roth, Joan Thierstein, and Jerry F. Janssen.

12. Defendants Pfizer Inc., Pfizer Ireland Pharmaceuticals, and Warner-Lambert are collectively referred to as "Pfizer."

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

14. Defendant Ranbaxy Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business located at 600 College Road East, Princeton, New Jersey, 08540. Ranbaxy Inc. is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

15. Defendant Ranbaxy Pharmaceuticals Inc. is a wholly-owned subsidiary of Ranbaxy Inc., with a place of business located at 9431 Florida Mining Boulevard East, Jacksonville, Florida 32257.

16. Defendants Ranbaxy Laboratories Limited, Ranbaxy Inc., and Ranbaxy Pharmaceuticals Inc. are collectively referred to as "Ranbaxy."

17. Defendants' actions, described below, were in furtherance of the alleged wrongdoing and were authorized, ordered, or performed by Defendants' officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

III. JURISDICTION AND VENUE

18. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the defendants.

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

20. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §1391(b) and (c), because Defendants transact business within this district and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

IV. LEGAL BACKGROUND

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

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

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

23. The FDA relies completely on the brand name manufacturer's truthfulness about patents' validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness.

1. The Hatch-Waxman Amendments

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

25. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Thus, bioequivalence demonstrates that the active ingredient of the proposed generic

[2] Generic manufacturers can also seek approval of non-AB-rated generics. The FDCA permits "hybrid" applications that are neither full NDAs containing safety and efficacy data, nor ANDA applications showing that the proposed product is the "same" as the NDA product. 21 U.S.C. § 355. Drug products approved under this section use a safe and effective active pharmaceutical ingredient, but modify the drug product so that it differs from the original NDA product in some way, either in dosage form, strength, route of administration, formulation, dosing regimen, or indication. These non-AB-rated generics are not bioequivalent to the innovator product. *See* 21 C.F.R. § 314.54.

drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

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

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

2. Paragraph IV Certifications

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

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

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

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

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

29. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of an ANDA simply by suing the ANDA applicant for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within forty-five 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 thirty months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market with its product.

30. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification gets a period of protection from competition with other generic versions of the drug. For Paragraph IV certifications made prior to December 2003, the first generic applicant is entitled to 180 days of market exclusivity. This means that the first approved generic is the only available generic for at least six months.

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

32. These regulations also permit the first generic applicant to delay the market entry of other generic manufacturers, as the first generic applicant can choose to not begin marketing

its drug (thereby delaying the start of the 180-day period of generic market exclusivity), and can collude with the brand name manufacturer to ensure that its patents are not invalidated.

B. The Benefits of Generic Drugs

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

34. There is an incentive to choose the less expensive generic equivalents in every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generics. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic products for more expensive branded ones. Health insurers are contractually obligated to pay for the bulk of their members' prescriptions, whether filled with branded or generic drugs, so they offer their members lower copays for generic drugs in order to encourage the use of generics. Members also face the threat of increased health insurance premiums if branded prescription drug costs continue to rise.

35. Once a generic equivalent hits the market, the generic quickly overtakes sales of the branded drug. More than 90% of prescriptions for drugs that are available in both branded and generic forms are filled with a generic. The speed with which generic drugs take over the market appears to be increasing: in a sample of drugs losing patent protection between 1991 and 1993, generics held, on average, a 44% market share after one year; by 2008, generic versions could capture as much as 86% to 97% of the market within the first month of availability.

36. Branded manufacturers are well aware of generics' steady erosion of their previously monopolized market. Branded manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any (illegal) means possible.

V. FACTUAL BACKGROUND

A. A Short Primer on Statins

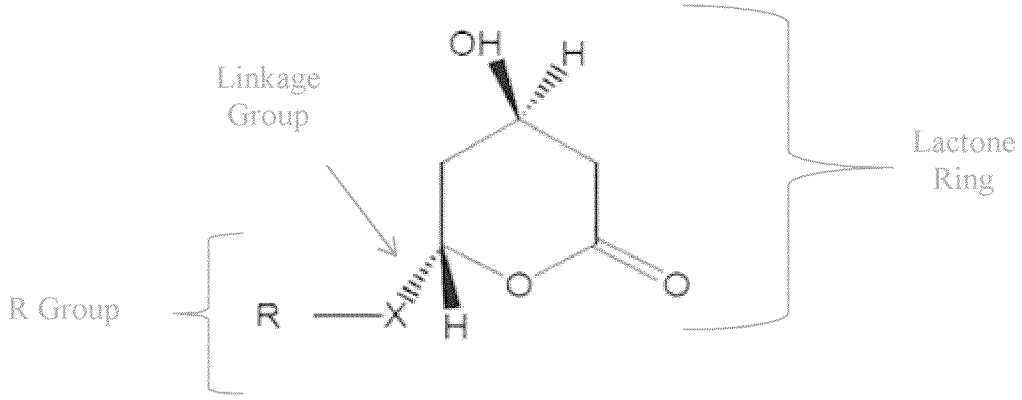
37. Lipitor belongs to a class of drugs called statins. Discovered in the 1970s, statins lower cholesterol by successfully inhibiting the liver enzyme 3-hydroxy 3-methylglutrayl-coenzyme A reductase ("HMG-CoA reductase"). HMG-CoA reductase controls the rate at which our bodies produce cholesterol; inhibiting HMG-CoA reductase reduces the production of cholesterol. High levels of cholesterol are thought to cause serious health problems, including coronary heart disease and atherosclerosis in some populations.

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

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

40. Statins consist of three structural parts: a lactone ring, a linkage group (denoted as "X"), and a group or groups connected to the linkage group (referred to herein as an "R group").

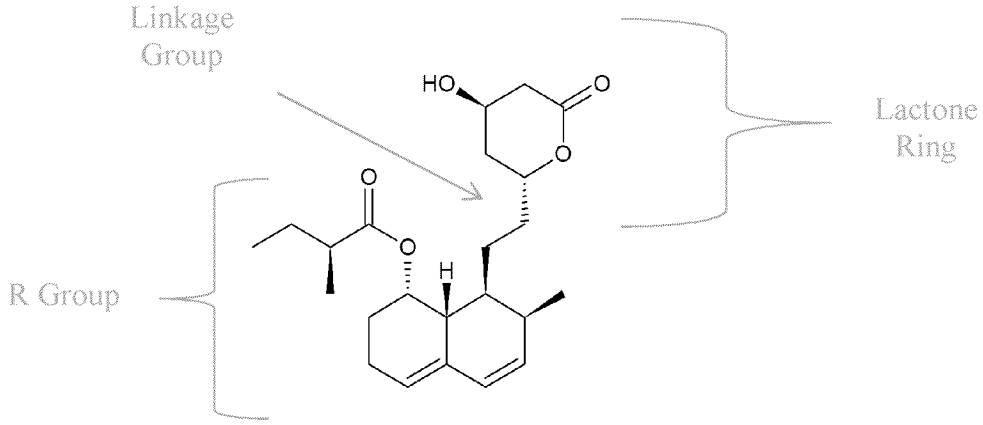
Figure 1: Generalized Structure of Statins[3]



41. The R group for the well-known statins can contain one or more single rings or fused rings, along with other substituent groups.

42. In the 1970s, researchers discovered that mevastatin, naturally occurring in red yeast and rice, inhibited cholesterol synthesis.

Figure 2: Mevastatin



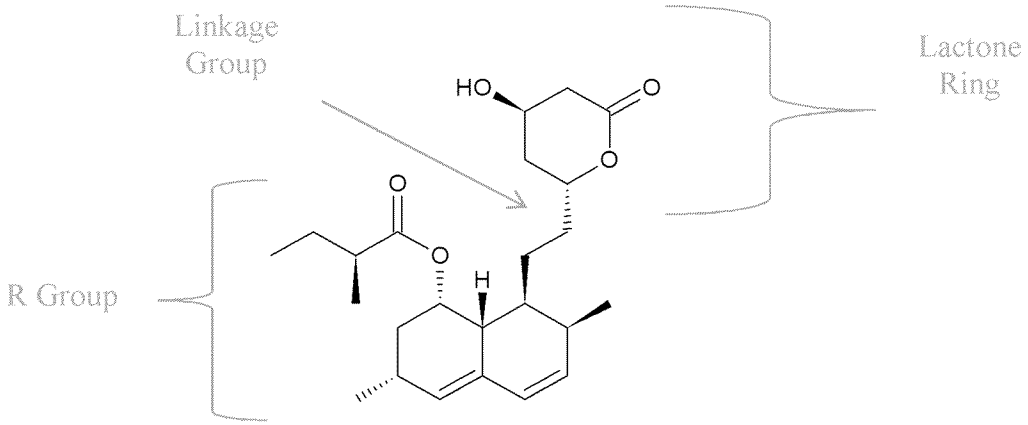
43. Mevastatin contains the lactone ring as shown in Figure 1, a linkage group, X (shown as), and an R group of two fused rings with substituents. One of the fused rings

[3] The three-dimensional structure of molecules can be represented pictorially in two dimensions using the following symbols to represent the orientation of the atoms in space: (solid wedge) indicates that the molecule is projecting out of the page; (dashed wedge) indicates that the molecule is projecting behind the page; — (solid line) indicates that the molecule is in the plane of the paper.

contains a methyl group (-CH_3, shown as) on the right ring and an additional O-linked substituent group on the left ring.

44. Around the same time, researchers discovered lovastatin, naturally occurring in red yeast rice and oyster mushrooms, was another highly potent HMG-CoA reductase inhibitor. In the early 1980s, Merck sought and gained approval for Mevacor, a brand name version of lovastatin, which became the first statin available in the United States.

Figure 3: Lovastatin



45. The structure of lovastatin is very similar to mevastatin. Lovastatin also contains a lactone ring and an R group joined to the lactone ring by a linkage group. Lovastatin's R group is similar to mevastatin's R group but has one additional methyl group.

46. In the early 1980s, Warner-Lambert sought to enter the market by developing a "me-too" version of the already-identified statins. Researchers at Warner-Lambert came up with a formulation that used the same lactone ring as mevastatin and lovastatin but contained different linked substituents as the R group. Warner-Lambert called their new statin "atorvastatin."

B. The Chemistry of Enantiomers

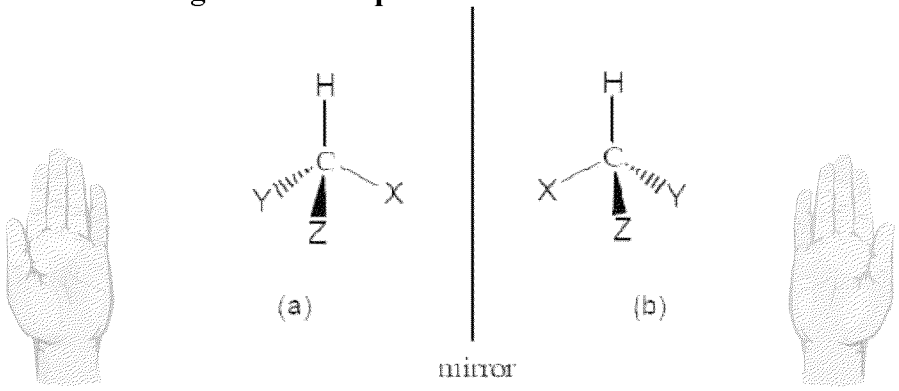
47. Some background on the chemistry of enantiomers is helpful to understand how the Original Lipitor Patent covered the compound that Warner-Lambert later sought to patent separately.

48. Isomers are two or more compounds with the same chemical formula (that is, containing the same atoms) but different arrangements of atoms. Stereoisomers are isomers in which the same atoms are bonded together, but where the three-dimensional configuration of those atoms differs.

49. Enantiomers are stereoisomers that are mirror images of each other and cannot be superimposed; they have the same atoms, bonded together in the same way, but one is arranged as a reflection of the other. Consider, for example, a left hand and a right hand.

50. Images (a) and (b) in Figure 4 below are enantiomers (where the carbon atom is the chiral center around which a compound's structure is built).

Figure 4: Example of Pair of Enantiomers



51. Pairs of enantiomers have many identical chemical and physical properties, such as shared melting points, solubility, and colors. Other properties, such as biological properties, may be vastly different.

52. Enzymes, including the cholesterol-producing HMG-CoA reductase, typically display a preference for interacting with one enantiomer over the other. It is common for one enantiomer to have all, or most, of the biological activity. The other enantiomer will have little or no biological activity.

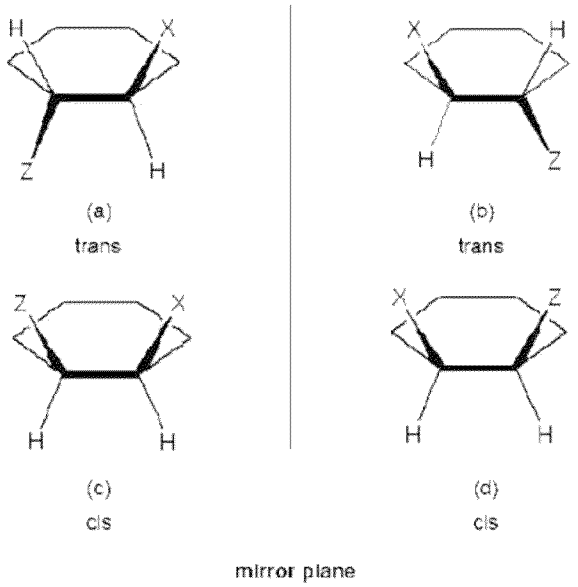
53. Enantiomers can be distinguished from one another by their effect on the rotation of polarized light. Enantiomers reflect polarized light in either a clockwise direction (right, denoted with a "+") or a counter-clockwise direction (left, denoted with a "-"). An unequal mixture of two enantiomers is optically active; the degree of optical rotation reflects the percentage of each enantiomer in the mixture. When equal mixtures of two enantiomers are present (called a racemic mixture or racemate), the optical rotations of the enantiomers cancel each other.

54. To differentiate enantiomers on paper, each enantiomer is assigned a configuration based upon priority rules that rank the atoms or substituent group of atoms that are attached to the compound's chiral center. If the priority proceeds in a clockwise direction, the enantiomer has an "R" (right) configuration; if the arrangement is counter-clockwise, the enantiomer has an "S" (left) configuration.

55. In addition to R/S and +/- configurations, a molecule's configuration can also reference the location of the substituent atoms or groups of atoms relative to each other. An arrangement where both the major substituents lie on the same side of the plane of reference is called a *cis* arrangement. An arrangement where the major substituents appear on the opposite

sides of the plane is called a *trans* arrangement. The placement of X and Z in the figure below demonstrates these cis and trans arrangements.

Figure 5: Examples of Cis and Trans Arrangements



56. The lactone rings found in statins have two chiral centers, one at the carbon atom attached to the hydroxyl group and the other at the carbon atom attached to the linkage group. Rings containing two chiral centers give rise to four possible isomers: the R-cisisomer ("R-cis"), the S-cisisomer ("S-cis"), the R-trans-isomer ("R-trans"), and the S-trans-isomer ("S-trans").

57. At the time Warner-Lambert was developing Lipitor, the preferred configuration for the lactone ring in a statin—that is, the configuration offering the highest level of cholesterol inhibition—was the R-trans configuration.[4] Both mevastatin and lovastatin have lactone rings in the R-trans configuration. In the case of HMG-CoA reductase inhibitors, the R-trans enantiomer appeared to be the active enantiomer that inhibited HMG-CoA reductase and reduced the production of cholesterol.

[4] *See, e.g.*, Alberts, A. *et al., J. Proc. Natl. Acad. Sci. USA* 1980, *77:*3957; Stokker, G.E., *et al., J. Med. Chem.* 1985, 28:347-358; Stokker, G.E. et al., *J. Med. Chem,* 1986, 29: 849-852.

C. Warner-Lambert Obtains the Original Lipitor Patent

58. On March 30, 1986, Warner-Lambert filed U.S. Patent Application No. 868867 for a group of compounds and pharmaceutical compositions useful as hypercholesterolemic and hypolipidemic agents. 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." This application eventually resulted in U.S. Patent No. 4,681,893 (the '893 Original Lipitor Patent).

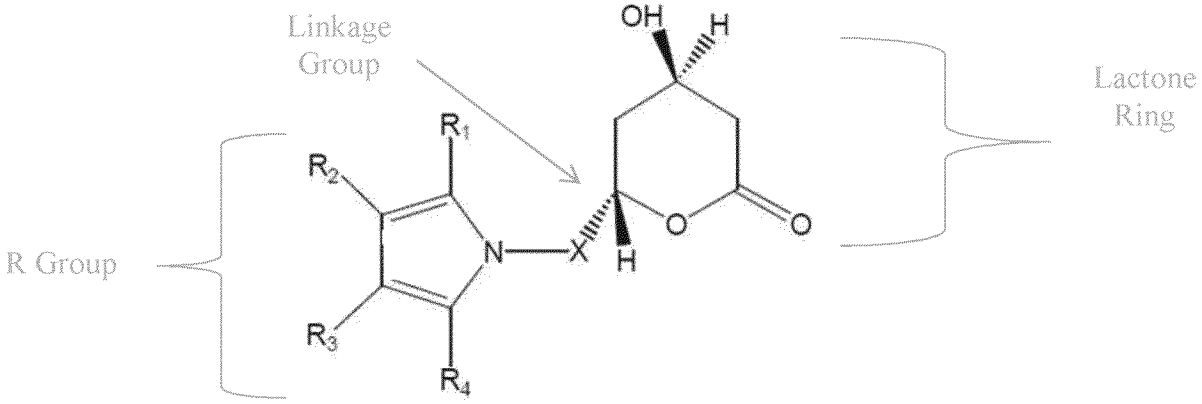
59. Dr. Bruce David Roth applied for the '893 Patent. Roth, who is not named as a defendant in this action, invented Lipitor. He was, at all relevant times, a leader of the drug discovery team at Warner-Lambert that developed Lipitor. Roth is the named inventor and patent applicant of both the '893 Patent and the '995 follow-on Patent. Both patents issued to Roth and were assigned to his employer, Warner-Lambert. Warner-Lambert's patent attorneys, including Jerry F. Janssen, prosecuted the application.

60. This lawsuit alleges that Warner-Lambert intentionally and affirmatively lied to the PTO regarding the material facts that enabled it to procure the follow-on patent as well as a later reissuance of that patent. That fraud included making misrepresentations about the Original Lipitor Patent. To understand that fraud, one must first understand the background, claims, and uses of the Original Lipitor Patent.

1. The Patent Specification for the Original Lipitor Patent

61. Warner-Lambert stated in the patent specification for the Original Lipitor Patent that "in its broadest aspect the present invention provides compounds of structural formula I."

Figure 6: Warner-Lambert's Structural Formula I



62. Like other statins, structural formula I contains a lactone ring, a linkage group (X), and an R group.

63. Consistent with conventional thinking at the time, Warner-Lambert's application for the Original Lipitor Patent contemplated the trans-form of compounds in structure formula I, including Warner-Lambert's "me-too" statin, atorvastatin. Furthermore, the application contemplated atorvastatin in a variety of formulations, including calcium salts.

64. Warner-Lambert claimed that the disclosed compounds were "useful as hypocholesterolemic or hypolipidemic agents by virtue of their ability to inhibit the biosynthesis of cholesterol through inhibition" of the HMG-CoA reductase enzyme. For support, the specification detailed the biological activity of three compounds as compared to the prior art.

65. Research in the 1980s demonstrated that statin molecules with open lactone rings were highly potent cholesterol synthesis inhibitors—often more potent than the closed lactone ring forms of the same molecules. Warner-Lambert claimed that the invention contemplated the hydroxyl acids, or structural formula I, with an open lactone ring:

> Also contemplated as falling within the scope of the present invention are the hydroxyl acids, and pharmaceutically acceptable salts thereof, derived from the opening of the lactone ring of the compounds of structural formula I above.

66. Importantly, *Warner-Lambert's patent application specifies and covers a compound in which the R-trans enantiomer is isolated:*

> The compounds of structural formula I above possess two asymmetric carbon centers, one at the 4-hydroxy position of the pyran-2-one ring, and the other at the 6-position of the pyran-2-one ring where the alkylpyrrole group is attached. This asymmetry gives rise to *four possible isomers*, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans- and S-trans-isomers. This invention contemplates only the trans- form of the compounds formula I above.

Emphasis added.

67. Neither Warner-Lambert nor Pfizer has ever disputed that the patent coverage of the Original Lipitor Patent for atorvastatin calcium, *i.e.*, a compound having the structural formula I, included versions in which the R-trans enantiomer is isolated. As the inventor of Lipitor testified, the compounds disclosed in the '893 application and covered by the Original Lipitor Patent were not limited to any particular stereochemistry; "this one structure is meant to represent four different stereo isomers," the R-trans, S-trans, R-CIS, and S-CIS isomers of atorvastatin acid.

2. The PTO Issues the Original Lipitor Patent

68. On July 21, 1987, the PTO issued the '893 Original Lipitor Patent. 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. Later extensions, discussed below, lengthened this period of patent protection until March 24, 2010.

69. The '893 Patent contemplated the future ability to have only 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.

70. Although the '893 Patent covered multiple formulations of structural formula I, Warner-Lambert focused on developing and commercializing atorvastatin, the R-trans enantiomer of a particular compound with structural formula I, in calcium salt form.

71. The '893 Patent thus covered atorvastatin calcium, the product that Warner-Lamber would sell as Lipitor.

D. Warner-Lambert Obtains by Fraud the '995 Enantiomer Patent

72. Although the '893 Patent would (and did) provide Warner-Lambert with many years of patent protection—and many years of exclusive sales of Lipitor—Warner-Lambert nevertheless sought to extend this monopoly by using any means, including fraud.

73. Warner-Lambert knew that the PTO would reject an application to patent the enantiomer of the racemic mixture of atorvastatin because enantiomers of the chemical were already covered by the '893 Patent; an enantiomer "invention" would be either anticipated by the '893 Patent or obvious in light of the '893 Patent. Thus, the only way that Warner-Lambert could bypass the PTO's restrictions and procure a follow-on enantiomer patent was to convince the PTO that the isolated R-trans enantiomer had some "surprising" or "unexpected" characteristic.

74. Senior management at Warner-Lambert instructed the Warner-Lambert researchers to review the pre-existing biologic data for the R-trans enantiomer to find some data that supported a claim that the activity of the isolated R-trans enantiomer was "surprising," and therefore patentable.

75. Warner-Lambert senior management asked Roth whether the pure R-trans enantiomer had patent coverage. When Roth responded that the R-trans enantiomer was covered under the '893 Patent, senior management asked whether there was anything about the pure R-trans enantiomer that would make it patentable in and of itself. Roth indicated that he was

unaware of any surprising characteristics that had unfolded over his years of working with the R-trans enantiomer atorvastatin. Don Maxwell, the vice president of discovery research, subsequently assigned him the task of reviewing existing laboratory books to see whether he could find any data that could be portrayed as showing something surprising about the R-trans enantiomer. Roth was instructed to provide any surprising data to Wyeth patent attorney Joan Thierstein.

76. Regarding the instructions from these senior Warner-Lambert officials, Roth has stated,

> [I]f I found something surprising I would provide that. And what I did do was I provided that information to the patent attorney for Warner-Lambert and asked if that was sufficient, and it was and so that was the data that was used.

77. Of course, when senior Warner-Lambert management sent Roth back to the old laboratory notebooks to "find" something surprising, there was a wealth of knowledge in the scientific community about statins and the formulation of isolated R-trans enantiomers. This state-of-the-art understanding of statin formulations gives context to Warner-Lambert's fraud.

1. The State of the Art: Knowledge of One Skilled in the Art of Statins in 1989

78. Statins are in the field of synthetic organic chemistry as it applies to the discovery of compounds suitable for use as drugs directed to the regulation of the cholesterol biosynthetic pathway and HMG-CoA reductase inhibitors. One of ordinary skill in the art of statins would possess at least a bachelor's degree in organic or medicinal chemistry; a general working knowledge of statins; several years of bench work in organic molecule synthesis; some general knowledge of biochemistry and enzymology; knowledge of stereochemistry of pharmaceutically active compounds; and knowledge of resolving racemates.

79. In 1989, when Warner-Lambert applied for a patent for the isolated R-trans enantiomer, one skilled in the art would have been knowledgeable about the biological pathway for the synthesis of cholesterol, including that HMG-CoA reductase is the rate-limiting enzyme in the biological pathway for cholesterol produced in an organism. One skilled in the art would also have known that statins were potent inhibitors of HMG-CoA reductase, and that the scientific literature had described *in vitro* assays as methods for testing a compound's ability to inhibit cholesterol synthesis.

80. One skilled in the art would have been aware that mevastatin (compactin) is a natural HMG-CoA reductase inhibitor that exists as a single enantiomer. One would also have been aware that lovastatin (mevinolin), another potent inhibitor of HMG-CoA reductase, had been isolated and was structurally very similar to compactin. One would also have known that both mevastatin and lovastatin have lactones in the R-trans configuration.

81. One skilled in the art would also have been aware that pravastatin (1979), symvastatin (1981), and fluvastatin (mid-1980s) were developed/isolated prior to 1989.

82. One skilled in the art would have understood that pharmaceutical research into improved inhibitors of HMG-CoA reductase was focused on analogues of known statins. One would have been aware that researchers were focused on retaining the lactone ring in known statins while investigating substitutions on the remainder of the molecule.

83. One skilled in the art would have known that the ring-opened form of the upper lactone portion of the previously discovered statins is significantly more active in inhibiting HMG-CoA reductase than the lactone (closed-ring) form.

84. One skilled in the art would have known that HMG-CoA reductase inhibitors are enantiomeric, and that one enantiomer is likely to be more active than the other. One would

have known that the biological activity of a racemate in a biological system can be quite different from that of a single enantiomer, and that one enantiomer is approximately twice as active as the racemate in terms of its operation in a target biological system (*i.e.*, one enantiomer is the "active" isomer, while the other is "inactive," and thus the active enantiomer is about twice as active as the racemic mixture). One would also have known that it is desirable to separate and remove the less active enantiomer.

85. In 1989, one skilled in the art would have known that, in the case of HMG-CoA reductase inhibitors, the R enantiomer was very likely to be the active enantiomer and, conversely, that the S enantiomer was very likely to be inactive. One would have known that these expected activities could be known with certainty by isolating and testing the activity of the enantiomers.

86. One skilled in the art would have understood that racemic mixtures can be separated or resolved into the individual enantiomers by well-known methods of separation or resolution. Similarly, one would have been aware that single enantiomers can be isolated by chiral or achiral synthesis.

87. One skilled in the art would have known that it was common practice among medicinal chemists and others working in the drug discovery field in 1989 to use a single structural formula to represent both enantiomer individually as well as mixtures of enantiomers. One would have been similarly aware that whether a diagram depicting the structural form for a molecule or class of molecules shows a particular stereochemistry configuration (whether absolute or relative) depends on the context in which the diagram appears. One would have known that if a diagram of a single enantiomer was intended to depict a racemate, to the

exclusion of the enantiomer, it was possible to add an additional descriptor, such as (+/-), RS, or ('rac'), which would make it clear that the structure represented only a racemate.

88. One skilled in the art, given the Original Lipitor Patent, would have known that compounds in the structural formula I were racemic, that there were a discreet number of enantiomers possible from the structural formula, and that there were known methods for dissolving the racemic mixture into the enantiomers.

2. Warner-Lambert Fraudulently Claims That the R-Trans Enantiomer is Ten Times More Active than the Racemate

89. On July 21, 1989—two years to the day after the '893 Patent issued—Warner-Lambert and Roth applied for a patent for the R-trans enantiomer, *i.e.*, for the R-trans form of the ring-opened acid described in the '893 Patent: [R-(R*R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid and "its lactone form and salts thereof." (U.S. Patent Application No. 384187.) This application would eventually lead (albeit by fraud) to the issuance of the '995 Enantiomer Patent.

90. Roth was the "inventor" and applicant for the patent. As part of the application, Roth provided a declaration acknowledging his duty to disclose information material to the examination of the application to the PTO, pursuant to 37 C.F.R. §§ 1.56-1.63. Roth appointed Warner-Lambert's patent attorneys as his attorneys/agents and authorized them to prosecute the application. He further directed that all correspondence related to the patent application be sent to Warner-Lambert attorney Joan Thierstein. The application itself was signed and submitted by Elizabeth M. Anderson, a Warner-Lambert employee.

91. Warner-Lambert, including Thierstein, Anderson, and Roth, prosecuted the application from 1989 to 1993.

92. In the application, Roth and Thierstein claimed, "[i]t is now *unexpectedly found* that the enantiomer having the R form of [a] ring-opened acid [described in the '893 Patent] . . . *provides surprising inhibition* of the biosynthesis of cholesterol." (Emphasis added). Roth and Thierstein further claimed that "an ordinarily skilled artisan may not predict the *unexpected and surprising inhibition* of cholesterol biosynthesis of the present invention in view of [prior] disclosures." (Emphasis added). In support of this contention, Warner-Lambert presented only one piece of evidence: a short table stating that Warner-Lambert's Cholesterol Synthesis Inhibition ("CSI") assay data demonstrates the R-trans enantiomer is *one hundred-times more active* than the S-trans enantiomer, and *ten-times more active* than the racemate, in inhibiting the synthesis of cholesterol *in vitro* ("CSI Table"):

Figure 7: Specification CSI Table

is now also incorporated by reference therefor. The CSI data of the compound I, its enantiomer the compound II and the racemate of these two compounds are as follows:

Compound	IC_{50} (micromoles/liter)
[R-(R*R*)] isomer	0.0044
[S-(R*R*)] isomer	0.44
Racemate	0.045

Accordingly, the present invention is the pharmaceutical composition prepared from the compound of the formula I or II or pharmaceutically acceptable salts thereof.

93. Warner-Lambert claimed the "present invention"—the R-trans enantiomer—based on the data presented in the CSI table.

94. A CSI assay measures the ability of a compound to inhibit cholesterol biosynthesis along the entire cholesterol biosynthesis pathway and is one of the most commonly

used methods to test a compound's ability to inhibit the synthesis of cholesterol *in vitro*.[5] The results of a CSI assay are reported as an IC_{50} value, the concentration of a test compound that produces 50% inhibition in the conversion of cholesterol-[^{14}C] acetate to radioactive cholesterol. The CSI assay does not identify the specific step in the cholesterol biosynthetic pathway that is being inhibited, nor is it specific to HMG-CoA reductase.

95. One skilled in the art of statins in 1989—and indeed one skilled in the art even today—would have expected the active R-trans enantiomer to be about twice as active as the racemate in inhibiting cholesterol synthesis. After all, the racemic mixture is simply the active enantiomer evenly combined with the inactive enantiomer (and thus equal amounts of each enantiomer yield an active enantiomer that is twice as active as the mixture).

96. It would indeed be "unexpected" and "surprising" if the activity of one enantiomer were truly *ten times* that of the racemic mixture. In fact, it would be an extraordinary development in the science of stereochemistry. In reality, Warner-Lambert's claim was a deliberate misrepresentation intended to overcome the statutory limitations governing follow-on patents.

a. The CSI Table Is Misleading and Affirmatively False

97. Warner-Lambert's biologic data—the CSI Table—was both affirmatively false and presented in an intentionally misleading manner. The CSI Table purports to present reliable scientific data. It does not. Rather, it contains limited data, cherry-picked from multiple flawed tests conducted over several years using different formulations of various atorvastatin salts. The

[5] Two other commonly used methods of measuring a compound's inhibition of cholesterol are the *in vivo* Acute Inhibition of Cholesterol Synthesis ("AICS") assay and the *in vitro* CoA Reductase Inhibition ("COR") assay. The COR assay measures a compound's ability to inhibit HMG-CoA reductase specifically, and is typically used to confirm that the activity seen in the CSI assay is attributable to inhibition of the desired target: HMG-CoA reductase.

reliable data actually shows that the R-trans enantiomer is, as expected, only about two times more active than the racemic mixture—far from the "surprising" tenfold increase that Warner-Lambert claimed.

(1) The CSI Table is Misleading

98. Warner Lambert's CSI Table is misleading because it purports to present reliable and confirmed data but does not do so. The CSI Table does not disclose the source of its data and fails to indicate the number of CSI assays performed, the degree of variation in the test results, what molecules were tested, the time period over which the assays were run, or whether the results presented were drawn from multiple tests. A skilled addressee would likely conclude, therefore, the data had been confirmed by a number of repeat assays and that the CSI Table fairly depicted all relevant data.

99. Warner-Lambert claimed in subsequent litigation that the CSI Table was created by averaging the results of all available CSI screens. This is not true. Warner-Lambert ran a number of CSI assays—over a multi-year period and on various salt formations—as it tested the R-trans enantiomer of structural formula I before applying for the '893 Patent. The results fluctuated wildly. Rather than averaging these assays, Warner-Lambert cherry-picked from among the results in order to generate a table that supported its claim of "surprising activity."

100. For example, the CSI Table combines results from a number of different CSI assays and compares them to a separate CSI assay. This was contrary to accepted scientific practice in the 1980s, which called for repeated head-to-head tests when providing data of the kind found in the CSI Table. Roth himself has repeatedly acknowledged that head-to-head testing provides the best way to compare quantitative differences in activity. However, the data presented to the PTO for the R-trans enantiomer and S-trans enantiomer were taken from a single run of the same experiment: CSI 120. And, in bizarre contrast, the data collected for the

racemate represents an "average" of five separate assays: CSI 92, CSI 93, CSI 95, CSI 102, and one of three recorded values from CSI 118.

Figure 8: Sources for Specification CSI Table

Compound	IC 50 (micromoles/liter)
R-trans Enantiomer	.0044
S-trans Enantiomer	.44
Racemate	.045

Source	Original Form	IC 50 (micromoles/liter)
CSI 120	Sodium Salt	.00444
CSI 120	Sodium Salt	.44
CSI 92	Lactone	.0346
CSI 93	Lactone	.0275
CSI 95	Lactone	.0631
CSI 102	Lactone	.0912
CSI 118	Sodium Salt	.0097

101. Moreover, the five "averaged" assays for the racemate were conducted over a three-year period from July 1985 through October 1988. Calculating an average across different days and experiments was not, and is not, consistent with accepted scientific practices. The results of these five experiments reported for the racemate are so variable that they cannot be averaged together with any reliability or scientifically meaningful result.

102. It is also inconsistent with accepted pharmaco-chemistry to "average" the results of CSI values derived from both opened lactones and separately synthesized sodium salts, as was done here. Four of the assays reflected in the racemate data in the CSI Table (CSI 92, 93, 105, 102) started with the lactone (unopened) form of racemic atorvastatin and were treated with

sodium hydroxide to open the lactone ring and to create a sodium salt during the testing process. The fifth assay (CSI 118) started with chemically synthesized sodium salt of racemic atorvastatin prepared by a medicinal chemist.

103. One skilled in the art in 1989 would have been aware that if lactone rings do not fully open when exposed to sodium hydroxide, the presence of inactive material will result in a higher IC 50 value, indicating that the compound is less active than it actually is. One skilled in the art would also have expected that the IC 50 values for the racemic lactones in each of the four CSI assays would be similar, not report a threefold difference (from .02 (CSI 93) to .09 (CSI 102)). One skilled in the art would also have expected that the IC 50 values for the racemic lactones would be similar to the value of the racemic sodium salt, not report a tenfold difference (from .009 (CSI 118) to .09 (CSI 120)). Such disparate values suggest that not all of the lactone rings opened during the test and/or other solubility issues that compromise the accuracy of the data.

104. Notwithstanding that accepted scientific standards reject the use of the average value, the CSI Table does not even constitute a true average. Though available, Warner-Lambert did not include all results from all conducted CSI assays, omitting the results from at least nine other CSI tests, including CSI 107, CSI 111, CSI 112, CSI 119, CSI 122, CSI 123, CSI 124, CSI 136, and CSI 138.

Figure 9: CSI Data (IC 50 in micromoles/liter)

CSI#	Date	Racemic Lactone	R-trans Lactone	S-trans Lactone	Racemic Sodium Salt	R-trans Sodium Salt	S-trans Sodium Salt	Racemic Calcium Salt	R-trans Calcium Salt	S-Trans Calcium Salt
92	7/24/85	.0346								
93	8/27/85	.0275								
95	10/15/85	.0631								
102	1/15/87	.0912								
107	7/20/87		.0355	.631						
111	2/25/88							.0024		
112	3/28/88							.0776		
118*	10/24/88				.00977			.257	.0251	> 1.0
					.00913			.234	.0216	
119	11/15/88							.00324		
120	2/2/89					.00498	.444			
122	4/21/89					.00313				
123	5/31/89								.00948	
124	6/12/89				.001					
136	7/31/91					.0322				
138	1/31/95					.0169				

* = test calculated multiple values using different methods.

Blue = Roth used in CSI table

Yellow = Roth reported in the Roth Declaration (discussed *infra*)

105. Depending on which assays were included or excluded, the CSI Table could have, and would have, reported very different results. For example, Roth has acknowledged that had the results of CSI 107 been included in his "average," there would be no "surprising" or "unexpected" result. Rather, had CSI 107 been included, the CSI Table would show only the

expected twofold increase in the activity of the R-trans enantiomer as compared to the racemate. Roth has claimed that he did not include CSI 107 because he believed that the compounds it tested were not enantiomerically pure; yet, he included the results of CSI 120, which suffered from a similar level of contamination.

106. Similarly, the CSI Table would have shown only this expected twofold increase had Warner-Lambert excluded the results of CSI 118 from its "average." As discussed below, CSI 118 suffered from myriad problems.

107. The fact remains that the R-trans enantiomer is only twice as active as the racemate, regardless of how Warner Lambert, Thierstein and/or Roth manipulated their data.

(2) The CSI Table is Affirmatively False

108. Warner-Lambert's claim that the R-trans enantiomer has surprising activity is false. Warner-Lambert's claim that the R-trans enantiomer is ten times more active than the racemate is false. Warner-Lambert, including Roth, knew that the R-trans enantiomer is, as would be expected by one skilled in the art, only about twice as active as the racemic mixture.

109. Warner-Lambert, including Thierstein and Roth, deliberately failed to tell the PTO that it possessed data that expressly contradicted representations in its patent specifications.

110. In addition to CSI assays, Warner-Lambert assessed the activity of the R-trans enantiomer, S-trans enantiomer, and the racemate through the *in vivo* AICS assay. The AICS assay—the only screen to be conducted twice and with consistent results—showed a twofold increase in activity of the R-trans enantiomer over the racemate. But Warner-Lambert never submitted the AICS data to the PTO.

111. Warner-Lambert also assessed the activity of the R-trans enantiomer, S-trans enantiomer, and the racemate through the *in vivo* COR assay. The COR data was consistent with

a twofold increase in activity of the R-trans enantiomer over the racemate. But Warner-Lambert never submitted the COR data to the PTO.

112. Warner-Lambert's own research reports conclude that the R-trans enantiomer was approximately twice as active as the racemate. A May 31, 1989 report signed by Dr. Sliskovic states that the R-trans enantiomer "was approximately *twofold* more active at inhibiting cholesterol synthesis acutely *in vivo* compared to the racemic mixture. . . . *This is to be expected* if 50% of the racemic salt is the inactive isomer." (Emphasis added). A June 1, 1989 report signed by Roth also reported a twofold increase in activity of the active enantiomer over the racemate: "[a]s expected, [the R-trans calcium salt] was twofold more potent than . . . the racemic calcium salt, which contains 50% inactive isomer." Other internal memoranda from September and December 1989 similarly conclude that, as expected, the R-trans enantiomer was twice as active as the racemate. But Warner-Lambert never shared its conclusions with the PTO.

113. Roth and Warner-Lambert knew and intended that a person skilled in the art would read the CSI Table as (1) fairly reflecting all of the appropriate CSI data available to Warner-Lambert for the relevant compounds, and (2) representing that the data as a whole provided reasonable grounds for the findings set forth in the CSI Table. Instead, Roth, Theirstein, and Warner-Lambert presented data that was affirmatively false, and intentionally presented data in a misleading manner, so that the CSI Table would be read as demonstrating a tenfold increase in activity and, therefore, support patentability.

114. Roth, Theirstein, and Warner-Lambert knew that the CSI data did not provide any "surprising" results. After all, Warner-Lambert scientists, including Roth, had conducted the various CSI assays over a period of more than three years. Certainly, if the assays had disclosed anything surprising—certainly something as shocking as a ten-fold increase in biological

activity—the scientists would have learned of the surprising results, in real time, as the tests unfolded. But none of Warner-Lamberts' internal documents (produced to date in related litigation[6]) or any of the literature published by Dr. Roth and his team concerning the discovery of atorvastatin refer to, or even suggest, a ten-fold increase in activity.

115. Instead, it was only after senior Warner-Lambert managers (not the scientists) instructed Roth to go back and "find" something surprising in the data, and after Warner-Lambert cobbled together a hodge-podge analysis of different tests on different compounds, that the claimed ten-fold biological activity materialized.

116. Furthermore, accepted chemistry practice in 1989 counseled to conduct controlled tests of the proposed hypothesis, *i.e.*, that there were some "surprising" attributes of the isolated R-trans enantiomer over the racemic mixture. Accordingly, if Warner-Lambert wanted to determine whether the R-trans enantiomer had any "surprising" attributes, it should have conducted *new* tests to research its hypothesis. Instead, Roth simply reviewed old data in order to create an impression, albeit a false one, of some type of "surprising" attribute.

3. The Initial Rejection: The PTO Determines the Claimed Compounds Are Anticipated By the '893 Patent

117. On March 22, 1990, pursuant to 35 U.S.C. 102(b), the PTO rejected all claims in the initial application as anticipated by (that is, covered by) the '893 Patent. The PTO determined that the '893 Patent "restrict[ed] the invention to the trans-isomers and . . . specif[ied] the R*, R* configuration. Thus, the claimed compounds, salts, compositions, and method are considered to be anticipated by [the '893 Patent]." Put simply, the PTO rejected Warner-Lambert's patent application for the isolated enantiomer because the invention was already covered by the claims in the Original Lipitor Patent.

[6] *See Ranbaxy Australia Pty Ltd. v. Warner-Lambert Company LLC*, 2006 FCA 1787 (December 20, 2006).

118. The concepts of "anticipation" and "non-obviousness" are distinct, but related, concepts under patent law. A proposed invention may be rejected under 35 U.S.C. §102(b) as being anticipated by a previous patent. Alternatively, even if a proposed invention is not identically disclosed or described as set for in Section 102, a patent may be rejected due to obviousness under 35 U.S.C. §103 "if the differences between the subject matters sought to be patented and the prior art such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Because the patent examiner had concluded that the Original Lipitor Patent anticipated, that is, already covered, the isolated R-trans enantiomer form of atorvastatin, the examiner did not need to reach the concept of obviousness.

119. In response to this rejection, Warner-Lambert argued against anticipation on technical grounds that the '995 Patent application addressed specific enantiomers, while the '893 Patent addressed only racemates, noting that "the presently claimed compounds are for individual enantiomers and therefore differ from the teaching in [the '893 Patent] only to mixtures of enantiomers."

120. Warner-Lambert, through Thierstein, argued that the '893 Patent did not specifically identify, and therefore did not technically "anticipate," the R-trans enantiomer:

> In molecules of the kind disclosed in [the '893 Patent], each possible isomer also exists in two forms which depend on a configuration which is expressed in absolute terms relative to the remainder of the molecule. The forms are denoted as an R form and an S form. These two forms are recognized by an ordinarily skilled artisan to be enantiomeric forms each having a specific chirality. In [the '893 Patent] the disclosure is not limited to compounds having such a specific chirality. Thus, each isomer of [the '893 Patent] is a mixture of enantiomers and not the currently claimed individual enantiomers having an R chirality.

Roth himself rejected this argument in later patent litigation.

121. The PTO issued a final rejection on anticipation grounds on November 7, 1990. The examiner determined that the '893 Patent described the R-trans enantiomer:

> Applicant's arguments . . . have been carefully considered, but such are not persuasive. Where a reference discloses a genus or compound of similar structure which are sufficiently limited in number, the reference is deemed to provide description of those compounds just as specifically as if they were identified by name.

The examiner observed that to isolate the claimed invention, the R-enantiomer, from the compounds disclosed in the '893 Patent, "one merely has to select from the limited possibility of isomers . . . and separate them using conventional techniques." Thus, the '893 Original Lipitor Patent anticipated the R-trans enantiomer.

122. Warner-Lambert abandoned the application following the final rejection on anticipation grounds.

4. The Renewed Application: Warner-Lambert Submits the Roth Declaration, Again Falsely Claiming that the R-Trans Enantiomer is Ten Times More Active than the Racemate

123. On February 29, 1991, Warner-Lambert revived its application and filed a preliminary amendment, signed by Thierstein.[7] The amendment included a supporting declaration from Roth (the "Roth Declaration"). The Roth Declaration was submitted in order to overcome an obviousness rejection and to support patentability of the R-trans enantiomer. In his declaration, Roth again acknowledges his duty to be truthful.

124. The Roth Declaration again claims a "surprising" and "unexpected" tenfold increase in activity. It (falsely) professes to present seemingly objective evidence of an unexpected characteristic of the isolated R-trans enantiomer. Warner-Lambert, through Thierstein and Roth, claimed this characteristic would allow issuance of an R-trans enantiomer

[7] The patent specification accompanying the renewed application also contains a chart (the "CSI Chart") showing that the R-trans enantiomer has ten times greater activity than the corresponding racemate. The information contained in this chart is identical to that presented in the original application.

patent despite the claimed invention being *prima facie* obvious in light of the Original Lipitor Patent. The Roth Declaration simply presented more of the same: misleading and affirmatively false biologic data.

a. Warner-Lambert Admits that the R-Trans Enantiomer Is *Prima Facie* Obvious

125. While continuing to argue that the proposed R-trans enantiomer patent was not technically anticipated by the Original Lipitor Patent, Warner-Lambert also raised, on its own, the issue of obviousness. Indeed, Warner-Lambert admitted that the R-trans enantiomer was *prima facie* obvious in light of the '893 Patent.

126. In its remarks in support of the renewed patent application, Warner-Lambert quoted the U.S. Court of Customs and Patent Appeals in *In re May and Eddy*, 197 USPQ 601, 607 (1978): "[a]s recognized in *In re Williams*, 36 CCPA 756, 171 F.2d 319, 80 USPQ 150 (1948), the novelty of an optical isomer is not negated by the prior art disclosure of its racemate."[8] "Clearly," Warner-Lambert asserts, "this case law is applicable here."

127. In *May*, the *applicant conceded prima facie obviousness*, but submitted "rebuttal evidence" in the form of four declarations indicating that it was "unexpected" that the compounds in question did not exhibit the addictive qualities of most opiates. The PTO refused to consider the rebuttal evidence. The U.S. Court of Customs and Patent Appeals reversed. "[B]alancing the *prima facie* case of obviousness made out by the PTO against appellants' objective evidence of nonobviousness," the Court concluded, "the subject matter of claims 11-13 would not have been obvious to one of ordinary skill in the art." Thus, *May* stands for the proposition that, when a claimed invention is *prima facie* obvious, an applicant may provide

[8] In *Williams*, as here, the applicant sought a patent on a particular enantiomer. The *Williams* court determined that there was no evidence in the record demonstrating actual knowledge that the original patented product was racemic, and thus the idea of resolving the product into components would not have occured to one skilled in the art. In contrast, the racemic nature of the compound at issue in this litigation was well-known at the time the Original Lipitor Patent was issued.

declarations identifying objective evidence of a surprising characteristic to overcome an obviousness rejection.

128. Warner-Lambert purported to do just that in its renewed application, thereby conceding that the R-trans enantiomer was *prima facie* obvious. In the remarks, Warner-Lambert states:

> Following the Williams case Applicant also now provides by a declaration a comparison among each enantiomer and mixture of enantiomers. This comparison is provided to overcome the Roth reference [that is, the reference in the '893 Patent] of the present rejection to facilitate a finding of patentability and moving the prosecution toward resolution of pertinent issues. In other words, *although Examiner has not included a rejection under 35 U.S.C. 103 [for obviousness] Applicants are including a rebuttal of such rejection to comply with the Williams case law.*

Warner-Lambert further describes the Roth Declaration as "provid[ing] the data as set out in the present application in a manner to provide patentability to the application," and states, "in other words, *the declaration is submitted to provide evidence of patentability* to the instant invention." (Emphasis added).

b. The Roth Declaration is Misleading and Affirmatively False

129. Warner-Lambert submitted the Roth Declaration in an effort to overcome an otherwise inevitable rejection on obviousness grounds. The Roth Declaration states that "the antihypercholesterolemia properties of ["R-enantiomer," or "Compound I"] and ["S-enantiomer," or "Compound II"] and mixtures thereof are assessed using essentially the CSI screen that is disclosed in [the '893 Patent]." The Roth Declaration further states that the R-trans enantiomer has "activity greater than *fifty-fold more* than that of Compound II and which indicates activity *at least ten-fold more* than that of the racemate." It also contains the following table (the "Roth Declaration Table"):

Figure 10: Roth Declaration Table

8. THAT, in said assessment, the datum from the Compound I, the datum from its enantiomer the Compound II and the datum from the racemate of the two compounds I and II are as follows:

	Compound	IC_{50} (micromoles/liter)
I	[R-(R*R*)] isomer	0.025
II	[S-(R*R*)] isomer	>1.00
	Racemate	0.26

9. THAT, the data demonstrate that the Compound I provides an IC_{50} which indicates activity greater than fifty-fold more than that of Compound II and which indicates activity at least ten-fold more than that of the racemate;

130. The Roth Declaration states that the available "datum from the compound I" (the R-trans enantiomer) and "the datum from the racemate" (the S-trans enantiomer) are presented below, implying (at minimum) that the values given reflect all appropriate, reasonably available CSI assay data. The Roth Declaration further claims that "the differences in the data . . . among Compounds I, II and racemate shows the activity of Compound I is *surprising and unexpected* because if the Compound II is accepted as inactive, the activity of the Compound I would be expected to be only twice that of the racemic mixture."[9] (Emphasis added).

131. The Roth Declaration, like the CSI Table, purports to present reliable scientific data but does not disclose the source of that data. A skilled addressee would conclude that Warner-Lambert would not have included the CSI Table in the specification in such an unqualified way unless the data had been confirmed by a number of repeat assays.

132. In fact, the Roth Declaration presents unreliable data from a single, deeply flawed screen—CSI 118—and is affirmatively false and misleading.

[9] Roth's Declaration concludes with a paragraph stating, in part, "these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both . . . and that such willful false statements may jeopardize the validity of the above identified US patent application . . . or any patent issuing thereon."

Figure 11: Sources for Roth Declaration Table (IC 50 in micromoles/liter)

* = test calculated multiple values using different methods.

Blue = Roth used in CSI Table (discussed *supra*)

Yellow = Roth reported in the Roth Declaration

133. In addition to generating a value for the racemic sodium salt, which Roth used in the CSI Table in the patent specification, CSI 118 compared all three forms of calcium salt (R-trans, S-trans, and racemate) in a single head-to-head assay. The screen was never re-run to confirm the reported results.[10] The test results are unusable for a number of reasons.

CSI #	Date	Racemic Lactone	R-trans Lactone	S-trans Lactone	Racemic Sodium Salt	R-trans Sodium Salt	S-trans Sodium Salt	Racemic Calcium Salt	R-trans Calcium Salt	S-Trans Calcium Salt
118*	10/24/88				.00977			.257	.0251	> 1.0
					.00913			.234	.0216	

134. First, in order to obtain accurate IC_{50} values, the concentration of the test solutions must be known prior to testing. Warner-Lambert did not determine the concentration of its test solutions prior to conducting the CSI 118 test. Without accurate information about the concentration of the solutions used in the CSI 118 test, the IC_{50} values obtained in CSI 118 cannot be used to demonstrate a tenfold increase in activity of the R-trans enantiomer over the racemate.

135. Second, Warner-Lambert's own lab books show that the compounds in CSI 118 did not dissolve completely in the stock solution. Using non-homogeneous suspensions can result in variations in the concentrations of the compound in the assay solution leading to wide variation in the results obtained. Given this limitation, the most that the CSI 118 results can be

[10] Roth has admitted that he did not conduct any additional tests to confirm that the biologic data presented in the patent was in fact correct: "it is true that [the biologic data that was included in the patent] went out without any subsequent tests being asked for by me to repeat that data."

said to determine is whether a compound has *any* activity, not whether a compound has a twofold, threefold, or tenfold increase in activity over another compound.

136. Third, an acceptable CSI test should record similar results for the racemic sodium salt and the racemic calcium salt. Roth has agreed that, in general, the results for the racemic sodium salt and the racemic calcium salt should be equivalent or similar. Yet, in CSI 118, the results of the racemic calcium salt (.257) were almost twenty-five times the results of the racemic sodium salt (.00977). The difference was so great that the IC_{50} value for the R-trans enantiomer calcium salt showed far less potency than the racemic sodium salt; that is, the R-trans enantiomer, *the active enantiomer*, of the calcium salt was *less active* than the racemate of the sodium salt. This should have alerted the scientists that something was wrong with the screen, likely a problem related to solubility issues.

137. Finally, the claim in the Roth Declaration of ten times greater activity is affirmatively false, as the activity of the isolated R-trans enantiomer is not in fact ten times greater than the racemate. Had Warner-Lambert employed a scientifically acceptable testing process, the data would have revealed that the R-trans enantiomer had at best a twofold advantage over the racemate.

138. Roth and Warner-Lambert were aware of the numerous problems with CSI 118 and knew that the results of CSI 118 were not scientifically sound. Yet, in the face of radically different results for the sodium and calcium salts, solubility problems, unknown solution concentrations, and results indicating that the racemate of one salt was more potent than the R-trans enantiomer of another salt, they used this questionable and unreliable data to support the false claim that the isolated R-trans enantiomer has ten times greater inhibition of cholesterol synthesis than the racemate. They specifically claimed that this was "a surprising level of

activity" which, in turn, supported patentability. Dr. Roth has admitted under oath that he submitted CSI data for the purpose of demonstrating "a surprising level of activity" which therefore supported patentability:

> Q. So [the biologic data] was put in to demonstrate this surprising level of activity for the purpose of obtaining a patent, was it not?
>
> A. [Dr. Roth:] Yes, I guess you would say that that would be true. I mean, the data supported a surprising level of activity, which we thought would be novel and surprising and therefore would support patentability.

139. Warner-Lambert knew that a person skilled in the art would read the Roth Declaration as fairly reflecting all appropriate CSI data for the relevant compounds that was available to Defendants, and as representing that the data as a whole provided reasonable grounds for the findings set forth therein. Roth and Warner-Lambert intended that the Roth Declaration be read as suggesting a tenfold increase in activity and therefore supporting patentability.

5. The Final Rejection: The PTO Determines that the R-Trans Enantiomer is Anticipated

140. The PTO examiner issued a final rejection of the follow-on patent application on September 16, 1991, rejecting all claims as anticipated by the '893 Patent for the reasons set forth in the two rejections issued in 1990.

6. The Appeal: the PTO Determines that the R-Trans Enantiomer is *Prima Facie* Obvious

141. On January 15, 1992, Warner-Lambert appealed the examiner's rejection to the Board of Appeals, asserting that "[t]he R isomer as claimed appears to be at least *100 times more active than its corresponding S isomer and more than 10 times more active than the mixture.* Under ordinary circumstances one would have expected only a two-fold difference between the

particular R isomer and the mixture." (Emphasis added). The appeal was signed by Attorney Ronald A. Daignault, a Warner-Lambert employee. Daignault states, "the present invention describes the particular R isomer which is found to have *greater than 10 times the activity* of the compound described in the prior art reference, namely, the racemic mixture," "the compound of the present invention . . . does not produce substantially the same result since it has *greater than 10 times the activity* than the reference compound," and "the R isomer is the most desired and the most *surprisingly active* isomer of the two possibilities if one is to select from the trans compounds." (Emphasis added).

142. Acknowledging that the isolated R-trans enantiomer is *prima facie* obvious over the Original Lipitor Patent, Warner-Lambert argued that the obviousness is overcome by the surprising and unexpected activity claimed in the Roth Declaration: "The examiner's rejection is erroneous as a matter of law by applying the facts of the present case to the wrong law. The issue here is whether an optical isomer is novel over its prior disclosed racemic mixture. The law as state[d] in May and Eddy affirming In re Williams says yes."

143. The examiner filed an answer to Warner-Lambert's appeal March 24, 1992. The examiner alleged no new grounds for denial of the application, instead reiterating the previously disclosed grounds and stating that "even if a preferred isomer were not disclosed [by the '893 Patent], one skilled in the art expects one of the individual isomers to be more active than the other since this, too, is knowledge contemporary in the art."

144. On October 19, 1992, the Board of Appeals overturned the Examiner's rejection of the application on the basis of *anticipation*, concluding that the '893 Patent did not technically anticipate the R-trans enantiomer:

> at best, [the '893 Patent] only describes the trans racemate containing the R-trans and the S-trans isomers in admixture.

> Nowhere does [the '893 Patent] state or suggest which optical isomer is preferred and, moreover, does not specifically mention how one skilled in the art could make the pure optical isomer separately. In view of the above, we are unable to subscribe to the examiner's contention that the ['893 Patent] anticipates the claimed subject matter.

145. However, the Board recommended to the examiner that, upon remand, the patent should be rejected on the basis of *obviousness:*

> Upon further prosecution of this application before the examiner, we recommend that the examiner analyze the claimed subject matter under the provisions of §103 of 35 USC. *An obviousness rejection of claims directed to an optically pure isomer appears to be in order when, as here, (1) the product of the prior art is known to be racemic and (2) where methods for resolving the racemic mixture into the pure optically active isomers are known to those skill[ed] in the art.*

7. The '995 Patent Issues: PTO Relies on Biologic Data to Overcome Obviousness

146. On March 16, 1993, apparently without any further formal proceedings or briefing, the PTO issued a Notice of Allowability for the follow-on, isolated R-trans enantiomer patent application. U.S. Patent Number 5,273,995 (the '995 Enantiomer Patent) was issued on December 28, 1993.[11]

147. Warner-Lambert had presented the results of CSI screens in both the '995 Patent specification and the Roth Declaration to support its contention that the R-trans enantiomer was surprisingly and unexpectedly ten times more active than the racemate and therefore not obvious in light of the '893 Patent. Warner-Lambert made this representation in the original follow-on application, in the Roth Declaration, in its appeal to the PTO, and in the final patent specification. This is the only "surprising" activity of the isolated R-trans enantiomer that was

[11] Defendant Pfizer Ireland Pharmaceuticals is the exclusive licensee of the '995 Patent.

discussed in the '995 Patent application, and was, therefore, the sole reason that Warner-Lambert was able to overcome an obviousness rejection.

148. The PTO relied on the Roth Declaration and the CSI Table to find that the R-trans enantiomer was not obvious in light of the '893 Patent. The Board of Appeals explicitly (i) directed the examiner to re-evaluate the application for obviousness, and (ii) stated that an obviousness rejection appeared to be appropriate. The only "surprising" or "unexpected" characteristic of the isolated R-trans enantiomer that Warner-Lambert claimed was the tenfold increase in activity compared to the racemic mixture. The only evidence presented in support of those claims was contained in the patent specification (the CSI Table) and the Roth Declaration. Thus, upon reevaluating the application in accordance with the Board of Appeals' directive, the examiner relied on Warner-Lambert's claim of "surprising" and "unexpected" activity, and determined that the evidence presented in support of that claim (in both the patent specification itself and the Roth Declaration) were sufficient to overcome a rejection on obviousness grounds.

149. The inclusion of particular language and data in the patent specification itself confirms that the PTO relied on both the claim of "surprising" and "unexpected" activity and the data submitted in support of that claim. The specification states, "[i]t is now unexpectedly found that the enantiomer having the R form of [a] ring-opened acid [described in the '893 Patent], …that is [R-(R*R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, provides surprising inhibition of the biosynthesis of cholesterol." The specification further states that "an ordinarily skilled artisan may not predict the unexpected and surprising inhibition of cholesterol biosynthesis of the present invention in view of [prior] disclosures."

150. Accordingly, the '995 Enantiomer Patent would never have issued but for Warner-Lambert's fraud.

E. Warner-Lambert Intended to Deceive the PTO

151. Warner-Lambert's false claims and data were made with knowledge they were false and misleading and with the specific intent that the PTO rely on those claims in order to issue a follow-on patent. Roth and Warner-Lambert knew that a person skilled in the art would read the CSI Table and the Roth Declaration as representations that the results therein fairly reflected all scientifically reliable CSI data for the relevant compounds that was available to Defendants, and that the data as a whole provided reasonable grounds for the findings set forth therein. Roth and Warner-Lambert intended that the CSI Table and the Roth Declaration be read as suggesting a ten-fold increase in activity, an assertion they knew to be false, so that the documents would support its application for the follow-on patent.

1. Warner-Lambert Manipulated the Existing Biologic Data to Show a Ten-Fold Increase in Activity and Intentionally Presented False Information

152. Warner-Lambert manipulated the existing biologic data in order to show a ten-fold increase in activity. It did so with the specific intent to deceive the PTO.

153. Warner-Lambert has acknowledged that head-to-head testing provides the best way to compare quantitative differences in activity, yet it did not present such head-to-head data in support of its claim that the R-isomer has ten times the activity of the racemate. Instead, Warner-Lambert selected results from various tests conducted on different days, using different salts, and suffering from various flaws, and it presented these manipulated results in the CSI Table that was included in the patent specification. Such a gross departure from accepted chemistry practice shows knowledge of falsity.

154. Warner-Lambert acknowledged that had the results of CSI 107 been included in its "average," there would be no surprising or unexpected result. Warner-Lambert has claimed that it did not include CSI 107 in its calculations because it believed that the compounds it tested were not enantiomerically pure, yet it included the results of CSI 120, which suffered from a similar level of contamination. Such a gross departure from accepted chemistry practice shows knowledge of falsity.

155. Warner-Lambert claimed that it did not provide the data from CSI 119 to the PTO because CSI 119 was not a head-to-head comparison, and it claimed to believe that it was inappropriate to compare individual data points from different experiments. Yet, Warner-Lambert used different data points from multiple experiments to generate the data contained in the CSI Table. Such a gross departure from accepted chemistry practice shows knowledge of falsity.

156. Warner-Lambert included one of the three results from CSI 118 in the CSI Table in order to show an alleged ten-fold increase in activity. The sodium salt prepared by opening the racemic lactone in CSI 92, 93, 95, and 102 should have given substantially identical, or at least very similar, values to the racemic sodium salt that was separately prepared by a medicinal chemist in CSI 118. Yet, the results for the racemic sodium salt in CSI 118 differs from the results of the four lactone CSI tests by a factor of ten. Such a gross departure from accepted chemistry practice shows knowledge of falsity.

157. In CSI 118, the results of the racemic sodium salt and racemic calcium salt are vastly different, showing as much as a twenty-five-fold difference. The difference was so great that the IC_{50} value for the R-trans enantiomer calcium salt showed far less potency than the racemic sodium salt—that is, the R-trans enantiomer of the calcium salt was less active than the

racemate of the sodium salt. This difference should have been a red flag that something was wrong with the screen, likely a problem related to the solubility of the compounds. Instead, Warner-Lambert used this questionable data to support the false claim that the R-trans enantiomer has a ten-fold greater inhibition of cholesterol synthesis as compared to the racemate.

158. Warner-Lambert was aware of the numerous problems with CSI 118 identified above, and it knew that the results of CSI 118 were not scientifically sound. Yet, in the face of radically different results for the sodium and calcium salts, solubility problems, unknown solution concentrations, and results that showed the racemate of one salt was more potent than the R-isomer of another salt, Warner-Lambert used this inconsistent outcome to further substantiate its claim that the R-isomer was ten times more active than the racemate in inhibiting cholesterol synthesis.

159. Warner-Lambert's patent attorneys submitted to the PTO the misleading and false Roth Declaration, the false and misleading Roth Declaration Table, and the misleading and false CSI Table, generated by Roth and others, in support of the '995 Patent application.

2. Warner-Lambert Admits that the Patent Specification Claims a Surprising Ten-Fold Increase in Activity

160. At numerous points in the prosecution of the '995 Patent, Warner-Lambert and Roth stated expressly that the "surprising" characteristic of the isolated R-trans enantiomer was that it had ten-times greater than the activity of the racemic mixture. Warner-Lambert knew that both the CSI Table and Roth Declaration presented false information about the activity of the R-trans enantiomer as compared to the S-trans enantiomer and the racemate. To acknowledge in court that the only claimed "surprising" characteristic of the R-trans enantiomer was false would result in the loss of the '995 Patent and/or its foreign counterparts. Thus, in subsequent patent litigation, Roth and Warner-Lambert tried to shy away from admitting that Warner-Lambert had

claimed that the surprising feature of the R-trans enantiomer was a tenfold increase in activity over the racemate.

161. Roth's evasive testimony on this topic is illustrative:

> Q. I suggest to you that you either do or do not rely on those figures. If you want to put out a merely qualitative statement that you have surprising activity you can put it in words. If you put it out in figures that suggests that it is a very surprising level of activity, being a 10-fold difference?
>
> A: But I believe the words we used were a surprising level of activity. We didn't say that it was surprising because it was a 10-fold difference. We simply said that it was surprising, the numbers suggest 10-fold. But frankly, again, anything more than twofold would be surprising. We didn't claim 10-fold in the patent. We said it was surprising.
>
> Q: You didn't put a qualification to the numbers that you give in the patent to say "beware of these numbers. We're only really saying that we get a better than two-fold improvement"; no mention of that, was there?
>
> A: What we say is that the compound has surprising activity and then we put data into the patent which supported the surprising level of activity. I don't think that we actually comment on the data except to say that it's surprising. The data is what the data is.
>
> Q: The data on its face quantify that is surprising level of activity, does it not, Dr. Roth?
>
> A: There are numbers given, yes.
>
> Q: So it quantifies that surprising level of activity?
>
> A: What do you mean by that?
>
> Q: Do you know what the meaning of the word "quantifies" is?
>
> A: There are numbers that are given. Again, we don't make any claims; all we say is that it's surprising. The numbers are what the numbers are.

162. Roth was ultimately forced to concede that the biologic data contained in the patent specification purports to show a ten-fold increase in activity, and that it was included in the specification for that reason:

Q: And you wanted those numbers to be taken at face value, did you not?

A: I'm not sure I know what you mean.

Q: What?

A: The data is what the data is. The data was included to support the rising level of activity. What the numbers suggest is that it's something like 10-fold, but we don't state that. We simply – what we simply do is we say it's surprising.

Q: Isn't it a fair reading of this passage on page 8 that having said it's surprising that you are saying now here is why and you set out figures which show a 10-fold increase and you don't provide any qualification at all to those numbers?

A: That is true. We simply report the data.

163. Roth acknowledged "[t]he data is what the data is," "the numbers are what the numbers are," and that "the data was included to support the surprising level of activity. What the numbers suggest is that it's something like 10-fold . . . ." The numbers submitted to the PTO show, based on cherry-picked test results, that the R-trans enantiomer is ten times more active than the racemate. In reality, the R-trans enantiomer is, as expected, only about twice as active as the racemate.

3. Warner-Lambert Intended for the PTO to Rely on the False Data and Claims

164. Roth has admitted under oath that he submitted CSI data for the purpose of supporting a surprising level of activity which therefore supported patentability: "the biologic data that was included in the patent I felt demonstrated and supported a surprising level of biological activity."

Q. So [the biologic data] was put in to demonstrate this surprising level of activity for the purpose of obtaining a patent, was it not?

A. Yes, I guess you would say that that would be true. I mean, the data supported a surprising level of activity, which we

thought would be novel and surprising and therefore would support patentability.

F. FDA Approval: The FDA approves Lipitor and the Original Lipitor Patent Provides Years of Patent Protection

165. On June 17, 1996, Warner-Lambert submitted a new drug application under Section 505(b) of the FDCA and Section 314.50 of Title 21 of the Code of Federal Regulations, seeking approval to sell atorvastatin calcium, *i.e.*, the isolated R-trans enantiomer formulated as a calcium salt. On December 17, 1996, the FDA approved atorvastatin calcium—named "Lipitor"—for the treatment of hypercholesterolemia and mixed dyslipidemia. The FDA initially approved 10 mg, 20, mg, and 40 mg tablets, adding approval of 80 mg tablets on April 7, 2000.

1. The Orange Book Listings for the '893 and '995 Patents

166. Following approval, Warner-Lambert listed both the '893 Original Lipitor Patent and the fraudulently-obtained '995 Enantiomer Patent in the Orange Book. When it did so, Warner-Lambert knew that it had procured the '995 Enantiomer Patent through actual fraud on the PTO.

167. By listing both patents in the Orange Book, a generic company seeking approval for an ANDA for generic atorvastatin calcium would need to file a Paragraph IV certification as to both the '893 and '995 Patents if it wished to enter the market before the expiration of the patents. This certification would trigger Warner-Lambert's ability to file infringement litigation, which in turn would trigger the Hatch-Waxman statutory delays for FDA generic approval.

168. At the time of FDA approval of Lipitor, the '893 Original Lipitor Patent was scheduled to expire on May 30, 2006. The '995 Enantiomer Patent would not expire until December 28, 2010.

2. The '893 Original Lipitor Patent Protected the Lipitor Franchise for Years

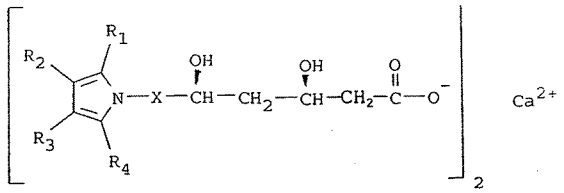
169. Shortly after FDA approval, Warner-Lambert applied for an extension of the patent term of the '893 Patent under 35 U.S.C. § 156. Section 156 provides that the period of patent protection may be extended to account for the time lag between the issuance of a patent covering the active ingredient in a new drug and FDA approval of that drug.

170. Warner-Lambert asked the PTO to extend Lipitor's period of market exclusivity granted by the '893 Original Lipitor Patent—not the '995 Patent—for about three years and four months. That is, *Warner-Lambert took the position that the '893 Patent covered the isolated R-trans enantiomer, atorvastatin, in calcium salt form.*

171. Warner-Lambert informed the PTO that (i) the FDA approved Lipitor, (ii) the active ingredient in the drug Lipitor is atorvastatin calcium, and (iii) atorvastatin calcium is covered by the '893 Patent. Warner-Lambert claimed that the '893 Original Lipitor Patent claims atorvastatin calcium as a new chemical entity (Claims 1-4), as a pharmaceutical composition (Claim 8), and as a method for using it to inhibit cholesterol biosynthesis (Claim 9).

172. Claim 1 requires "a compound of structural formula I" or "a hydroxyl acid or pharmaceutically acceptable salt thereof, corresponding to the opened lactone ring of the compounds of structural formula I above." In the extension application, Warner-Lambert claimed that Lipitor is a pharmaceutically acceptable salt of structural formula I, and is thus covered by Claim 1 of the Original Lipitor Patent:

> Lipitor is a pharmaceutically acceptable salt (i.e., calcium salt) of the hydroxy acid corresponding to the opened lactone ring of a compound of structural formula I. Lipitor has the general structure:



where: X is $-CH_2CH_2-$

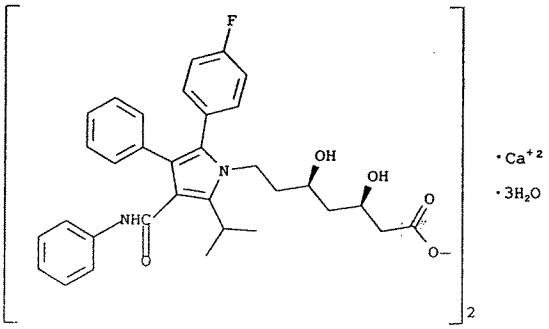
R_1 is 4-fluorophenyl;

R_2 is phenyl;

R_3 is -CONH-phenyl; and

R_4 is 1-methylethyl, an alkyl group having three carbon atoms.

Lipitor™ thus has the specific chemical structure



173. The PTO granted the patent term extension. With extensions for the delay in FDA approval and for pediatric testing, the '893 Original Lipitor Patent was to expire on March 24, 2010.

174. The Defendants also sought and obtained a six-month extension for pediatric testing for the '995 Enantiomer Patent. As a result, the expiration date of the '995 Enantiomer Patent was June 28, 2011.

175. In effect, the '893 Patent and the '995 Patent would provide more than fourteen years of patent exclusivity to market and sell branded Lipitor: the Original Lipitor Patent would provide protection from the 1997 launch until March 2010, and the fraudulently-obtained follow-on patent (if enforced by Warner-Lambert or its successors) would tack on almost a year and a half of additional market exclusivity.

3. The 1997 Launch of Lipitor

176. Prior to commercialization, Warner-Lambert faced serious challenges in bringing Lipitor to market. Lipitor would be the fifth statin available to patients and physicians. One of Lipitor's biggest challenges was to overcome the perception that it was a "me-too" product. Merck and Bristol-Myers Squibb, the primary incumbents, already had proven products in the market.

177. Warner-Lambert wanted to employ a "saturation" approach to selling Lipitor, an essential approach because the medical community was largely content with the drugs already available to treat high cholesterol. The intent of the "saturation" strategy was to have as many sales representatives as possible contacting physicians. As Anthony Wild, Warner-Lambert Pharmaceutical Sector President, explained, "[t]he more soldiers you have out there, the more guns, the more likely you are to achieve your ends." Although Warner-Lambert clearly understood that the sales force was a key success factor in any drug's performance, a 1995 sales force deployment study revealed that the Warner Lambert's sales force was inadequate in size and focus to effectively launch Lipitor.

178. Warner-Lambert chose Pfizer to help market Lipitor. Warner-Lambert and Pfizer outgunned the competition with the largest statin sales force in history. Between Warner-Lambert and Pfizer, more than 2,200 sales representatives were believed to be selling Lipitor at the time of its launch in the United States.

179. After launching in January 1997, Lipitor reached $1 billion in domestic sales within its first twelve months on the market. By the end of 1998, Lipitor was available for sale in fifty countries. Lipitor claimed U.S. market share leadership in the statin drug class in October 1997 with a 30% share of all new statin prescriptions.

G. Patent Litigation: Pfizer Sues for Infringement of the '995 Patent to Keep Generics off the Market

180. Defendants used the '995 Patent to delay the efforts of at least four generic manufacturers that sought approval to manufacture and sell generic atorvastatin calcium. The generic pharmaceutical manufacturers who have filed and are seeking to sell generic versions of Lipitor, and which have been sued for infringement of the '995 Enantiomer Patent, are: Ranbaxy Pharmaceuticals Inc. (now known as Ranbaxy), Teva Pharmaceuticals USA, Inc. ("Teva"), Cobalt Pharmaceuticals Inc. ("Cobalt") and Apotex Inc. ("Apotex"). Defendants knew that the '995 Patent was invalid and/or unenforceable and commenced these actions to keep generic atorvastatin calcium off the market for as long as possible. But for the commencement of these actions by Pfizer, generic atorvastatin calcium would have been available on or about March 24, 2010, that is, upon expiration of the Original Lipitor Patent.

1. *Pfizer v. Ranbaxy*, 03-CV-209-JJF

181. Ranbaxy was the first to file an ANDA for generic atorvastatin. Ranbaxy was also the first stymied by Pfizer's allegation that its product infringed the '995 Enantiomer Patent.

182. In early 2003, Ranbaxy filed ANDA 76-477, seeking approval to sell a generic version of Lipitor. As the first to file an ANDA for generic atorvastatin calcium, Ranbaxy acquired the exclusive right to manufacture and sell generic Lipitor for the first six months following the expiration of relevant, valid Lipitor patents.

183. On January 23, 2003, Ranbaxy sent two paragraph IV certification letters to Pfizer with respect to the '893 and '995 Patents. In these letters, Ranbaxy asserted that no valid patent claims covering Lipitor would be infringed by the sale, marketing, or use of Ranbaxy's generic product.

184. On February 21, 2003, Pfizer filed an action against Ranbaxy in the United States District Court for the District of Delaware, alleging infringement of the '893 and '995 Patents.

185. From 2003 to 2007, the '893 and '995 Ranbaxy infringement litigation progressed through discovery, a jury-waived trial, and an eventual appeal and decision by the United States Court of Appeals for the Federal Circuit. Multiple factual issues for both the '893 and the '995 Patents were litigated as between Ranbaxy and Pfizer.[12]

186. On August 2, 2006, the Federal Circuit reversed the lower court's decision regarding the '995 Patent, determining that claim six of the patent was technically invalid.[13] The Federal Circuit did not address the district court's other determinations. The Federal Circuit affirmed that Ranbaxy had infringed the '893 Patent and upheld that patent's time extension.

187. On remand, the district court indicated that Pfizer's market exclusivity for Lipitor extended until March 24, 2010, the date on which the '893 Patent expired.

188. In light of the Federal Circuit's invalidation of claim 6 of the '995 Enantiomer Patent, Pfizer filed with the PTO amendments to the '995 Enantiomer Patent to correct the technical nomenclature error and to obtain reissuance of the '995 Enantiomer Patent. Ranbaxy remained foreclosed from entering the market for atorvastatin calcium by reason of Pfizer's continued assertion that it was protected by the '995 Enantiomer Patent.

189. On March 24, 2008, Pfizer instituted a second action against Ranbaxy, citing the February 28, 2003 letter from Ranbaxy informing Pfizer of Ranbaxy's filing of ANDA 76-477 in

[12] Among the numerous issues litigated before the district court in the jury-waived trial between Ranbaxy and Pfizer was the early form of the evidence adduced by Ranbaxy regarding Warner-Lambert's inequitable conduct in the procurement of the '995 Enantiomer Patent. On that record, which did not include much of the evidence now available, and as between those parties, Pfizer prevailed. Of course, the Plaintiff in this action and the proposed End-Payor Class were not parties to that litigation and are not bound by any of the determinations made therein. The issue of Warner-Lambert's representations regarding the biological activity of the R-trans enantiomer as compared to its racemate has also been litigated in other fora worldwide. There, when addressed on a more fully developed record, Pfizer lost on the issues relating to the integrity of the "surprising" data for the enantiomer.

[13] More recently, the PTO accepted Pfizer's application to correct a technical defect in claim two of the '995 Enantiomer Patent, which would presumably repair the invalidity of claim six. In March 2009, the PTO allowed the reissue of the patent as no. RE40,667, which retained the expiration date of June 28, 2011.

connection with the '995 Patent. This time, Pfizer's lawsuit focused on two patents that cover processes for making atorvastatin calcium, patent numbers 6,274,740[14] and 6,087,511.[15] As process patents, neither of these patents are listed in the Orange Book, and thus do not implicate the usual paragraph certification and statutory stay provisions of the Hatch-Waxman Amendments. As a practical matter, neither of these two process patents posed any legitimate threat of infringement to Ranbaxy at the time of the litigation or subsequent settlement, as the '995 Enantiomer Patent presented the bar to entry.

190. On June 17, 2008, Ranbaxy and Pfizer abandoned their adversarial positions and settled the second action. The parties agreed that Ranbaxy would be enjoined from engaging in the manufacture, use, or sale of generic Lipitor until November 30, 2011. As discussed below, this agreement, too, was a sham and part of Pfizer's overarching scheme to delay unlawfully the introduction of generic Lipitor. Moreover, because Ranbaxy was first to file an ANDA for Lipitor, all other generic entrants were required, except in limited circumstances, to await Ranbaxy's entry before being allowed to enter the market.

191. But for Warner-Lambert's fraud in procuring the '995 Enantiomer Patent, the PTO would not have issued the'995 Enantiomer Patent.[16] Pfizer, which acquired the license to the fraudulently-procured '995 Enantiomer Patent, used that patent to delay unlawfully Ranbaxy's entry into the market for atorvastatin calcium. Thus, but for the fraudulent procurement of the '995 Enantiomer Patent, Ranbaxy would have entered the market for atorvastatin calcium on or about the end of March 2010 (when the Original Lipitor Patent

[14] Scheduled to expire July 16, 2016.

[15] Scheduled to expire July 16, 2016.

[16] The procurement and enforcement of the Original Lipitor Patent against Ranbaxy is not at issue in this litigation. Plaintiff and the End-Payor Class have reserved all appropriate rights under the civil rules to amend this claim at a later date in the event that claims relating to the Original Lipitor Patent are discovered in due course.

expired). Other generic manufacturers were prevented from entering the market for atorvastatin calcium by reason of Ranbaxy's delay.

2. *Pfizer v. Teva*, 07-CV-360 (D. Del. 2007)

192. On April 24, 2007, Teva notified Pfizer, pursuant to the Hatch-Waxman Amendments, that it had filed ANDA 78-773 seeking approval to sell a generic version of Lipitor. Teva included a Paragraph IV certification that the '995 Enantiomer Patent was invalid, unenforceable, or would not be infringed by Teva's proposed generic product.

193. On June 7, 2007, Pfizer responded by filing an action against Teva in the United States District Court for the District of Delaware, alleging infringement of the '995 Patent (excepting claim 6). The parties reached a settlement of this action on July 15, 2009, whereby Teva agreed to not seek approval for its generic product for a certain period of time.

194. But for Warner-Lambert's fraudulent procurement of the '995 Enantiomer Patent, Teva would have entered the market for generic atorvastatin calcium in or about September 2010 (the month in which Ranbaxy's period of generic market exclusivity would have expired).

3. *Pfizer v. Cobalt*: 07-CV-790 (D. Del. 2007)

195. At some time prior to December 2007, Cobalt notified Pfizer, pursuant to the Hatch-Waxman Amendments, of its application seeking FDA approval to market atorvastatin and its Paragraph IV certification that the '995 Enantiomer Patent was invalid, unenforceable, or would not be infringed by Cobalt's proposed generic product.

196. On December 6, 2007, Pfizer filed an action against Cobalt in the United States District Court for the District of Delaware, alleging infringement of the '995 Enantiomer Patent (excepting claim 6). In consenting to judgment on May 15, 2008, Cobalt admitted that the '995 Patent would be infringed by the product proposed in its ANDA. The consent also restricted the

effective date of any approval of ANDA 22-245 to be no earlier than the expiration of the '995 Patent.

197. But for Warner-Lambert's fraudulent procurement of '995 Enantiomer Patent, Colbalt would have launched a generic formulation of atorvastatin in or about September 2010 (the month in which Ranbaxy's period of generic market exclusivity would have expired).

4. *Pfizer v. Apotex*, 08-CV-7231 (N.D. Ill. 2008)

198. On November 4, 2008, Apotex notified Pfizer, pursuant to the Hatch-Waxman Amendments, that it had filed ANDA 90-548 seeking FDA approval to market atorvastatin calcium. Apotex included a Paragraph IV certification that Pfizer's patent nos. 5,273,995, 6,126,971, 5,686,104, and 5,969,156 were invalid, unenforceable, or would not be infringed by Apotex's proposed generic product.

199. On December 17, 2008, Pfizer responded by filing an action against Apotex in the United States District Court for the Northern District of Illinois, alleging infringement of the '995 Enantiomer Patent.

200. But for Warner-Lambert fraudulent procurement of '995 Enantiomer Patent, Apotex would have entered the market for generic atorvastatin calcium in or about September of 2010 (the month in which Ranbaxy's period of generic market exclusivity would have expired).

H. The PTO's Reissuance of the '995 Patent Does Not Absolve Warner-Lambert's Fraud or Otherwise Sanitize the '995 Patent

201. As alleged above, but for Warner-Lambert's fraud on the PTO during the initial prosecution of the '995 Patent, the '995 Patent never would have issued. But for the '995 Patent's additional period of patent protection, at least one generic version of atorvastatin would have been available on or about March 24, 2010 upon the expiration of the '893 Patent's marketing exclusivity period.

202. That Pfizer later went back and sought reissuance of the '995 Patent to correct a technical defect in one of its claims—claims that were found patentable in the first instance only because of Warner-Lambert's fraudulent assertion that the R-trans enantiomer was ten times more active than the racemate—does not change the fact that the '995 Patent would have never issued initially but for Warner-Lambert's fraud. And without the *original issuance* of the '995 Patent, there could be no *reissuance* of it. The PTO's decision to reissue the '995 Patent is therefore immaterial to this action.

203. Instead, the reissuance proceedings simply confirm what Warner-Lambert had long known: the biologic data submitted as part of the application for the '995 Enantiomer Patent was false, inaccurate, incorrect, and riddled with errors. Throughout the reissuance proceedings, Pfizer itself eschewed all reliance on biologic data (including CSI data), at one point explicitly acknowledging that the biologic data originally used to support patentability was "inaccurate."

204. Rather than submit "corrected" biologic data, Pfizer took an entirely new tact: Pfizer argued that Lipitor is entitled to additional protection under the '995 Patent because of Lipitor's overwhelming commercial success. But Pfizer's commercial success argument is no more viable as support for reissuance of the '995 Enantiomer Patent than Warner-Lambert's "surprising activity" argument was during the initial application process.

1. Pfizer Admits that the Biologic Data is False

205. In January 2007, in the wake of the Federal Circuit decision invalidating Claim 6 of the '995 Enantiomer Patent on technical grounds, Pfizer sought re-issuance of the '995 Patent "to correct a technical defect in some of the patent claims."

206. Pfizer knew, as a result of international patent litigation, that it could no longer rely publicly on the falsified biologic data that Warner-Lambert had submitted to the PTO during

its prosecution of the '995 Patent, conducted from 1989 to 1993. As a result, during the reissuance proceedings, Pfizer expressly disavowed reliance on that biologic data, including the data presented in the CSI Table and Roth Declaration.

207. In the absence of Warner-Lambert's original fraud on the PTO, which was supported only by data that Pfizer has expressly disavowed, the '995 Enantiomer Patent would never have issued. But for the '995 Patent's issuance in 1993, reissuance proceedings for that patent (conducted from 2007 to 2009) would not have been possible. As a result, the PTO's eventual decision with respect to those reissuance proceedings is irrelevant to this antitrust action.

208. The reissuance proceedings, do however, confirm what Pfizer had long known: the biologic data submitted as part of the application for the '995 Enantiomer Patent is false, inaccurate, incorrect, and riddled with errors.

209. On January 16, 2007, Roth and Pfizer submitted the Claim 6 '995 Patent reissue application. The applicants did not amend or modify the '995 Patent specification as part of the reissuance proceedings. Roth's remarks include a list of the "objective evidence" that "completely refutes any suggestion of obviousness." Notably, this list does **not** include the purported surprising effectiveness of the R-trans enantiomer or the alleged ten times greater activity of the R-trans enantiomer as compared to the racemate.

210. Moreover, Pfizer's Informational Disclosure Statement eschews reliance on CSI and COR biologic data:

> 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 no COR data were relied on by either U.S. court in reaching their decisions regarding the validity of '995 claim 6."

(Emphasis added). Pfizer similarly 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."

211. On June 7, 2007, Defendants submitted a Second Informational Disclosure Statement that discusses "Foreign Proceedings on '995 Counterparts" and attaches additional materials produced as part of certain non-U.S. proceedings. Pfizer acknowledges therein that the biologic data submitted in support of its patent applications—in the CSI Table, the Roth Declaration, and the foreign "'995 counterparts"— was 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 date, and *some of that biological data is now understood to be inaccurate* (due to transcription errors, calculation errors, experimental errors, etc.). Applicant 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.

(Emphasis added).

212. Elsewhere in the reissuance proceedings, Roth and Pfizer refer 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.*" (Emphasis added). Similarly, Roth and Pfizer state

that the "[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." (Emphasis added).

213. At one point during the reissuance proceedings, the examiner 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.*

(Emphasis added).

214. In response, Pfizer reiterated that it was "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 acknowledged that the examiner relied on the Roth Declaration and asked her to "withdraw her reliance on the data in the Roth Declaration" and to focus on Pfizer's new argument: that it was entitled to additional patent protection based on Lipitor's commercial success.

215. On April 24, 2008, the PTO issued a non-final rejection of claims 6, 13, and 14. In doing so, the Examiner formally withdrew her reliance on the Roth Declaration. Instead, the Examiner relied on secondary considerations identified by the Applicants, namely Lipitor's commercial success.

216. On April 6, 2009, the PTO reissued claims 6, 13, and 14 of the '995 Patent (the "'667 Patent"). The reissued Patent retained the same expiration date as the '995 Patent.

2. Lipitor's Commercial Success Has No Bearing on Whether the Invention Claimed by the '995 Patent is Obvious

217. The PTO based its ruling to grant the reissuance of the '995 Enantiomer Patent not on the basis of the biological studies and the associated representations made by Warner-Lambert (even though a version of the CSI assay data remains in the specification for the patent), but instead on Pfizer's arguments that the commercial success of Lipitor shows that the '995 Enantiomer Patent could not have been obvious.

218. Pfizer's argument that Lipitor's commercial success means that the invention claimed in the '995 Patent could not have been obvious in light of the Original Lipitor Patent is patently wrong as a matter of fact and law.

219. First, Lipitor was commercially successful during the 1997-2010 time period, a period during which it enjoyed patent protection under both the '893 Original Lipitor Patent and the '995 Enantiomer Patent. Since the relevant question of obviousness is whether the '995 Patent is obvious when compared to the '893 Patent, the fact that Lipitor, which is covered by both patents, has been commercially successful generally, provides no meaningful information as to the distinctions *between* the two patents.

220. Second, when Pfizer boasts of Lipitor's "commercial success," it makes comparisons between Lipitor and other statins, or between Lipitor and the overall growth in the statin market generally. But the relevant issue of obviousness does not involve a comparison of Lipitor to other statins or to growing statin use. Instead, the relevant issue of patent obviousness is whether the invention under the '995 Enantiomer Patent would have been successful as compared to an invention under the '893 Original Lipitor Patent. However, because both the '893 and '995 Patents cover the same product, looking to Lipitor's general success, or to its success as compared to other statins, provides no insight as to whether the '995 Patent is obvious

as compared to the earlier '893 Patent. To have any kind of a meaningful "commercial success" information as it relates to whether the '995 Enantiomer Patent was obvious, one must compare an invention under the '995 Patent to a *different* invention under the '893 Patent. There is no invention that fulfills these parameters.

221. In summary, Pfizer and its predecessors obtained, by actual fraud, the '995 Enantiomer Patent. If Pfizer and its predecessors had not committed actual fraud during the prosecution of the '995 Patent, the PTO would not have issued the'995 Enantiomer Patent, and no other argument as to the validity of the '995 Patent could or would have been made.

222. Without the '995 Patent, generic manufacturers, many of which filed their ANDAs years ago, would have entered the market for generic atorvastatin calcium in March 2010 or September 2010 (depending on whether the generic manufacturer was the first generic applicant or a subsequent applicant).

223. Pfizer and its predecessors have unlawfully foreclosed the market for generic versions of Lipitor. Upon market entry of generic Lipitor, it is estimated that U.S. consumers, the state and federal governments, and third-party payers could save between $10.0 million and $18.6 million per day, or roughly $3.97 billion to $6.8 billion in potential savings a year.

3. Pfizer and Ranbaxy Conspire to Divide Markets and Cause Reissuance of the '995 Patent

224. Ranbaxy filed a protest with the PTO arguing against Pfizer's application for reissuance of the '995 Patent. During the time that Ranbaxy pursued its protest, the PTO rebuffed Pfizer's efforts to obtain such reissuance.

225. Around the time that Ranbaxy filed its protest, however, a prospective purchaser of a $3 billion portion of Ranbaxy insisted that it would not make the purchase unless Ranbaxy worked out a deal with Pfizer, pursuant to which it could share with Pfizer monopoly profits

from Lipitor beyond the terms permitted under the drug's only valid patent, the '893 Original Lipitor Patent, which was set to expire in March 2010.

226. Pfizer knew at this time that its efforts to get reissuance of the '995 Patent were unjustified under *any* reading of the facts and the law.

227. As a result, Ranbaxy and Pfizer cut a deal. Ranbaxy agreed to drop its protest before the PTO and to abstain from marketing in the United States a generic version of Lipitor until November 30, 2011. In exchange, Pfizer authorized Ranbaxy to sell generic Lipitor in at least seven foreign markets prior to the expiration of Pfizer's patents in those countries. Pfizer also gave Ranbaxy the right to sell Caduet, a Pfizer product that combines Lipitor with an off-patent blood pressure medicine. In addition, Pfizer forgave the payment of certain money judgments that had been entered against Ranbaxy. By dropping challenges to the reissuance proceedings and agreeing not to enter the U.S. market until November 2011 (a period of time even after expiry of the '995 reissue patent), Ranbaxy enabled Pfizer to maintain an unlawful monopoly for over another year and a half in connection with a drug that costs American payers many *billions* of dollars per year.

228. The agreement is, of course, an unlawful agreement to divide markets, restrain competition and maintain extraordinarily high prices for a widely used maintenance medication. It also follows on the heels of an effort by Pfizer, dating back over twenty years, to do anything, without any recognition of the law, to profit from the sale of this incredibly lucrative drug.

229. Pfizer's second infringement suit against Ranbaxy, which sought to enforce certain process patents (a claim the first infringement court refused to allow), was sham litigation, intended to operate as a cover for the "settlement" agreement. There was no risk to Ranbaxy and no real case or controversy because the parties knew there was no imminent (or

even realistic) threat of injury under the asserted patents; this point had already been decided in the first infringement litigation.

VI. INTERSTATE COMMERCE

230. Defendants' efforts to monopolize and restrain competition in the market for atorvastatin calcium have substantially affected interstate, intrastate, and foreign commerce.

231. At all material times, Pfizer manufactured, promoted, distributed, and sold substantial amounts of 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.

232. At all material times, Pfizer transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Lipitor and/or AB-rated bioequivalents. Beginning around November 30, 2011, Ranbaxy did the same with respect to generic Lipitor.

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

VII. MONOPOLY POWER AND MARKET DEFINITION

234. At all relevant times, Pfizer had monopoly power over Lipitor and its generic equivalents because it had the power to maintain the price of the drug it sold as Lipitor at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Lipitor, with the exception of AB-rated generic versions of Lipitor.

235. A small but significant, non-transitory price increase for Lipitor by Pfizer would not have caused a significant loss of sales to other products prescribed and/or used for the same purposes as Lipitor, with the exception of AB-rated generic versions of Lipitor .

236. 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.

237. Because of, among other reasons, its use and varying ability to inhibit the production of cholesterol, Lipitor is differentiated from all products other than AB-rated generic versions of Lipitor.

238. Defendants 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 their current prices of Lipitor without losing substantial sales.

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

240. Defendants have had, and exercised, the power to exclude and restrict competition to Lipitor and AB-rated bioequivalents.

241. To the extent that Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges 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, Defendants have been able to profitably maintain the price of Lipitor and/or AB-rated bioequivalents well above competitive levels.

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

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

244. Pfizer's market share in the relevant market was 100% until November 30, 2011, implying a substantial amount of monopoly power.

VIII. MARKET EFFECTS

245. Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Lipitor from generic competition. Defendants' actions allowed Pfizer to maintain a monopoly and to exclude competition in the market for Lipitor and its AB-rated generic equivalents, to the detriment of Plaintiffs and all other members of the End-Payor Class.

246. Defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Pfizer to sell Lipitor without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Lipitor earlier than November 30, 2011, the date on which Ranbaxy first marketed its generic version of the drug. A generic Lipitor would have been on the market on or about March 24, 2010, and in no event later than June 28, 2011.

247. Pfizer, acting alone and/or in concert with Ranbaxy, willfully and unlawfully maintained its monopoly power and unlawfully conspired in restraint of trade by engaging in an overarching scheme to exclude competition that discouraged, rather than encouraged, competition on the merits. This scheme was designed for the anticompetitive purpose of forestalling generic competition and was carried out with the anticompetitive effect of maintaining supracompetitive prices for the relevant product. Pfizer implemented its scheme by,

inter alia, manipulating the prosecution of the '995 Patent, manipulating the reissuance process for the '995 Patent, prosecuting multiple sham patent infringement lawsuits, settling on terms outside the scope of the patent to divide the market, and abusing the Hatch-Waxman framework, in concert with Ranbaxy, to serve its anticompetitive goals. These acts in combination were anticompetitive.

248. The generic manufacturers seeking to sell generic Lipitor had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products.

249. Defendants' illegal acts, which delayed introduction into the U.S. marketplace of generic versions of Lipitor, have caused Plaintiff and the Class to pay more than they would have paid for atorvastatin calcium products absent Defendants' illegal conduct.

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

251. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, end-payors, such as Plaintiff and members of the 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) receiving discounts on their remaining branded Lipitor purchases, and (c) purchasing generic Lipitor at lower prices sooner.

252. Defendants' unlawful conduct had substantial and significant intrastate effects in each state because, *inter alia*, Lipitor and AB-rated generic Lipitor were sold to consumers and third-party payors in each state at higher prices than would have existed absent the unlawful conduct, and Defendants entered into an unlawful agreement that affected commerce, product availability, and competition in each state.

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

254. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT

255. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Lipitor indirectly from Defendants and/or purchased substantial amounts of AB-rated Lipitor bioequivalent generic indirectly from Defendants or others. As a result of Defendants' illegal conduct, members of the End-Payor Class were compelled to pay, and did pay, artificially inflated price 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, (2) Class members were deprived of the opportunity to purchase

lower-priced generic versions of Lipitor sooner, and/or (3) the price of AB-rated Lipitor generic atorvastatin calcium was artificially inflated by Defendants' illegal conduct.

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

257. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Hovencamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624. According to Professor Hovencamp, "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." Professor Hovencamp also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

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

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

260. The prices were inflated as a direct and foreseeable result of Pfizer's anticompetitive conduct individually and with Ranbaxy.

261. The inflated prices the End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges by Pfizer and Ranbaxy.

X. CLASS ACTION ALLEGATIONS

262. Plaintiff, on behalf of itself and all End-Payor Class members, seeks damages, measured as overcharges, trebled, against Defendants based on allegations of anticompetitive conduct in the market for Lipitor and AB-rated generic equivalents.

263. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(3), as representatives of an End-Payor Class defined as follows:

> All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price for Lipitor and/or its AB-rated generic equivalents in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiares (the "Class"), other than for resale, during the period March 25, 2010 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Lipitor or its generic equivalent if they paid or reimbursed some or all of the purchase price.

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

a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for governmental funded employee benefit plans;

c. All persons or entities who purchased Lipitor or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates;

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

e. Any "flat co-pay" consumers whose purchases were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price;

f. Any "brand loyalist" consumers or third-party payors who purchased Lipitor and who did not purchase any AB-rated generic equivalent after such generics became available; and

g. The judges in this case and any members of their immediate families.

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

266. Plaintiff's claims are typical of the claims of the members of the End-Payor Class. Plaintiff and all members of the End-Payor Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for atorvastatin calcium and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Lipitor as a result of Defendants' wrongful conduct.

267. Plaintiff will fairly and adequately protect and represent the interests of the End-Payor Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the End-Payor Class.

268. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

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

270. Questions of law and fact common to the End-Payor Class include:

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

b. whether Warner-Lambert improperly listed the '995 Patent in the Orange Book;

c. whether Defendants unlawfully excluded competitors and potential competitors from the market for Lipitor and its AB-rated generic bioequivalents;

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

e. whether Defendants maintained monopoly power by delaying generic entry;

f. whether Defendants entered into an unlawful agreement in restraint of trade;

g. whether the law requires definition of a relevant market when direct proof of monopoly power is available and, if so, the definition of the relevant market;

h. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

i. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and the members of the Class; and

j. the quantum of aggregate overcharge damages to the Class.

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

272. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
For Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Defendants' Violations of Sections 1 and 2 of the Sherman Act (Asserted Against All Defendants)

273. Plaintiff incorporates by reference the preceding allegations.

274. Defendants knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of atorvastatin calcium, *i.e.*, AB-rated generic versions of Lipitor, and to willfully to maintain their monopoly power. This scheme included, *inter alia*, (i) obtaining by actual fraud the '995 Enantiomer Patent, (ii) fraudulently listing the '995 Enantiomer Patent in the Orange Book, (iii) filing infringement litigation against multiple generic manufacturers claiming infringement of the fraudulently-obtained '995 Enantiomer Patent, (iv) fraudulently obtaining reissuance of the '995 Patent, (v) unlawfully agreeing with Ranbaxy to divide a market and delay price reductions for Lipitor, and (vi) otherwise engaging in an overarching scheme to unlawfully monopolize, conspire to monopolize, and allocate the market for atorvastatin calcium.

275. Defendants conspired to monopolize, and did wrongfully and intentionally maintain monopoly power, with respect to atorvastatin calcium in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiff and members of the Class paid artificially inflated prices for their atorvastatin calcium requirements.

276. By their agreements, Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act. As a result of this unreasonable restraint on competition, Plaintiff and members of the Class paid artificially inflated prices for their atorvastatin calcium requirements.

277. Plaintiff and members of the Class have been injured in their business or property by Defendants' antitrust violations. Their injury consists of being deprived of the ability to purchase less expensive, generic versions of Lipitor, and having paid, and continuing to pay, higher prices for their atorvastatin calcium requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent, flows from that which makes Defendants' conduct unlawful, and Plaintiff and the Class are the proper entities to bring a case concerning this conduct.

278. Although at least one generic version of Lipitor has entered the market, Plaintiffs continue to suffer and will continue to suffer in the future from paying higher prices for Lipitor and/or AB-rated generic versions than they would have absent Defendants' anticompetitive conduct.

279. Defendants' anticompetitive conduct is not entitled to qualified *Noerr-Pennington* immunity.

280. Plaintiffs and the Class, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a) hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Sections 1 and 2 of the Sherman Act.

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

SECOND CLAIM FOR RELIEF
For Monopolization Under State Law
(Asserted Against Pfizer)

282. Plaintiff incorporates by reference the preceding allegations.

283. As described above, from at least July 21, 1987 until November 30, 2011, Pfizer possessed monopoly power in the market for atorvastatin calcium products. No other manufacturer sold a competing version of Lipitor before November 30, 2011.

284. Pfizer willfully and unlawfully acquired and maintained its monopoly power in the atorvastatin calcium market through at least November 30, 2011 by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

285. Pfizer knowingly and intentionally engaged in an anticompetitive scheme to monopolize the atorvastatin calcium products (*i.e.*, Lipitor in all its forms and dosage strengths) and AB-rated bioequivalent atorvastatin calcium products market, as described above. Pfizer accomplished this scheme by, *inter alia*, (i) obtaining by actual fraud the '995 Enantiomer Patent, (ii) fraudulently listing the '995 Enantiomer Patent in the Orange Book, (iii) filing infringement litigation against multiple generic manufacturers claiming infringement of the fraudulently-obtained '995 Enantiomer Patent, (iv) fraudulently obtaining reissuance of the '995 Patent, (v) unlawfully agreeing with Ranbaxy to divide a market and delay price reductions for Lipitor, and (vi) otherwise engaging in an overarching scheme to unlawfully monopolize and conspire to monopolize the market for atorvastatin calcium.

286. The goal, purpose and effect of Pfizer's scheme was to prevent and delay the sale of atorvastatin calcium products in the United States at prices significantly below Pfizer's prices

for Lipitor, thereby effectively preventing the average market price of atorvastatin calcium products from declining dramatically.

287. The goal, purpose and effect of Pfizer's scheme was also to maintain and extend its monopoly power with respect to atorvastatin calcium products. Pfizer's illegal scheme allowed Pfizer to continue charging supracompetitive prices for atorvastatin calcium products, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

288. Plaintiff and members of the Class purchased substantial amounts of Lipitor and/or AB-rated generic equivalents indirectly from Pfizer and/or other manufacturers.

289. Pfizer knowingly and intentionally engaged in sham litigation against potential manufacturers of AB-rated generic equivalents of Lipitor. Pfizer repeatedly asserted that the generic Lipitor formulations of its competitors infringed its patents, despite knowing that the Lipitor patents were fraudulently procured, invalid, and/or unenforceable. Pfizer filed these sham lawsuits for purposes of using a governmental process as an anticompetitive weapon to keep AB-rated generic equivalents off the market.

290. Pfizer also knowingly and intentionally engaged in a second sham litigation against Ranbaxy when it raised process patent claims (that had been rejected by a Delaware District court in the earlier litigation) in order to provide cover for a "settlement" agreement that extended Pfizer's atorvastatin calcium monopoly and provided for global market allocation. Pfizer knew at the time it filed the second sham lawsuit that it had no realistic likelihood of success; therefore, Pfizer knew that no reasonable pharmaceutical manufacturer in its position would have believed it had a reasonable chance of succeeding on the merits.

291. As a result of Defendants' illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, more than they would have paid for their atorvastatin

calcium requirements absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun selling generic Lipitor sooner than they did, and prices for atorvastatin calcium products would have been lower, sooner.

292. Had manufacturers of generic atorvastatin calcium products entered the market and lawfully competed with Pfizer in a timely fashion, Plaintiff and other members of the Class would have substituted lower-priced generic atorvastatin calcium products for the higher-priced brand-name Lipitor for some or all of their atorvastatin calcium products requirements, and/or would have paid lower net prices on their remaining Lipitor and/or AB-rated bioequivalent purchases.

293. By engaging in the foregoing conduct, Pfizer has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee commerce, with thousands of end-payors in Tennessee paying substantially higher prices for Lipitor and AB-rated bioequivalents at Tennessee pharmacies.

294. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic atorvastatin calcium products, sooner, and (2) paying higher prices for atorvastatin calcium products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

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

THIRD CLAIM FOR RELIEF
For Conspiracy to Monopolize Under State Law
(Asserted Against All Defendants)

296. Plaintiff incorporates by reference the preceding allegations.

297. As described above, from at least July 21, 1987 until November 30, 2011, Pfizer possessed monopoly power in the market for atorvastatin calcium products. No other manufacturer sold a competing version of Lipitor before November 30, 2011.

298. Defendants willfully and unlawfully engaged in a continuing illegal conspiracy to monopolize the atorvastatin calcium market through at least November 30, 2011 by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

299. Defendants knowingly and intentionally conspired to monopolize the atorvastatin calcium products (*i.e.*, Lipitor in all its forms and dosage strengths) and AB-rated bioequivalent atorvastatin calcium products market, as described above. Defendants accomplished this scheme by, *inter alia*, (i) obtaining by actual fraud the '995 Enantiomer Patent, (ii) fraudulently listing the '995 Enantiomer Patent in the Orange Book, (iii) filing infringement litigation against multiple generic manufacturers claiming infringement of the fraudulently-obtained '995 Enantiomer Patent, (iv) fraudulently obtaining reissuance of the '995 Patent, (v) unlawfully agreeing to divide a market and delay price reductions and generic competition for Lipitor, and (vi) otherwise conspiring to unlawfully monopolize and conspire to monopolize the market for atorvastatin calcium.

300. The goal, purpose and effect of Defendants' scheme was to prevent and delay the sale of atorvastatin calcium products in the United States at prices significantly below Pfizer's

prices for Lipitor, thereby effectively preventing the average market price of atorvastatin calcium products from declining dramatically.

301. The goal, purpose and effect of Defendants' scheme was also to maintain and extend Pfizer's monopoly power with respect to atorvastatin calcium products. Defendants' illegal scheme allowed Pfizer to continue charging supracompetitive prices for atorvastatin calcium products, without a substantial loss of sales, reaping substantial unlawful monopoly profits. Defendants' scheme allowed Ranbaxy to reap the benefits of reduced generic competition in the United States and premature access to foreign markets.

302. Plaintiff and members of the Class purchased substantial amounts of Lipitor and/or AB-Rated generic equivalents indirectly from Defendants and/or other manufacturers.

303. The agreements between Pfizer and Ranbaxy are overt acts between separate economic entities—actual and potential competitors—and are illegal *per se* under state antitrust laws. Alternatively, this Complaint alleges that the agreements and conspiracy to monopolize are a violation of state antitrust law under a "quick look" or "rule of reason" analysis.

304. Defendants knowingly and intentionally engaged in sham litigation regarding process patent claims (that had been rejected by a Delaware District court in earlier litigation) that Defendants knew, or should have known, were objectively baseless, in order to provide cover for an anticompetitive "settlement" agreement that extended the atorvastatin calcium monopoly and provided for global market allocation.

305. Defendants knew at the time Pfizer filed the second sham lawsuit that Pfizer had no realistic likelihood of success; therefore, Defendants knew that no reasonable pharmaceutical manufacturer in Pfizer's position would have believed it had a reasonable chance of succeeding

on the merits. Ranbaxy knew, or should have known, that it was at no risk in the second litigation.

306. As a result of Defendants' illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, more than they would have paid for their atorvastatin calcium requirements absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun selling generic Lipitor sooner than they did, and prices for atorvastatin calcium products would have been lower, sooner.

307. Had manufacturers of generic atorvastatin calcium products entered the market and lawfully competed with Defendants in a timely fashion, Plaintiff and other members of the Class would have substituted lower-priced generic atorvastatin calcium products for the higher-priced brand-name Lipitor for some or all of their atorvastatin calcium products requirements, and/or would have paid lower net prices on their remaining Lipitor and AB-rated bioequivalent purchases.

308. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Lipitor well before November 30, 2011, and they would have been able to market such versions more successfully.

309. There was a dangerous probability that Defendants' efforts to monopolize the atorvastatin calcium market would be successful.

310. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee commerce, with thousands of end-payors in Tennessee

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

311. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic atorvastatin calcium products, sooner, and (2) paying higher prices for atorvastatin calcium products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

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

FOURTH CLAIM FOR RELIEF
For Conspiracy and Combination in Restraint of Trade Under State Law
(Asserted Against All Defendants)

313. Plaintiff incorporates by reference the preceding allegations.

314. Defendants willfully and unlawfully engaged in a continuing illegal contract, combination, and conspiracy to restrain trade in the atorvastatin calcium market by engaging in an anticompetitive scheme to keep generic equivalents from the market and to allocate the market between horizontal competitors.

315. Defendants accomplished this scheme by, *inter alia*, (i) obtaining by actual fraud the '995 Enantiomer Patent, (ii) fraudulently listing the '995 Enantiomer Patent in the Orange Book, (iii) filing infringement litigation against multiple generic manufacturers claiming infringement of the fraudulently-obtained '995 Enantiomer Patent, (iv) fraudulently obtaining reissuance of the '995 Patent, (v) unlawfully agreeing to divide the market and delay price reductions and generic competition for Lipitor in the United States, and (vi) entering into

anticompetitive sham litigation and anticompetitive sham litigation settlements to cover the terms of the agreement allocating the market for atorvastatin calcium in the United States.

316. The goal, purpose and effect of Defendants' scheme was to prevent and delay the sale of atorvastatin calcium products in the United States at prices significantly below Pfizer's prices for Lipitor, thereby effectively preventing the average market price of atorvastatin calcium products from declining dramatically. This effectively fixed the price of atorvastatin calcium products.

317. The goal, purpose and effect of Defendants' scheme was also to maintain and extend Pfizer's monopoly power with respect to atorvastatin calcium products. Defendants' illegal scheme allowed Pfizer to continue charging supracompetitive prices for atorvastatin calcium products, without a substantial loss of sales, reaping substantial unlawful monopoly profits. Defendants' illegal scheme allowed Ranbaxy to reap the benefits of reduced generic competition in the United States and premature access to foreign markets.

318. Plaintiff and members of the Class purchased substantial amounts of Lipitor and/or AB-rated generic equivalents indirectly from Defendants and/or other manufacturers.

319. The agreements between Defendants are horizontal market allocation and price fixing agreements between actual or potential competitors and are illegal *per se* under state antitrust laws. Alternatively, this Complaint alleges that these agreements are an unreasonable restraint of trade, in violation of state antitrust law, under a "quick look" or "rule of reason" analysis.

320. Defendants knowingly and intentionally engaged in sham litigation regarding process patent claims (that had been rejected by a Delaware District court in earlier litigation) that Defendants knew, or should have known, were objectively baseless in order to provide cover

for an anticompetitive "settlement" agreement, outside the scope of the relevant patents, which divided the relevant market between horizontal competitors.

321. Defendants knew at the time Pfizer filed this sham suit that Pfizer had no realistic likelihood of success; therefore, Defendants knew that no reasonable pharmaceutical manufacturer in Pfizer's position would have believed it had a reasonable chance of succeeding on the merits. Ranbaxy knew, or should have known, that it was at no risk in the second litigation.

322. As a result of Defendants' illegal conspiracy and combination in restraint of trade, Plaintiff and members of the Class were compelled to pay, and did pay, more than they would have paid for their atorvastatin calcium requirements absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun selling generic Lipitor sooner than they did, and prices for atorvastatin calcium products would have been lower, sooner.

323. Had other manufacturers of generic atorvastatin calcium products entered the market and lawfully competed with Defendants in a timely fashion, Plaintiff and other members of the Class would have substituted lower-priced generic atorvastatin calcium products for the higher-priced brand-name Lipitor for some or all of their atorvastatin calcium products requirements, and/or would have paid lower net prices on their remaining Lipitor and/or AB-rated bioequivalent purchases.

324. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Lipitor well before November 30, 2011, and would have been able to market such versions more successfully.

325. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn.

Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee commerce, with thousands of end-payors in Tennessee paying substantially higher prices for Lipitor and AB-rated bioequivalents at Tennessee pharmacies.

326. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic atorvastatin calcium products, sooner, and (2) paying higher prices for atorvastatin calcium products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

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

FIFTH CLAIM FOR RELIEF
Unjust Enrichment
(Asserted Against All Defendants)

328. Plaintiff incorporates by reference the preceding allegations.

329. Defendants have benefited from the monopoly profits on their sales of Lipitor and/or AB-rated bioequivalents resulting from the unlawful and inequitable acts alleged in this Complaint.

330. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Lipitor and AB-rated bioequivalents by Plaintiff and members of the Class.

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

332. It would be futile for Plaintiff and the Class to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiff and the Class.

333. It would be futile for Plaintiff and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Lipitor or its generic equivalents, as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Defendants.

334. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Lipitor and/or its generic equivalents is a direct and proximate result of Defendants' unlawful practices.

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

336. It would be inequitable under the laws of all states and jurisdictions within the United States for the Defendants to be permitted to retain any of the overcharges for Lipitor and/or AB-rated bioequivalents derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

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

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

339. Plaintiff and the Class have no adequate remedy at law.

XII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the End-Payor Class, demands judgment for the following relief:

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 Plaintiff representative of the End-Payor Class;

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

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

D. Enter joint and several judgments against Defendants in favor of Plaintiff and the End-Payor Class;

E. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

F. Award the End-Payor Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

G. Award Plaintiff and the End-Payor Class their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

XIII. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiff on behalf of itself and the proposed class demand a trial by jury on all issues so triable.

Dated: March 26, 2012

Respectfully submitted,

/s/ Jonathan Shapiro

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