CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

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STATE OF FLORIDA by Attorney General Bill McCollum)	
STATE OF ARIZONA by Attorney General Terry Goddard)	
STATE OF ARKANSAS by Attorney General Dustin McDaniel)	
STATE OF CALIFORNIA) by Attorney General Edmund G. Brown, Jr.)	
STATE OF CONNECTICUT by Attorney General Richard Blumenthal)	-
DISTRICT OF COLUMBIA by Interim Attorney General Peter J. Nickles)	
STATE OF IOWA) by Attorney General Thomas J. Miller)	
STATE OF KANSAS by Attorney General Stephen N. Six)	
STATE OF MAINE by Attorney General G. Steven Rowe)	
STATE OF MARYLAND) by Attorney General Douglas F. Gansler)	
STATE OF MINNESOTA) by Attorney General Lori Swanson)	
STATE OF MISSOURI) by Attorney General Jeremiah (Jay) W. Nixon)	
STATE OF NEVADA by Attorney General Catherine Cortez Masto)	
STATE OF NEW YORK) by Attorney General Andrew M. Cuomo)	
)	

STATE OF OREGON)
by Attorney General Hardy Myers	
COMMONWEALTH OF PENNSYLVANIA)
by Attorney General Tom Corbett	
STATE OF SOUTH CAROLINA)).
by Attorney General Henry McMaster)
STATE OF WASHINGTON)
by Attorney General Rob McKenna)
STATE OF WEST VIRGINIA by Attorney General Darrell V. McGraw, Jr.)))
Plaintiffs, v.)) No.)
ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTE, and LABORATOIRES FOURNIER, S.A.,)))) JURY TRIAL DEMANDED
Defendants.)

COMPLAINT

The States of Florida, Arizona, Arkansas, California, Connecticut, Iowa, Kansas, Maine, Maryland, Minnesota, Missouri, Nevada, New York, Oregon, South Carolina, Washington, West Virginia, the Commonwealth of Pennsylvania, and the District of Columbia (collectively "Plaintiff States"), by their Attorneys General, on behalf of and/or for the benefit of their respective citizens and government entities, complain against Defendants Abbott Laboratories ("Abbott") and Defendants Fournier Industrie et Sante and Laboratories Fournier, S.A., (collectively "Fournier") as follows:

Nature of the Action

- 1. Plaintiff States seek injunctive relief, penalties, damages, disgorgement and restitution for the Defendants' unlawful monopolization of the fenofibrate market. Abbott and Fournier feared that competition from generic manufacturers would significantly decrease prices for fenofibrate drugs and dilute their TriCor monopoly profits when consumers and state purchasers switched to lower-priced generic drugs. Once generic competition began, Abbott and Fournier knew that sales of TriCor would decline significantly. As a result, they conspired to implement their anti-generic strategy.
- 2. TriCor is a brand-name prescription drug that uses the active ingredient, fenofibrate, to regulate triglyceride and cholesterol levels. TriCor and other fenofibrate drugs lower triglyceride levels, reduce low-density lipoprotein cholesterol ("LDL" or "bad cholesterol"), and increase the levels of high-density lipoprotein cholesterol ("HDL" or "good cholesterol"). Fenofibrate drugs are prescribed for patients with hypercholesterolemia (high bad cholesterol), hypertriglyceridemia (high triglycerides), and mixed dyslipidemia (high bad cholesterol, high triglycerides, and low good cholesterol). TriCor is a maintenance drug that is generally prescribed for long-term cholesterol problems. Prescriptions for TriCor often provide numerous refills.
- 3. Since 1998, Abbott and Fournier have sold TriCor in the United States and have conspired to maintain monopoly power in fenofibrate drugs by excluding generic competition through improper means. As a result, consumers and state governments have paid more for fenofibrate drugs while Abbott and Fournier enjoyed annual revenues from TriCor sales that exceeded \$1 billion.

- 4. Abbott and Fournier conspired to monopolize and implemented an antigeneric strategy by orchestrating a scheme that involved:
 - a) Obtaining multiple patents through inequitable conduct, listing these patents with the Food and Drug Administration, knowing they were obtained improperly, and then filing sham patent litigation without a reasonable basis to believe those patents were enforceable and/or were infringed, for the purpose of delaying generic entry and foreclosing competition in the market; and
 - b) Forcing the market to convert to new formulations before generic entry by:
 - i. Reformulating TriCor with only minor changes to a form and dosage strength, which did not provide any significant new clinical benefit;
 - ii. Creating an artificial product differentiation to be used as a marketing tool to convince physicians to stop writing prescriptions for the old formulation and to write prescriptions only for the new formulation;
 - iii. Stopping promotion and sales of the previous TriCor formulation upon the introduction of the new formulation;
 - iv. Removing the old TriCor formulation from the market, so as to make it commercially unavailable by the time a generic competitor could enter the market, and
 - v. Interfering with the normal and customary channels of distribution used by generics to compete in the market.
- 5. Abbott's and Fournier's anti-generic strategy was successful. When the patent litigations against the generic manufacturers of fenofibrate concluded, the old formulations of TriCor were no longer commercially available for any entering generic manufacturer to compete against. Abbott and Fournier have executed this on-going scheme to convert the fenofibrate market twice: first in 2001-2002, when they converted the market from TriCor 200mg capsules to TriCor 160mg tablets; and then in 2004-2005,

when they converted the market from TriCor 160mg tablets to TriCor 145mg tablets.

Moreover, Abbott and Fournier plan to continue their reformulation strategy for TriCor.

- 6. Abbott's and Fournier's anti-generic scheme was designed and undertaken for the purpose of, and had the intended effect of, preventing generic substitution, foreclosing competition, and denying consumer choice.
- 7. As a result of Abbott's and Fournier's anticompetitive conduct, consumers and state governments have been and continue to be deprived of the lower prices that generic competition brings, while Abbott and Fournier have continued to reap monopoly profits from the sale of TriCor.
- 8. Furthermore, Abbott's and Fournier's conduct has been deceptive or unconscionable, has included unfair practices and/or unfair methods of competition, or has been otherwise unlawful under the consumer protection laws of certain of the Plaintiff States and has caused harm to those Plaintiff States, their governmental entities and consumers by forcing them to pay more for fenofibrate than they otherwise would have in a competitive market.

Jurisdiction & Venue

9. Under 28 U.S.C. §§1331 and 1337, this Court has subject matter jurisdiction over the federal antitrust claims under the Sherman Act. This Court also has supplemental jurisdiction over the state law claims under 28 U.S.C. §1367 because those claims are so related to the federal claims that they form part of the same case or controversy. The exercise of supplemental jurisdiction avoids unnecessary duplication and multiplicity of actions and is in the interests of judicial economy, convenience, and fairness.

10. Venue is proper in this district under 15 U.S.C. §22 and 28 U.S.C. §1391(b) and (c). Each Defendant resides, transacts business, committed an illegal or tortious act, or is found in this district, and a substantial part of the events giving rise to the claims arose in this district.

Parties

- 11. Defendant Abbott Laboratories is a corporation organized, existing and doing business under the laws of the State of Illinois. Its office and principal place of business is located at 100 Abbott Park Road, Abbott Park, Illinois. Abbott is engaged principally in the development, manufacture, and sale of pharmaceuticals and health care products and services throughout the United States.
- 12. Defendant Fournier Industrie et Sante is a French corporation headquartered at 42, Rue de Longvic, 21300 Chenove, France. Formerly known as Fournier Innovation et Synergie, Fournier Industrie et Sante was the holding company for a conglomerate of French and international companies.
- 13. Defendant Laboratoires Fournier, S.A. is a wholly-owned French subsidiary of Fournier Industrie et Sante and is also headquartered at 42, Rue de Longvic, 21300 Chenove, France. Fournier Industrie et Sante and Laboratoires Fournier, S.A. collaborated with Abbott for regulatory approval, production, and sale of TriCor in the United States.
- 14. Plaintiff States bring this action by and through their Attorneys General:

 (a) in their sovereign capacities as representatives and/or for the benefit of natural persons and/or as parens patriae of natural persons under state or federal law; (b) as parens patriae in their sovereign capacities to redress injury to their respective states'

general economies; (c) in their sovereign and/or proprietary capacities, which may include state departments, bureaus, agencies, political subdivisions, and other instrumentalities as purchasers (either directly, indirectly, or as assignees), based on purchases of TriCor; and/or (d) as the chief law enforcement agency or other enforcement agency of each state to the extent that violations of the states' antitrust and consumer protection laws and regulations are alleged herein.

Relevant Market

- 15. The relevant product market is any drug with fenofibrate as the active ingredient. Fenofibrate has a unique therapeutic effect on cholesterol and triglyceride levels and differs from other lipid-regulating drugs such that they are not reasonably interchangeable. The fenofibrate market includes TriCor and generics that can be substituted.
 - 16. The relevant geographic market is the United States.
- 17. At all relevant times, Abbott and Fournier enjoyed a market share in the United States fenofibrate market between 90% and 100%.

Trade and Commerce

- 18. Since May 1998, TriCor has been sold in interstate commerce throughout the United States.
- 19. TriCor has been transported across state lines and has been sold in each of the Plaintiff States. Abbott's and Fournier's unlawful activities alleged in this Complaint have occurred in and have had a substantial effect upon interstate commerce. Abbott's and Fournier's annual revenues for TriCor sold in the U.S. have surpassed \$1 billion.

Factual Background

I. The Hatch-Waxman Act

- 20. The manufacture and commercial sale of pharmaceutical drugs are regulated by the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301, *et seq*. The manufacturer of a new drug must submit a new drug application ("NDA") that demonstrates, among other things, a drug's safety, clinically-proven effectiveness, composition, and patent coverage.
- 21. To speed the entry of generic drugs and to facilitate price competition with branded drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). Under the Hatch-Waxman Act, generic drug manufacturers may receive FDA approval for generic drugs without replicating costly and time-consuming clinical trials. Instead, a generic drug manufacturer may submit an abbreviated new drug application ("ANDA") and incorporate data, such as clinical studies, that the NDA filer submitted to the FDA. To be approved, an ANDA must demonstrate that the generic drug has the same active ingredients as, is pharmaceutically equivalent to, is bioequivalent to, and has the same labeling as the previously approved drug. The FDA publishes a list of all approved drugs and therapeutically equivalents in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book").
- 22. The Orange Book also lists all patents, if any, covering an approved drug. If the ANDA applicant seeks approval to market a drug before the expiration date of one or more of the patents listed in the Orange Book, the ANDA applicant must certify that each patent "is invalid, unenforceable or will not be infringed by the manufacture, use, or

sale of the new drug for which the application is submitted." 21 U.S.C. §355 (j)(2)(A) (vii)(IV). This is commonly referred to as a Paragraph IV Certification. An ANDA applicant must also notify the patent owner and NDA holder of the Paragraph IV Certification and provide a written statement of the reasons each patent is not infringed, is invalid, or is unenforceable.

that believes the generic will infringe a valid and enforceable patent may sue the ANDA applicant for patent infringement. If such an action is brought within 45 days from receipt of that notice, the FDA is precluded from granting final approval of the ANDA until the earlier of: 1) 30 months from the receipt of the Paragraph IV notice; 2) the date on which the court holds the patent is invalid, not infringed, or unenforceable; or 3) the date on which the case is withdrawn, discontinued, dismissed, or otherwise terminated by the patent holder or NDA holder. This time period is often referred to as a "30-month stay." If the patent holder or NDA holder does not file a patent infringement action within the 45-day period, the FDA may grant final approval of the ANDA, if the FDA's other regulatory requirements are satisfied.

II. Generic Substitution

- 24. In most States and under most health plans, a pharmacist may substitute a generic drug for a prescribed brand name drug when the FDA has given the generic drug an AB rating to that branded drug.
- 25. An AB rating requires the generic drug to be both pharmaceutically equivalent and bioequivalent to the branded drug. The FDA considers a drug product to be a pharmaceutical equivalent if the drug contains the same active ingredient; is of the

same dosage, form, and route of administration; and is identical in strength. The FDA considers a drug product bioequivalent if the drug shows comparable bioavailability, which is the rate and extent that the active ingredient is absorbed from the drug product when studied under similar experimental conditions.

26. Once the FDA approves an ANDA for a generic drug and determines it is AB-rated to the branded drug, state laws govern how the generic drug may be substituted for the brand name drug prescribed by physicians. Generally, state laws permit pharmacists to substitute an AB-rated generic drug for the brand name drug, unless there is a doctor or patient request otherwise.

III. Insurance Coverage and Patient Co-Pays

- While some patients are responsible for the full cost of prescription drugs, health plans, insurers and other third-party payors pay most of the direct costs of acquiring prescription drugs and use various means to control costs, including a formulary. A formulary is a list of preferred drugs that a payor predetermines that it will cover for its enrollees. Formularies can be open, closed or incentive-based. An incentive-based formulary generally tiers the drugs on the formulary by preference and charges enrollees the lowest co-pay for drugs from the first tier.
- 28. Healthcare insurers and other third parties who pay for prescription medications use private databases, like First DataBank's National Drug Data File ("NDDF"), to access prescription drug descriptions and pricing data, to identify AB-rated drugs and to obtain other information about FDA-approved drugs. For example, the NDDF uses a "Generic Indicator" code to identify whether a drug is a "single-source product" (i.e. the drug is supplied by only one company), or whether it is a "multi-source

product" (i.e. the drug is supplied by multiple companies). Identifying a drug as a "multi-source product" indicates that an AB-rated generic drug is available.

- 29. Brand-name drug manufacturers can manipulate the NDDF to restrain generic competition. For example, if a manufacturer's reference number or NDC number for the branded drug is removed from the NDDF, the branded drug is no longer listed in that database. The branded drug would no longer be linked to any generic that obtains an AB-rating to the branded drug. A later-listed generic then would be identified as a single source product, causing insurers and other payors to classify the intended generic drug as a branded product and either not cover it or charge patients higher co-pays for it. The result is that it is less likely that the generic drug will be either dispensed or purchased.
- 30. Similarly, the removal of the reference to the branded drug and/or the NDC number would impede a pharmacist's ability to advise the consumer that an AB-rated generic drug is available, or to contact the consumer's physician to suggest the physician re-write a prescription for that generic. Thus, manufacturers can manipulate the availability of important information that third-party payors and pharmacists frequently rely on, causing normal channels of distribution for generic manufacturers to be disrupted, if not entirely foreclosed.

Abbott's and Fournier's Anticompetitive Conduct

I. Abbott's and Fournier's First TriCor Switch

- A. Abbott and Fournier Developed an Anti-Generic Strategy
- 31. Fournier received FDA approval in 1993 for a fenofibrate drug called Lipidil. Fournier did not market Lipidil in the United States so it sought and found an experienced, United States-based collaborator: Abbott. In January 1998, Abbott and

Fournier reached an agreement under which Fournier licensed to Abbott the rights to sell Fournier's fenofibrate drug in the United States. Since then, Abbott and Fournier have been collaborators in developing and marketing fenofibrate drugs in the United States under the brand name TriCor.

- 32. In February 1998, Fournier received FDA approval to sell 67mg TriCor capsules to treat high triglyceride levels, and later Abbott received FDA approval to sell TriCor capsules at 134mg and 200mg strengths (collectively "TriCor 200mg Capsules").
- 33. Abbott and Fournier expected that generic competition could occur within two to three years after the launch of TriCor 200mg Capsules. They feared that if an ABrated generic fenofibrate drug reached the market, substitution would occur and TriCor's market share would fall significantly.
- 34. Shortly after Abbott introduced TriCor in the United States, Abbott and Fournier began developing a sophisticated scheme to unlawfully thwart generic competition and maintain their monopoly in the fenofibrate market. Abbott and Fournier executives discussed how to exclude and defeat generic competition for TriCor. They agreed that the number one priority was to develop an anti-generic strategy and changing TriCor's formulation was critical to forestall generic competition.
- as Abbott and Fournier agreed to an anti-generic strategy that included enforcing multiple patents with the knowledge that the patents were not infringed. This strategy was intended to generate enough time to introduce a reformulated TriCor product so that any generic competition would be foreclosed. Abbott and Fournier used the 30-month stay triggered by their patent litigation to ensure that they had sufficient time to launch the new formulation, to force the market to convert to it and to withdraw the prior

formulation from the market. This left consumers, physicians, pharmacists and thirdparty payors with no choice but to use the reformulated product. Abbott and Fournier planned to switch the market to a reformulated TriCor product every few years, thereby creating a "moving target" for generic manufacturers.

- B. Abbott and Fournier Used Patent Litigation to Create Time to Reformulate TriCor
- 36. Fournier obtained U.S. Patent No. 4,895,726 ("'726 Patent"), which was listed in the FDA's Orange Book for TriCor 200mg Capsules.
- 37. In December of 1999, a generic manufacturer, Novopharm Ltd., which was later acquired by Teva Pharmaceuticals USA, Inc., (collectively known as "Teva") filed an ANDA with the FDA seeking approval of a generic version of TriCor 200mg Capsules. Pursuant to the Hatch-Waxman Act, Teva submitted a Paragraph IV notice for each strength to Abbott stating that its generic capsules did not infringe the '726 Patent. As part of their anti-generic scheme, after receiving Teva's three Paragraph IV notifications, Fournier and Abbott filed three baseless patent infringement suits against Teva claiming infringement of the '726 Patent, triggering a 30-month stay and delaying the FDA's approval of Teva's generic fenofibrate capsules.
- 38. In May of 2000, Impax Laboratories, Inc. ("Impax") also filed an ANDA for generic fenofibrate capsules and submitted a Paragraph IV Certification stating that its formulation for a generic capsule did not infringe the '726 Patent. After receiving Impax's Paragraph IV notice, Fournier and Abbott filed a baseless patent infringement suit against Impax claiming infringement of the '726 Patent, triggering a 30-month automatic stay and delaying the FDA's approval of Impax's generic fenofibrate capsules.

- 39. The claims contained within the '726 Patent require, among other things, that fenofibrate be co-micronized with a solid surfactant in the absence of any excipients. Because the '726 Patent claims require co-micronization of the fenofibrate and solid surfactant in the absence of excipients, and Teva's and Impax's Paragraph IV notifications expressly indicated they did not use that process, Abbott and Fournier had no basis to sue nor to continue to prosecute their suits against Teva and Impax by asserting that their capsule ANDAs infringed the '726 Patent. These suits began a pattern of Abbott and Fournier filing baseless patent lawsuits against Teva and Impax.
- 40. On March 19, 2002, the District Court granted summary judgment for Teva finding it did not infringe the '726 Patent. Two weeks later the FDA granted final approval of Teva's ANDA for two of the capsule strengths, and by September 2002, the FDA had granted approval for all strengths of Teva's generic fenofibrate capsules. Summary judgment of noninfringement was also later granted in favor of Impax. The Court of Appeals for the Federal Circuit later affirmed the summary judgment in favor of Teva, stating that "there can be no dispute that fenofibrate and a solid surfactant are not 'co-micronized' as that term is used in the '726 Patent."
- 41. Abbott's and Fournier's purpose in filing and maintaining these patent infringement suits against Teva and Impax, both separately and as part of their overall scheme, was to trigger a series of 30-month automatic stays to delay FDA approval of and Teva's and Impax's entry into the market with a generic version of TriCor capsules to interfere with their ability to introduce generic fenofibrate capsules and to compete with TriCor.

- C. Abbott and Fournier Forced the Market to Switch to TriCor 160mg
 Tablets
- 42. During the 30-month stays, triggered by their lawsuits, Abbott and Fournier successfully forced the market to switch to TriCor tablets before competition from generic fenofibrate capsules could begin to erode their monopoly position in the fenofibrate market.
 - 1. The Reformulation: Abbott and Fournier Reformulated TriCor to Avoid Competition from an AB-Rated Drug and to Justify their Marketing Campaign
- 43. While delaying generic entry by filing their patent infringement litigation, Abbott and Fournier executed the rest of their strategy to convert the market to a new formulation of TriCor.
- 44. Abbott and Fournier executed this strategy by making minor changes to TriCor 200mg Capsules, which had no new clinical benefit, to facilitate marketing the next formulation of TriCor to doctors, pharmacists, health insurers and third-party payors.
- 45. During the FDA review of Abbott's NDA, Abbott submitted data to show that the formulation in TriCor 160mg Tablets could raise HDL, or good cholesterol levels. The FDA approved this additional indication for HDL, permitting Abbott to include it on the label for TriCor 160mg Tablets and in their marketing materials.
- 46. In reality, TriCor 160mg Tablets and TriCor 200mg Capsules had the same effect on HDL. Abbott's data demonstrating this effect came from the same Fournier studies previously submitted to the FDA for TriCor 200mg Capsules. This HDL indication could have been sought for TriCor 200mg Capsules. Instead, Abbott and

Fournier chose to delay that request to artificially differentiate TriCor 160 mg Tablets from TriCor 200mg Capsules.

- 47. TriCor 160mg Tablets were not AB-rated to TriCor 200mg Capsules or any generic fenofibrate capsules. While the reformulated TriCor 160mg Tablets were bioequivalent to TriCor 200mg Capsules, the tablets had a different dosage and a different form and were not pharmaceutical equivalents. This change in dosage and form precluded an AB rating for TriCor 160mg Tablets and TriCor 200mg Capsules or any AB-rated generic 200mg capsules. As a result, pharmacists could not substitute TriCor 160mg Tablets with any generic fenofibrate capsules, including those for which Teva and Impax would obtain FDA approval.
- 48. While Abbott's new formulation thwarted the AB-rating, the FDA did not recognize these changes as clinically or therapeutically significant. Abbott's own managers and scientist viewed the capsule and tablet formulations to be clinically and therapeutically equivalent. Moreover, Abbott priced TriCor 160mg Tablets the same as TriCor 200mg Capsules, reflecting that Abbott viewed them as clinically equivalent.
- 49. In switching from capsules to tablets, Abbott and Fournier changed TriCor's labeling, but not its efficacy and safety for consumers. Abbott and Fournier could promote an indication for raising HDL levels as "new" but, in fact, the effect was not "new" because there was no demonstrated change in efficacy between TriCor 200mg Capsules and TriCor 160mg Tablets.

2. The Switch: Abbott Launched a Marketing Blitz

50. A cornerstone of Abbott's and Fournier's marketing strategy was to convince physicians, health insurers, pharmacists and consumers that TriCor 160mg

Tablets had an advantage over TriCor 200mg Capsules. The "new" HDL indication on the label for TriCor 160mg Tablets allowed Abbott to have a new marketing spin for them. A majority of physicians were already aware that TriCor—in capsules or tablets—could raise HDL levels. As a result, the HDL label change was expected to have little-to-no impact on Abbott's sales of TriCor 160mg Tablets.

- 51. Abbott and Fournier launched an aggressive marketing campaign to promote TriCor 160mg Tablets to physicians, pharmacists, insurers and third-party payors. Abbott's sales force canvassed key TriCor prescribers to convince physicians to write all prescriptions and refills for TriCor 200mg Capsules for the newly reformulated TriCor 160mg Tablets.
- 52. Abbott was concerned that if insurers and other third-party payors thought the switch to TriCor 160mg Tablets was a strategy to deter generic competition, they might not place TriCor 160mg Tablets in a preferred position in their formularies.

 Abbott's sales force thus took extra measures to meet with insurers and payors to convince them to list the reformulated TriCor 160mg Tablets as a preferred drug on the formulary.
- 53. Additionally, as part of Abbott's and Fournier's plan, they sent Abbott's sales force to retail pharmacies to discourage them from stocking any fenofibrate drugs other than TriCor 160mg Tablets. Defendants undertook this tactic to deter generic entry and retain their monopoly on fenofibrate.
- 54. To further persuade physicians and pharmacists to prescribe and stock
 TriCor 160mg Tablets, Abbott informed them that they were discontinuing TriCor 200mg
 Capsules.

3. The Forced Conversion: Abbott and Fournier Discontinued Sales and Production of TriCor 200mg Capsules

- 55. As part of their strategy to rapidly convert TriCor purchasers from capsules to tablets prior to the entry of generic competition, Abbott and Fournier planned to discontinue all production, sales and promotion efforts for TriCor 200mg Capsules, and instead to focus all sales and promotional efforts on TriCor 160mg Tablets.
- 56. To accelerate the switch from capsule to tablet formulations, Fournier stopped manufacturing TriCor 200mg Capsules. At the same time, Abbott stopped taking orders and began withdrawing the Capsules from the market.

4. The Purge: Abbott Reclaimed TriCor 200mg Capsules

- 57. In addition to ceasing sales, Abbott and Fournier sought to ensure that the existing inventory of TriCor 200mg Capsules at wholesalers' warehouses and/or on pharmacy stores' shelves was removed so that neither refills nor new prescriptions could be filled due to lack of supply.
- 58. Abbott sought to recover existing inventories of TriCor 200mg Capsules in an effort to purge the market of TriCor 200mg Capsules prior to any generic entry.

 Abbott and Fournier took this extra step because they realized that if TriCor 200mg Capsules were available, especially for refills, there could be no forced conversion to TriCor 160mg Tablets.
- 59. Abbott's and Fournier's plan was to contact wholesalers and large retailers and to offer to exchange TriCor 200mg Capsules for the reformulated TriCor 160mg Tablets. Abbott's plan was to accept capsules in exchange for tablets as well as credits. In doing so, Abbott deviated from its standard return policy in order to expedite the

removal of TriCor 200mg Capsules from the market. After recovering TriCor 200mg Capsules, Abbott destroyed the capsules.

- 60. Abbott's and Fournier's forced conversion strategy was successful. By the end of February 2002, Abbott had killed TriCor 200mg Capsules.
 - 5. The Final Nail: Abbott and Fournier Interfered with the Normal and Customary Methods Generics Use to Compete
- 61. By effectively purging the market of TriCor 200mg Capsules, Abbott and Fournier prevented pharmacists from substituting generic fenofibrate capsules, thereby effectively forcing the market to TriCor 160mg Tablets.
- Abbott and Fournier also sought to eliminate incentives for consumers to ask physicians to re-write TriCor prescriptions for capsules so generic fenofibrate capsules could be dispensed. Abbott accomplished this by manipulating a dominant source of information relied upon by the medical community: First DataBank's NDDF. By April 2002, shortly after Abbott had completed the switch to tablets, but before the generic capsules became available, Abbott instructed First DataBank to delete the NDC number for all TriCor capsules in its NDDF database. The removal of the reference for TriCor 200mg

 Capsules, including its NDC number, prevented pharmacists from identifying any ABrated generic substitute in First DataBank's NDDF. Thus, due to Abbott's manipulation of the NDC number for TriCor 200mg Capsules in the NDDF, when Teva launched generic fenofibrate capsules in mid-2002, they were the only fenofibrate capsule listed in the NDDF and were coded as a single-source drug, not as a generic.

- 63. As a single-source drug in the NDDF, Teva's fenofibrate capsules generally were not afforded the preferred formulary status given generic drugs. Some insurers did not add Teva's generic capsules to their drug formularies and refused to pay for them at all. Other health insurers charged a higher co-pay than typically charged for a generic. As a result, Abbott prevented incentives for patients to request their TriCor 200mg Capsule prescriptions be rewritten for Teva's generic capsules.
- 64. With no opportunity to substitute TriCor prescriptions and scant incentive for patients or pharmacists to purchase generic fenofibrate capsules, there was little demand for generic fenofibrate capsules. Not surprisingly, potential manufacturers of generic fenofibrate capsules had little interest in entering the market.

D. Abbott's and Fournier's Anti-Generic Strategy was Successful

- 65. Abbott's and Fournier's efforts to force the market to convert were successful. By March 2002, most prescriptions for TriCor were for TriCor 160mg Tablets.
- 66. As a result, Abbott's and Fournier's reformulation and forced conversion strategy succeeded in thwarting generic fenofibrate entry. While most generic launches capture a large percentage of the market within weeks, when Teva launched generic fenofibrate capsules in mid-2002, Abbott and Fournier had already switched the market. As a result, more than a year after Teva's generic capsules came to market, generic fenofibrate drugs accounted for fewer than 2% of all fenofibrate prescriptions in the United States. Moreover, Impax, after obtaining FDA approval for its fenofibrate capsule, which were AB-rated to TriCor 200mg Capsules, never attempted to enter the market.

67. Substitution laws did not allow pharmacists to substitute a generic capsule to fill a prescription written for TriCor 160mg Tablets. The outcome was that purchasers, including consumers, state governments, and third-party payors were required to pay supracompetitive prices for TriCor 160mg Tablets and effectively denied the cost advantages of a competing generic drug.

II. Abbott's and Fournier's Second TriCor Switch

- 68. Even as Abbott and Fournier prevented competition from generic fenofibrate capsules, they also conspired to extend their anti-generic strategy to defeat anticipated generic competition for TriCor 160mg Tablets.
- 69. Abbott and Fournier undertook the same strategy they used to defeat entry of generic fenofibrate capsules. They improperly obtained several patents, and knowing these patents were unenforceable, submitted them to the FDA to be listed in the Orange Book. Then, Abbott and Fournier filed baseless patent infringement litigation to obtain 30-month stays barring FDA approval of the generics' ANDAs. During those stays, Abbott launched a reformulated TriCor product, and followed that launch with a market switch from TriCor 160mg Tablets to the reformulated TriCor 145mg tablets. Abbott also reclaimed any remaining TriCor 160mg Tablets as quickly as possible, so as to complete the conversion of the fenofibrate market before entry of any generic 160mg tablets. Finally, Abbott caused any reference to TriCor 160mg Tablets, including the NDC number, to be deleted, interfering with the normal and customary channels of distribution used by generic competitors. As a result, when the patent-based tablet litigation resulted in summary judgment for the generic manufacturers and was otherwise

dismissed by Abbott and Fournier, terminating the 30-month stay blocking FDA approval of the ANDAs, there were no commercially available TriCor 160mg Tablets remaining.

A. The Stamm Patents Were Improperly Obtained

- 70. Fournier filed and prosecuted the applications for U.S. Patent Nos. 6,074,670 ("'670 Patent"), 6,277,405 ("'405 Patent"), 6,589,552 ("'552 Patent"), and 6,652,881 ("'881 Patent") (collectively, "Stamm Patents"), and communicated with Abbott concerning the prosecution of the Stamm Patents before the PTO.
- 71. Fournier committed inequitable conduct before the PTO by intentionally failing to disclose highly material data in the Stamm applications and supporting declarations, the omission of which caused the data presented to be misleading.

 Moreover, in response to the PTO's initial determination that the Stamm Patents were unpatentable due to the prior art, including its own '726 Patent, Fournier intentionally and knowingly relied on the misleading data to argue that the applications were patentable due to superior and unexpected dissolution rates. Fournier knew that the dissolution rates of the various fenofibrate compositions being claimed in the applications for the Stamm Patents were critical to the patentability of those compositions.
- 72. In its applications for each of the Stamm Patents, Fournier represented to the PTO that the fenofibrate formulations had "unexpectedly" faster dissolution rates than that of earlier fenofibrate products and patents, including its own '726 Patent. Fournier represented to the PTO that the dissolution and bioavailability of fenofibrate compositions created in accordance with the '726 Patent were "incomplete due to the poor hydrosolubility of fenofibrate." In contrast, Fournier claimed that the Stamm

formulations achieved a "superior" dissolution of greater than "10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes."

- 73. To convince the PTO that the Stamm formulations dissolved faster than the earlier '726 Patent, Fournier presented the PTO with tests that purported to compare the dissolution of two 100mg tablets of the Stamm formulations with TriCor 200mg Capsules made using the '726 Patent.
- 74. Fournier represented to the PTO that the test results "clearly showed the composition, according to the [Stamm] invention, has a dissolution profile which is distinctly better [faster] than that of the prior art compositions."
- 75. But at the time that Fournier made these representations to the PTO, Fournier had other data, which it did not disclose to the PTO, showing that TriCor 200mg Capsules had faster dissolution rates than were represented. Some of the new data showed that TriCor 200mg Capsules dissolved just as fast, if not faster, than the supposedly "unexpectedly superior" dissolution results claimed in the Stamm applications.
- 76. Specifically, Fournier failed to disclose to the PTO two sources of data that contradicted its assertions of "unexpectedly superior" dissolution results. First was a May 30, 1997, memorandum by a Fournier employee, Pascale Blouquin, ("Blouquin Memo") that revealed dissolution tests performed pursuant to the '726 Patent. The Blouquin Memo reported dissolution results of Lipanthyl 200M (later marketed as TriCor 200mg Capsules) in a medium of .025 sodium lauryl sulfate that were even faster than dissolution results presented to the PTO in the Stamm applications. Second, Fournier documents also contained dissolution data for TriCor 67mg capsules that were as fast as

the dissolution rates claimed in the Stamm applications, except for the 5 minute interval.

None of these tests were disclosed at the time Fournier was prosecuting the Stamm Patent applications.

- 77. Additionally, a declaration submitted by Philippe Reginault, a Fournier employee, in support of the Stamm applications, also failed to disclose these sources. Reginault's sworn declaration, submitted in support of the Stamm Patent application that resulted in the issuance of the '881 Patent, failed to disclose data despite his affirmation that he knew and understood that he had a duty to disclose all material information when providing submissions to the PTO during prosecution of a patent application.
- 78. As Fournier's director of pharmaceutical development between 1988 and 2002, Reginault was intimately involved in Fournier's fenofibrate formulation and analytical development projects. In 2002, Reginault became Fournier's director of pharmaceutical technologies evaluation and continued his involvement with Fournier's fenofibrate projects. Moreover, it was Reginault who was instrumental to Fournier using patents to delay generic competition and was Fournier's primary technical contact with Abbott.
- 79. The PTO initially rejected all of the Stamm Patent applications on the grounds that the fenofibrate formulations claimed in those applications were too similar to and not patentably different from the formulations claimed in the '726 Patent and other earlier patents. Fournier disputed the PTO's rejections, citing and relying on the misleading data to argue that the formulations in the Stamm Patent applications had a surprisingly and unexpectedly faster dissolution rate, and hence should be patented. Fournier repeatedly cited in each Stamm Patent application the misleading comparisons

of the dissolution rates of the earlier fenofibrate products with those being claimed in the "new" invention. Fournier continued to withhold the material data showing faster dissolution rates for earlier products and patents throughout the prosecution of the Stamm Patents to overcome rejections based on the '726 Patent and other earlier patents. At no time during the prosecution of the Stamm Patents did Fournier disclose the data that was less favorable to, and indeed contradicted, its argument that the Stamm Patents produced a formulation with dissolution results superior to those reflected in earlier patents.

Instead, Fournier continued to rely on the misleading data in arguing that the Stamm applications were patentable and non obvious.

- 80. In issuing the Stamm Patents, the PTO relied upon Fournier's continued use of and reference to the misleading data on unexpected, superior dissolutions of the Stamm formulations.
- 81. The data withheld by Fournier and Reginault was highly material both in view of (1) Fournier's original arguments that the Stamm Patents were different from the prior art in the '726 Patent and other patents due to an allegedly faster dissolution profile in each of the four Stamm Patents, and (2) Fournier's other arguments made during prosecution to overcome rejections based on prior art, including the '726 Patent.'
- 82. The material information was withheld and the misleading declaration was submitted by Fournier and Reginault with intent to deceive the PTO. Fournier and Reginault made misleading representations and withheld highly material information with the intent and objective of inducing the PTO to issue the Stamm Patents. Each of the Stamm Patents is tainted by inequitable conduct and thus none of the Stamm Patents are enforceable.

- 83. Fournier's overall purpose in obtaining each of the Stamm Patents was to prohibit or delay generic competition for TriCor. Fournier's repeated misstatements and failures to disclose highly material information was part of Fournier's and Abbott's single, overall coordinated scheme, and evidenced their intent to deceive the PTO for the purpose of wrongfully excluding competition.
- 84. Fournier and Abbott intended to and did deceive the PTO because they knew that by obtaining any patent that claimed fenofibrate, they could improperly submit those patents to the FDA to be listed in the Orange Book. This would force any ANDA filer to file a Paragraph IV Certification, opening the door to infringement litigation that would trigger a 30-month stay of the FDA's approval of the ANDA, regardless of the strength of the patent or the outcome of the patent litigation.
 - B. Abbott and Fournier Abused the Hatch-Waxman Regulatory Scheme by Having Unenforceable Patents Listed in the Orange Book
- S5. The Stamm Patents were issued by the PTO at various times beginning on June 13, 2000, through November 25, 2003. Upon issuance, each Stamm Patent was listed in the Orange Book. Because Abbott and Fournier knew that the Stamm Patents were unenforceable, they unlawfully impeded generic entry by listing each of the Stamm Patents in the FDA's Orange Book.
- 86. Because of the Orange Book listing, Teva and Impax were required to file ANDAs with Paragraph IV Certifications, asserting that each patent was unenforceable, invalid or not infringed by their generic fenofibrate tablet. Abbott and Fournier intended to and knew that by listing the unenforceable Stamm Patents in the Orange Book, Teva and Impax and other potential generic entrants would be required to file Paragraph IV

Certifications as to each of the Stamm Patents. They also knew that any infringement litigation would automatically trigger multiple 30-month stays preventing FDA approval of Teva's and Impax's ANDA applications for generic fenofibrate tablets.

- Abbott's and Fournier's overall scheme to monopolize and block generic competition in the fenofibrate market. As a result of the wrongful listing of the Stamm Patents in the Orange Book, Abbott was able to obtain multiple 30-month stays on the FDA's approval for generic 160mg fenofibrate.
- 88. Obtaining several of the Stamm Patents by inequitable conduct was a component of Abbott's and Fournier's overall anticompetitive scheme. Standing alone, having the unenforceable Stamm Patents listed in the Orange Book was also a wrongful and unreasonable restraint on trade.
 - C. Abbott's and Fournier's Lawsuits were Baseless as the Stamm Patents were Unenforceable and they had No Reasonable Basis to Believe there was Infringement

1. The Tablet Lawsuits

- 89. Less than a year after Abbott and Fournier launched TriCor 160mg
 Tablets, generic manufacturers began filing ANDAs with the FDA seeking approval to
 launch generic versions of fenofibrate tablets. Along with filing the ANDAs, the generic
 manufacturers certified that their products did not infringe the '726, '670 and '405
 Patents that Abbott and Fournier had listed in the FDA's Orange Book for its TriCor
 160mg Tablet.
- 90. After Teva and Impax provided their Paragraph IV notices, Abbott and Fournier commenced three lawsuits against Teva and Impax in the District of Delaware

(Civil Action No. 02-1512 filed on October 4, 2002; Civil Action 03-120 filed on January 23, 2003; and Civil Action No. 03-0288 filed on March 14, 2003) ("Original Tablet Lawsuits"), alleging that Teva infringed the '726, '670 and '405 Patents and that Impax infringed the '670 and '405 Patents. These suits triggered 30-month stays of the FDA's approval of Teva's and Impax's ANDAs.

- 91. In July of 2003, the PTO granted Fournier a new patent, the 6,589,552 ("'552 Patent''), which was a continuation of the '670 and '405 Patents. Abbott and Fournier promptly listed the '552 Patent in the Orange Book.
- 92. Teva and Impax then submitted new Paragraph IV Certifications for the '552 Patent and notified Abbott and Fournier that their ANDAs did not infringe the '552 Patent.
- 93. Starting in August of 2003, Abbott and Fournier filed additional tablet patent infringement lawsuits against Teva and Impax in the District of Delaware, including Civil Action No. 03-847 on August 29, 2003, and Civil Action No. 03-890 on September 22, 2003, alleging that their respective requests to the FDA for approval of their Tablet ANDAs infringed the '552 Patent ("'552 Lawsuits").
- 94. Again, Abbott's and Fournier's newly filed '552 Lawsuits triggered additional 30-month stays that prohibited the FDA from granting final approval of Teva's or Impax's Tablet ANDAs.
- 95. In November of 2003, Fournier was granted yet another patent from the Stamm Patent applications, U.S. Patent No. 6,652,881 ("'881 Patent") which Abbott promptly listed in the Orange Book.

- 96. Teva and Impax then submitted Paragraph IV notices for the '881 patent and, in response, Abbott and Fournier filed yet another round of tablet patent infringement lawsuits in the District of Delaware against Teva and Impax including Civil Action no. 04-0047 on January 22, 2004, and Civil Action no. 04-0048 on January 22, 2004 ("'881 Lawsuits").
 - 2. All the Tablet Lawsuits were Baseless and Brought for the Purpose of Preventing Generic Competition, and all were Ultimately Dismissed
- 97. Each and every lawsuit brought by Abbott and Fournier asserting infringement of the Stamm Patents by Teva's and Impax's tablet formulations (the "Tablet Litigation") were baseless because Fournier obtained all of the Stamm Patents through inequitable conduct as described supra. Thus, at the time that Abbott and Fournier filed each of their infringement actions enforcing all of the Stamm Patents, and/or during the time that they maintained these suits, they lacked a reasonable basis to believe that Teva's and Impax's ANDAs for generic fenofibrate tablets infringed valid and enforceable patents.
- 98. In bringing and maintaining the Tablet Litigation, Abbott and Fournier also lacked a reasonable basis for alleging that Teva's and Impax's ANDAs for generic fenofibrate tablets infringed the '726 Patent and the Stamm Patents, or any one of them. In addition, Abbott and Fournier never had any objective basis for alleging that Teva's or Impax's Tablet ANDAs or their fenofibrate tablets infringed any of the asserted Stamm Patents because they failed to make a good faith analysis of Impax's and Teva's products and product specifications to determine whether they contained all the elements asserted in each of the Stamm Patents, including the weight limitation. Abbott and Fournier also

failed to consider facts and information that Teva and Impax had made known to Abbott and Fournier prior to the filing of the Tablet Litigation. Finally, Abbott and Fournier failed to consider highly relevant and material information Teva and Impax gave them in response to discovery requests during the Tablet Litigation.

- 99. As previously discussed, Abbott and Fournier sued both Impax and Teva for allegedly infringing the '726 Patent after they sought FDA approval to market fenofibrate capsules (the "Capsule Litigation"). During Abbott's and Fournier's prosecution of the Tablet Lawsuits, Abbott and Fournier knew, as a result of the District Court decision in the Capsule Litigation, that they had no basis for alleging that Teva's fenofibrate tablets infringed the '726 Patent. Clearly, Teva's tablets did not infringe the '726 Patent for the same reasons the court found in the Capsule Litigation that Teva's capsules did not infringe.
- March 20, 2003, further confirmed that Abbott and Fournier had no basis for alleging that Teva's fenofibrate tablets infringed the '726 Patent, or for maintaining any action against Teva for infringement of the '726 Patent. Had Abbott and Fournier dismissed their claims against Teva concerning the '726 Patent, as they should have, any automatic stay caused by litigation over the '726 Patent would have been lifted.
- 101. In addition, the Tablet Lawsuits were baseless in that there was no reasonable basis to believe that the products of Teva and Impax met the other claims limitations of the '670, '726 and '405 Patents as further discussed infra.
- 102. Teva's and Impax's alleged infringement of the claims of the '670, '405 and '552 Patents rested, in part, on Abbott's and Fournier's proffered interpretation of the

patent term "hydrophilic polymer." Abbott's and Fournier's asserted interpretation was directly inconsistent with, and contrary to, the definition of "hydrophilic polymer" explicitly recited in the Stamm Patents themselves. No reasonable litigant objectively and subjectively could have expected to prevail on the claim interpretation of the term "hydrophilic polymer" that Abbott and Fournier asserted in the Original Tablet and the '552 Lawsuits. In the Original Tablet and the '552 Lawsuits, the Court rejected Abbott's and Fournier's proffered interpretation of the term "hydrophilic polymer" and noted that "the specification [in the Stamm Patents] clearly defines the term" in a manner inconsistent with Abbott's and Fournier's proffered interpretation.

- 103. The court granted summary judgment of non-infringement of the '670 Patent, claim 9 of the '405 Patent, and the '552 Patent in Teva's and Impax's favor based on the proper interpretation of "hydrophilic polymer."
- overall anti-generic scheme, were brought by Abbott and Fournier intentionally and solely for the purpose of delay and to preclude generic competition. They knew that simply filing the lawsuits, without regard to the merits, would automatically provide a series of 30-month stays to delay FDA approval of Teva's and Impax's ANDAs and would otherwise burden and delay lawful generic competition from Impax, Teva and others. Moreover, they knew they needed to delay generic approval so they could reformulate TriCor, as TriCor 145mg tablets, obtain FDA approval, launch and force the market to convert to TriCor 145mg tablets before generic entry.
- 105. Abbott and Fournier brought all of the Tablet Lawsuits with the intent to delay and thwart generic competition without regard to the merits of these actions. Many

of Abbott's and Fournier's infringement claims in the Tablet Lawsuits were the subject of successful summary judgment motions brought by Teva and Impax. After Abbott and Fournier converted the market, they dismissed all claims and Tablet Lawsuits that had not already been dismissed or terminated. These dismissals further reflect Abbott's and Fournier's true purpose in bringing and maintaining the Tablet Lawsuits, to delay generic competition. The filing and maintenance of the Tablet Lawsuits singly and collectively are wrongful and actionable both standing alone and as a component in their overall antigeneric scheme.

D. Abbott and Fournier Forced the Market to Convert a Second Time

- 1. The Reformulation: Abbott and Fournier Reformulated TriCor to Avoid Competition from an AB-Rated Drug and to Justify their Marketing Campaign
- 106. During 2002, Abbott and Fournier met and planned to reformulate TriCor for a second time, this time by reducing the dosage from 160mg and 54mg to 145mg and 48mg tablets ("TriCor 145mg Tablets") and by seeking to change the dosing instructions on the basis that the reformulated tablets had "no food effect" ("NFE"), meaning they would perform similarly whether taken with or without a meal.
- 107. In the fall of 2003, Abbott filed with the FDA the NDA for TriCor 145mg Tablets. To support this NDA, Abbott demonstrated the reformulated TriCor 145mg Tablets were bioequivalent to the TriCor 200mg Capsules. In other words, Abbott demonstrated that the TriCor 145mg Tablets performed with substantially the same efficacy as the TriCor 200mg Capsules, and it relied upon the same clinical efficacy and safety data that Fournier had submitted to the FDA in 1998 when it sought approval for the TriCor 200mg Capsules. This showing of bioequivalency meant that the TriCor

145mg Tablets were as safe and as effective as the TriCor 200mg Capsules, and vice versa.

- 108. The reformulated TriCor 145mg Tablets contained just 15 milligrams less fenofibrate than the TriCor 160mg Tablets. Because the reformulated tablet was, like TriCor 160mg Tablets, still bioequivalent to the original 200mg TriCor Capsules, the dosage change was clinically meaningless. Abbott and Fournier expected most physicians, health care plans, and third-party payors to view this distinction as insignificant. Reflecting that Abbott and Fournier anticipated that TriCor 145mg Tablets would be viewed the same as TriCor 160mg Tablets, they priced TriCor 145mg Tablets the same as TriCor 160mg Tablets. The real significance of the lower dose was that it prevented TriCor 145mg Tablets from being given an AB rating to TriCor 160mg Tablets.
- 109. Abbott also claimed that TriCor 145mg Tablets had NFE, meaning the reformulated tablets would be absorbed at the same rate regardless of whether they were consumed with a meal. This modified dosing instruction provided Abbott with a way to differentiate TriCor 145mg Tablets from TriCor 160mg Tablets in their marketing materials. Abbott lacked any evidence that patients would benefit from this change.

2. The Switch: Abbott Launched a Marketing Blitz

110. In March 2004, both Teva and Impax received preliminary approval from the FDA for their ANDAs for a generic fenofibrate tablet. With FDA approval of generic entry delayed by patent-based litigation stays, Abbott and Fournier made plans for an aggressive launch of the TriCor 145mg Tablets.

- 111. Abbott and Fournier knew that an effective and complete conversion of TriCor 160mg Tablets to TriCor 145mg Tablets would protect TriCor from any AB-rated generic. Whereas the first switch had been virtually completed in six months, Abbott and Fournier hoped to execute a switch to the 145mg Tablet in half that time. They estimated that if they accomplished the switch and conversion to TriCor 145mg Tablets before a generic version of TriCor 160mg Tablets could enter the market, they would earn hundreds of millions of dollars more in revenues.
- 112. On November 5, 2004, Abbott received FDA approval of the TriCor 145mg Tablets and, with Fournier, immediately launched an expensive marketing campaign, which sent an expanded Abbott and Fournier sales force canvassing physicians across the country to "educate" them on the reformulated TriCor and to persuade them to switch their prescriptions to the new formulation. Abbott and Fournier sales representatives also contacted pharmacists and managed health care organizations across the country to encourage them to stock TriCor 145mg Tablets and to include the reformulated products in their formularies of covered drugs. In this marketing blitz, Abbott's and Fournier's sales representatives touted the reformulated product, especially the NFE claim.
- 113. However, Abbott and Fournier knew that many members of the health care community would view their reformulated product with skepticism. Their own marketing studies showed that whether TriCor could be taken without a meal was not viewed as a significant issue among most physicians.

3. The Forced Conversion: Abbott and Fournier Discontinued Sales and Production of TriCor 160mg Tablets

- 114. To further ensure conversion of the market to TriCor 145mg Tablets, Abbott and Fournier stopped making and selling the TriCor 160mg Tablets. During the fall of 2004, in anticipation of FDA approval of the reformulated TriCor 145mg Tablets, they slowed production of TriCor 160mg Tablets and carefully bled-down inventories of TriCor 160mg Tablets. In early November 2004, when they launched TriCor 145mg Tablets, they completely stopped production and sales of TriCor 160mg Tablets.
- TriCor stock if the new formulation was not approved by September 2004. Abbott's and Fournier's slow-down in production facilitated the depletion of TriCor 160mg Tablets on the market following the launch of TriCor 145mg Tablets, thereby helping to force the medical community to adopt the reformulated product. These efforts also helped to ensure that TriCor 160mg Tablets would not be commercially available within the distribution chain by the time a generic entered the fenofibrate market.

4. The Purge: Abbott Reclaimed TriCor 160mg Tablets

116. Initially, Abbott and Fournier hoped to remove TriCor 160mg Tablets from the market by simply bleeding down the existing retail inventories within the distribution chain, i.e., the inventories of wholesalers and retail pharmacies. However, as they awaited FDA approval of TriCor 145mg Tablets, their concern about impending generic entry increased and they sought to accelerate that removal. Abbott and Fournier made plans and budgeted for other means of removing TriCor 160mg Tablets from the market.

- 117. In March 2005, several months after introducing TriCor 145mg Tablets, Abbott wrote to retail chains and wholesalers requesting that they return any remaining TriCor 160mg Tablets in exchange for discounts and credits.
- 118. In offering this incentive to wholesalers and retail pharmacies, Abbott deviated from its standard policy for returned goods. Abbott's policy was to provide an allowance on returned goods equal to 1% of total sales. Instead, to encourage the return of TriCor 160mg Tablets, Abbott crafted a special tablet-exchange program and buy-back policy for TriCor 160mg Tablets.
- 119. This additional tactic prompted the return of TriCor 160mg Tablets worth over \$6.0 million dollars. Following Abbott's recovery of TriCor 160mg Tablets, the tablets were destroyed.
- 120. Abbott's efforts to reclaim the remaining TriCor 160mg Tablets from the market prior to generic entry succeeded in ensuring that all or nearly all pharmacists did not have any TriCor 160mg Tablets on their shelves by the time the generic version of the product was able to enter the market. These efforts further helped to ensure that TriCor 160mg Tablets would not be commercially available within the distribution chain by the time a generic entered the fenofibrate market.
- Abbott's and Fournier's forced conversion strategy was successful, and by February of 2005 most prescriptions for TriCor were for TriCor 145mg Tablets. By May 2005, Abbott had depleted its inventory of TriCor 160mg Tablets and had killed TriCor 160mg Tablets.

- 5. The Final Nail: Abbott and Fournier Interfered With the Normal and Customary Methods Generics Use to Compete
- 122. As they had done following the first switch from TriCor 200mg Capsules to TriCor 160mg Tablets, Abbott and Fournier effectively removed the TriCor 160mg Tablets from First DataBank's NDDF, a pharmaceutical industry resource relied upon by many physicians, pharmacists and third-party payors, thus removing any meaningful reference to this product.
- 123. In May of 2005, Abbott notified First DataBank that they had discontinued TriCor 160mg Tablets and thereby "obsoleted" TriCor 160mg Tablets. Thereafter, the reference was removed from the NDDF.
- 124. Once the reference to TriCor 160mg Tablets was removed from the NDDF, the subsequently approved generic 160mg tablets were coded as a "single-source" product. As a result, many healthcare insurers treated the generic product as a brand name drug and did not give it preferred status on their formularies, causing higher co-pays for consumers.
- 125. By designating the TriCor 160mg Tablets as "obsolete" in the NDDF, Abbott and Fournier prompted the removal of information from the market that would have informed physicians and pharmacists that Teva's generic drug was AB-rated to the TriCor 160mg Tablets, making it more difficult for a generic competitor to enter or compete in the fenofibrate market.

E. Abbott and Fournier Thwarted Generic Entry

126. Following Abbott's direction to First DataBank to "obsolete" TriCor 160mg Tablets, the trial court in the Tablet Litigation entered a partial summary

judgment in Teva's favor, which lifted the 30-month stay against FDA approval of the Teva ANDA, and the FDA granted final approval to Teva's generic version of the TriCor 160mg Tablets.

127. Teva was then legally able to enter the fenofibrate market with a generic version of the TriCor 160mg Tablets. But Abbott's and Fournier's withdrawal of TriCor 160mg Tablets and conversion of the fenofibrate market was complete. Abbott and Fournier had, again, foreclosed competition against TriCor and had denied consumers the choice of a generic fenofibrate tablet.

Anticompetitive Effects

- 128. Abbott's and Fournier's acts, practices, and scheme discussed herein were for the purpose of, and had the effect of, restraining competition unreasonably by preventing the entry of generic fenofibrate drugs.
- 129. Absent Abbott's and Fournier's illegal anticompetitive conduct, at least one generic competitor would have begun marketing a generic version of fenofibrate.
- 130. If a generic competitor had been able to enter the relevant market at either the time of the capsule or tablet switch and thereby compete with Abbott and Fournier, consumers and state entities (payors and reimburses) would have had the choice to substitute, and many would have substituted a lower-priced generic for the higher-priced brand-name drug.
- 131. By preventing generic competitors from entering the market, Abbott and Fournier have deprived Plaintiff States and their consumers of the benefits of the competition that the federal and state antitrust laws, consumer protection laws and/or

unfair competition statutes and related state laws are designed to promote, preserve, and protect.

Injury

- Plaintiff States and consumers were not and are not able to purchase, or pay reimbursements for purchases of, fenofibrate at prices determined by free and open competition. Instead, they were forced to pay artificially high monopoly prices.

 Consequently, they have been injured in their business and property in that, *inter alia*, they have paid more and continue to pay more for fenofibrate than they would have paid in a free and open competitive market. The Plaintiff States cannot quantify at this time the precise amount of monetary harm which they have sustained, but allege that such harm is substantial.
- 133. As a direct and proximate result of the unlawful conduct alleged above, the general economies of the Plaintiff States have sustained injury and the Plaintiff States are threatened with continuing injury to their business and property unless Abbott and Fournier are enjoined from their unlawful conduct.
- 134. As a direct and proximate result of the unlawful conduct alleged above, Abbott and Fournier have unjustly profited through inflated profit margins and will continue to do so.
- 135. Abbott's and Fournier's unlawful conduct is continuing and will continue unless the injunctive and equitable relief requested by the Plaintiff States is granted.
 - 136. Plaintiff States do not have an adequate remedy at law.

Count I: Monopolization under Sherman Act §2

- 137. The preceding paragraphs are incorporated as if set forth herein.
- 138. From 1998 to the present, Abbott has possessed monopoly power in the relevant market of fenofibrate products in the United States.
- 139. Abbott willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct which had the intent, purpose and effect of illegally preventing and blocking competition in the United States fenofibrate market in violation of Section 2 of the Sherman Act, 15 U.S.C. §2.
- 140. Beginning in 1998, Abbott engaged in exclusionary conduct including, but not limited to: devising and implementing an anti-generic strategy, wrongfully asserting that Teva's and Impax's 200mg fenofibrate ANDAs infringed the '726 Patent, improperly procuring and enforcing the Stamm Patents, wrongfully listing the Stamm Patents in the Orange Book, systematically asserting unenforceable patents against Teva's and Impax's non-infringing 160mg fenofibrate ANDAs, stopping sales of 200mg Capsules and 160mg Tablets to force the market to accept the reformulated TriCor tablets that provided no new clinical benefit to patients, soliciting and accepting returns of TriCor 200mg Capsules and 160mg Tablets to accelerate the forced conversion scheme, and obsoleting any references, including the NDC number, from the NDDF for TriCor 200mg Capsules and TriCor 160mg Tablets.
- 141. As a direct and proximate result of Abbott's exclusionary scheme, generic manufacturers have been unable to market and sell generic alternatives that pharmacists can substitute for TriCor prescriptions. Plaintiff States and consumers, therefore, have

been injured in their business or property because they had to purchase TriCor without the reasonable availability of a lower-priced generic alternative.

Count II: Conspiracy to Monopolize under Sherman Act §2

- 142. The preceding paragraphs are incorporated as if set forth herein.
- 143. Abbott and Fournier conspired to monopolize and did unlawfully monopolize the relevant market for fenofibrate products in the United States, thereby violating Section 2 of the Sherman Act, 15 U.S.C. §2.
- 144. Abbott and Fournier have acted in concert to maintain willfully and unlawfully their monopoly power in the relevant market for fenofibrate drugs in the United States by engaging in unlawful exclusionary conduct which had the purpose and effect of unreasonably restraining competition.
- 145. Abbott and Fournier engaged in their conspiracy with the specific intent to prevent generic competition in the United States fenofibrate market.
- 146. Abbott and Fournier committed a series of acts in furtherance of their conspiracy, including, but not limited to: devising and implementing an anti-generic strategy that involved wrongfully asserting that Teva's and Impax's 200mg fenofibrate ANDAs infringed the '726 Patent, improperly procuring and enforcing the Stamm Patents, wrongfully listing the Stamm Patents in the Orange Book, systematically enforcing unenforceable patents against Teva's and Impax's, non-infringing 160mg fenofibrate ANDAs, stopping sales of 200mg Capsules and 160mg Tablets to force the market to accept reformulated TriCor products that provided no new clinical benefit to patients, soliciting and accepting returns of TriCor 200mg Capsules and 160mg Tablets

to accelerate the forced conversion scheme, and obsoleting any reference, including the NDC number, from the NDDF for TriCor 200mg Capsules and TriCor 160mg Tablets.

- 147. The conspiracy between Abbott and Fournier created a realistic threat to competition in the United States fenofibrate market.
- 148. As a direct and proximate result of Abbott's and Fournier's exclusionary scheme, generic manufacturers have been unable to market and sell generic alternatives that pharmacists can substitute for TriCor prescriptions. Plaintiff States and consumers, therefore, have been injured in their business or property because they had to purchase TriCor without the reasonable availability of a lower-priced generic alternative.

Count III: Illegal Restraint of Trade under Sherman Act §1

- 149. The preceding paragraphs are incorporated as if set forth herein.
- 150. From 1998 to the present, Abbott and Fournier entered into a contract, combination, or conspiracy to restrain trade in the U.S. market for fenofibrate drugs and thereby violated Section 1 of the Sherman Act, 15 U.S.C. §1.
- 151. From 1998 to the present, Abbott and Fournier have possessed market power in the relevant market. Abbott and Fournier have willfully and unlawfully maintained their market power by excluding generic competitors from the relevant market.
- 152. From 1998 to present, Abbott and Fournier unreasonably restrained trade through an exclusionary scheme that included, among other things: planning and committing a series of acts in furtherance of their conspiracy, devising and implementing an anti-generic strategy that involved wrongfully asserting that Teva's and Impax's 200mg fenofibrate ANDAs infringed the '726 Patent, improperly procuring and

enforcing the Stamm Patents, wrongfully listing the Stamm Patents in the Orange Book, systematically asserting unenforceable patents against Teva's and Impax's non-infringing 160mg fenofibrate ANDAs, stopping sales of 200mg Capsules and 160mg Tablets to force the market to accept reformulated TriCor products that provided no new clinical benefit to patients, soliciting and accepting returns of TriCor 200mg Capsules and 160mg Tablets to accelerate the forced conversion scheme, and obsoleting any reference, including the NDC number, from the NDDF for TriCor 200mg Capsules and TriCor 160mg Tablets.

- 153. As a direct and proximate result of Abbott's and Fournier's exclusionary scheme, generic manufacturers have been unable to market and sell generic alternatives that pharmacists can substitute for TriCor prescriptions. Plaintiff States and consumers, therefore, have been injured in their business or property because they had to purchase TriCor without the reasonable availability of a lower-priced generic alternative.
- 154. The anticompetitive effects of Abbott's and Fournier's conspiracy outweigh pro-competitive effects, if any, that their conduct may have had.

Count IV: State Law Claims

Arizona

- 155. Plaintiff State of Arizona repeats and realleges each and every allegation contained in paragraphs 1 through 154.
- 156. Defendants' acts violates the Arizona Uniform State Antitrust Act, A.R.S. §§44-1401, *et seq.*, and Plaintiff State of Arizona, on behalf of itself, its states agencies and all persons who directly or indirectly purchased TriCor or fenofibrate-containing products, is entitled to relief thereunder.

Arkansas

- 157. Plaintiff State of Arkansas repeats and realleges each and every allegation contained in paragraphs 1 through 154.
- 158. Defendants' acts violate, and Plaintiff State of Arkansas is entitled to relief on behalf of consumers and state government entities under the Arkansas Deceptive Trade Practices Act, Ark. Code Arm. §4-88-101, et seq., and the Arkansas Unfair Practices Act, Ark. Code Ann. §4-75-301, et seq.

California

- 159. California realleges and incorporates all of the allegations above from paragraphs 1 through 154.
- 160. The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. code sections 16700, et seq., and the California Unfair Competition Act, Cal. Bus. & Prof. Code, sections 17200, et seq. As a result of Abbott's and Fournier's anticompetitive acts and unfair and deceptive practices and violations of the California's Cartwright Act and Unfair Competition Act, all as more fully described above, the State of California and its residents have suffered and been injured in business and property and will continue to suffer ascertainable loss and damages in an amount to be determined at trial.
- 161. Accordingly, the State of California, including its state agencies, on behalf of itself and its residents, seeks all relief available under California's Cartwright Act and the Unfair Competition Act, including damages, restitution, disgorgement, unjust enrichment, injunctions, treble damages, costs, reasonable attorneys' fees, and/or civil

penalties, and any such other equitable or monetary relief that might be available under statute or equity.

Connecticut

- 162. Plaintiff State of Connecticut repeats and realleges each and every allegation contained in paragraphs 1 through 154.
- 163. Defendants' acts violate, and Plaintiff State of Connecticut is entitled to relief under, the Connecticut Antitrust Act, Conn. Gen. Stat. §35-24, et seq., and the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §42-110a, et seq.

District of Columbia

- 164. District of Columbia realleges and incorporates all of the allegations above from paragraphs 1 through 154.
- 165. Defendants' acts violated provisions of the District of Columbia Antitrust Act, D.C. Code §28-4502 (2001) and D.C. Code §28-4503 (2001). These acts restrained competition in Defendants' sale of TriCor or fenofibrate-containing products in the District of Columbia.
- 166. The District of Columbia (District), its political subdivisions and public agencies, along with residents of the District, have been injured by Defendants' actions, by reason of paying artificially inflated prices as direct or indirect purchasers of TriCor or fenofibrate-containing products.
- 167. Plaintiff, the District, for its political subdivisions and public agencies, and as parens patriae on behalf of persons residing in the District, is entitled to monetary

relief for injuries directly or indirectly suffered by the District, its political subdivisions and public agencies, and said persons, by reasons of the violations alleged above.

Florida

- 168. Florida realleges and incorporates all of the allegations above from paragraphs 1 through 154.
- 169. The State of Florida, its departments, agencies and units of government purchased TriCor from Abbott through contracts that are assigned to the State of Florida. The State of Florida, Office of the Attorney General, asserts claims for damages and penalties under the Florida Antitrust Act on behalf of such entities, pursuant to § 542.27(2), Florida Statutes.
- 170. As described above Defendants' acts violate § 542.18, Florida Statutes, and the State of Florida is entitled to relief, including damages, under § 542.22, Florida Statutes, for all direct purchases made pursuant to contracts that are assigned to the State of Florida.
- 171. The State of Florida is entitled to a civil penalty of up to the maximum amount permitted by § 542.21, Florida Statutes, for each violation of § 542.18, Florida Statutes.
- 172. The State of Florida is entitled to recover its costs and attorneys' fees pursuant to § 542.22(2), Florida Statutes.
- 173. The State of Florida requests that the Court order such additional relief as it may deem just and proper.
- 174. Certain Florida governmental entities and individuals residing in Florida purchased TriCor from Abbott. The State of Florida, Office of the Attorney General,

asserts claims for damages under the Florida Deceptive and Unfair Trade Practices Act on behalf of such entities and individuals, pursuant to § 501.207(1)(c), Florida Statutes.

- 175. As described above, Defendants' unfair methods of competition and unconscionable acts and practices in the conduct of trade and commerce offend established public policy and are immoral, unethical, oppressive, unscrupulous or substantially injurious to governmental entities and individuals resident in the State of Florida. Thus, Defendants' unfair methods of competition and unconscionable acts and practices in the conduct of trade and commerce violate § 501.204, Florida Statutes.
- 176. The sale of TriCor involves the conduct of "trade or commerce" within the meaning of § 501.203(8), Florida Statutes.
- 177. The Attorney General of Florida has reviewed this matter and determined that an enforcement action serves the public interest.
- 178. The State of Florida is entitled to relief, including damages, under § 501.207, Florida Statutes, for all direct and indirect purchases from Defendants.
- 179. The State of Florida is entitled to a civil penalty of up to the maximum amount permitted by §§ 501.2075 or 501.2077, Florida Statutes, as applicable, for each violation of § 501.204, Florida Statutes.
- 180. The State of Florida is entitled to recover its costs and attorneys' fees pursuant to § 501.2105, Florida Statutes.
- 181. The State of Florida requests that the Court order such additional relief as it may deem just and proper.

<u>Iowa</u>

- 182. Iowa realleges and incorporates all of the allegations above from paragraphs 1 through 154.
- 183. Defendants' acts as alleged in this complaint violate the Iowa Competition Act, Iowa Code sections 553, et seq., the Iowa Consumer Fraud Act, Iowa Code section 714.16, and Iowa common law, and Plaintiff State of Iowa is entitled to all remedies available for such violations including damages for injuries sustained by state government agencies.

Kansas

- 184. Plaintiff State of Kansas repeats and realleges each and every allegation contained in paragraphs 1 through 154.
- 185. Defendants' acts violate, and Plaintiffs State of Kansas is entitled to relief under, the Kansas Restraint of Trade Act, Kan. Stat. Ann §50-101, *et seq.* Plaintiffs State of Kansas is entitled to all remedies available for violations of these provisions including civil penalties up to the maximum amount permitted by K.S.A. 50-160, treble damages for injuries sustained by state government agencies and purchasers pursuant to K.S.A. 50-161(b), and reasonable attorneys' fees and costs pursuant to K.S.A. 50-161(c).

Maine

186. Maine realleges and incorporates all of the allegations above from paragraphs 1 through 154.

- 187. Defendants' acts violate the Maine Monopolies and Profiteering Law, 10 MRSA §§1101 and 1102, and Plaintiff State of Maine is entitled under 10 MRSA §1104 to the following relief:
 - a. Treble damages for injuries suffered directly or indirectly on behalf of itself, its state agencies and its citizens as parens patriae; (b) injunctive relief to restrain continuing violations of law; (c) civil penalties in the amount of \$100,000 for each course of conduct alleged herein that constitutes a violation of 10 M.R.S.A §§1101 or 1102; and (d) necessary and reasonable costs, expert fees and attorney fees.

Maryland

- 188. Maryland realleges and incorporates all of the allegations above from paragraphs 1 through 154.
- 189. The aforementioned practices by Defendants were, and are in violation of the Maryland Antitrust Act, Md. Com. Law Code Ann. §§11-201 through 213.
- 190. During the relevant period, TriCor and other fenofibrate products were in the regular, continuous and substantial flow of intrastate commerce in Maryland. TriCor was shipped to pharmacies located in Maryland which sold TriCor to persons in Maryland. TriCor purchases were also paid for by the Maryland Pharmacy Program (which serves Maryland Medicaid clients) and by Maryland's prescription benefits program (which serves Maryland employees and retirees).
- 191. During the relevant period, the Maryland Pharmacy Program paid in excess of \$3.2 million for TriCor. Maryland's State Employee and Retiree Health and Welfare Benefits Program paid in excess of \$8.6 million for TriCor. As a result of the

defendants' unlawful conduct, consumers, the Maryland Pharmacy Program and the State Employee and Retiree Health and Welfare Benefits Program paid more for TriCor than they would have paid in a competitive market.

- 192. Plaintiff State of Maryland brings this action against Defendants in the following capacities:
 - a. Pursuant to Md. Com. Law Code Ann. §11-209(a) in its sovereign capacity for injunctive relief, civil penalties and all other available equitable remedies; (b) pursuant to Md. Com. Law Code Ann. §11-209(b) to recover three times the amount of damages sustained by the Maryland Pharmacy Program and Maryland's prescription benefits program. These Maryland State entities are entitled to money damages regardless of whether they purchased TriCor directly or indirectly from Defendants. Md. Com. Law Code Ann. §11-209(b)(2); (c) pursuant to Md. Com. Law Code Ann. §11-209(b)(5) as parens patriae on behalf of persons residing in Maryland. These persons are entitled to three times the amount of money damages sustained regardless of whether they purchased TriCor directly or indirectly from Defendants. Md. Health-Gen. Code Ann. §21-1114.
- 193. Plaintiff State of Maryland also seeks, pursuant to Md. Com. Law Code §11-209(b) reimbursement of reasonable attorneys fees, expert fees and costs.

Minnesota

- 194. Plaintiff State of Minnesota repeats and realleges each and every allegation contained in paragraphs 1 through 154.
- 195. Defendants' acts violate, and Plaintiff State of Minnesota on behalf of itself, its state agencies, and as parens patriae on behalf of its consumers is entitled to

relief under the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49-.66, the Uniform Deceptive Trade Practices Act of 1973, Minn. Stat. §§ 325D.43-.48, Minn. Stat. Chapter 8, and Minnesota common law for unjust enrichment.

- 196. Plaintiff State of Minnesota is entitled to treble damages under Minn. Stat. § 325D.57. Plaintiff State of Minnesota is entitled to costs and reasonable attorneys' fees under Minn. Stat. § 325D.45 and .57. Plaintiff State of Minnesota is entitled to injunctive relief under Minn. Stat. §§ 325D.45 and .58.
 - 197. Defendants shall be subject to civil penalties under Minn. Stat. § 325D.56.

Missouri

- 198. Plaintiff State of Missouri repeats and realleges each and every allegation contained in paragraphs 1 through 154 with the same force and effect as if here set forth in full.
- 199. The aforementioned acts and practices of the Defendants were in violation of the Missouri Antitrust Law, specifically, §416.031 Revised Statutes of Missouri (RSMo) 2000. The State of Missouri brings this action both on behalf of itself and its public agencies, including by right of assignment, and as parens patriae as to natural persons, to enforce public rights and to protect citizen consumers against the violation of such laws and, specifically, seeks injunctive relief, damages and all other relief available pursuant to §416.071 and §416.121, RSMo (2000).
- 200. The aforementioned acts and practices of the Defendants were also in violation of the Missouri Merchandising Practices Act, §407.020, RSMo 2000, and the Missouri Code of State Regulations, specifically 15 CSR 60-7.010 et seq., 15 CSR 60-8.010, et seq., and 15 CSR 60-9.010, et seq., which prohibit the act, use or employment

by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce, including such acts, uses and employments, committed before, during or after the sale. The Attorney General brings this action in its sovereign capacity to enforce such law and to obtain the relief available pursuant to §§ 407.100, 407.130 and 407.140, RSMo (2000), including injunctions, restitution, the assessment of civil penalties and recovery of all costs of its investigation and litigation as provided therein.

Nevada

- 201. Plaintiff State of Nevada repeats and realleges each and every allegation contained in paragraphs 1 through 154.
- 202. Defendants' acts violate, and Plaintiff State of Nevada is entitled to relief under Nev. Rev. §598A, et seq.

New York

- 203. Plaintiff State of New York repeats and realleges each and every allegation contained in paragraphs 1 through 154.
- 204. The State of New York brings this action in its sovereign capacity to protect its citizens and recover civil penalties.
- 205. The State of New York brings this action on behalf of itself and its public state and local entities that purchased TriCor directly and/ or indirectly.
- 206. The State of New York brings this action as parens patriae as to natural persons who purchased TriCor directly and/or indirectly.

- 207. Defendants' acts unreasonably restrained trade and commerce causing injury and damage to public state and local entities and natural persons in the State in violation of New York General Business Law §§340 347, and Plaintiff New York is entitled to damages, injunctive relief, penalties and other appropriate relief thereunder.
- 208. Defendants engaged in repeated and persistent fraudulent and illegal acts in the conduct of their business to thwart competition from generic fenofibrate in violation of New York Executive Law §63(12), and Plaintiff New York is entitled to damages, injunctive relief, penalties and other appropriate relief thereunder.
- 209. By unlawfully thwarting competition from generic fenofibrate, Defendants wrongfully deprived purchasers of the lower, competitive price that generic fenofibrate would have sold for in a free and open competitive market. Defendants thereby wrongfully appropriated for themselves monetary benefits that they would not have had in a competitive market, and have been unjustly enriched. Plaintiff New York is entitled to restitution, disgorgement and other appropriate relief as a result of Defendants' unlawful conduct.

Oregon

- 210. Plaintiff State of Oregon, ex rel. Hardy Myers, Attorney General of Oregon ("State of Oregon" or "Oregon"), realleges and incorporates all of the allegations above from paragraphs 1 through 154.
- 211. The State of Oregon represents itself, including its state agencies, and as parens patriae, its political subdivisions and natural persons in the State who have purchased TriCor.

- 212. Defendants' acts of conspiracy and unreasonable restraint of trade and commerce had the purpose and effect of suppressing competition in the sale of TriCor in Oregon and elsewhere, and had a substantial and adverse impact on prices for TriCor in Oregon.
- 213. Defendants' acts have caused substantial injury and damage to the State of Oregon, its state agencies and political subdivisions, and to natural persons in the State.
- 214. The State of Oregon, on behalf of itself, including its state agencies, and as parens patriae, its political subdivisions and natural persons in the State who purchased TriCor, is entitled to relief under the Oregon Antitrust Law, Oregon Revised Statutes § ("ORS") 646.705, et seq.
- 215. The Defendants' activities are *per se* violations of Oregon's Antitrust Law, ORS 646.725 and ORS 646.730. Pursuant to ORS 646.760, 646.770, ORS 646.775, and ORS 646.780, the Attorney General of Oregon possesses authority to seek equitable and monetary relief for antitrust injuries sustained by the State, including its state agencies, and by its political subdivisions and natural persons in the State.
- 216. Pursuant to ORS 646.775 and ORS 646.780, the State of Oregon is entitled to recover three times the total damages sustained by the State, including its state agencies, and by its political subdivisions and natural persons in the State, by reason of Defendants' violations of the Oregon Antitrust Law.
- 217. Pursuant to ORS 646.760, Defendants are each liable to the State of Oregon for civil penalties of \$250,000 for each of their violations of the Oregon Antitrust Law.

218. Pursuant to ORS 646.760, 646.770, ORS 646.775, and ORS 646.780, the State of Oregon is entitled to its costs incurred in bringing this action, plus reasonable attorney fees, expert witness fees and costs of investigation.

Pennsylvania

- 219. Pennsylvania realleges and incorporates all of the allegations above from paragraphs 1 through 154.
- 220. The acts and practices of Defendants, as set forth herein, constitute unfair methods of competition and unfair or deceptive acts or practices in the conduct of Defendants' business in violation of the Unfair Trade Practices and Consumer Protection Law ("UTPCPL").
- 221. In distributing, marketing and selling TriCor to the Commonwealth and Pennsylvania Consumers, and in otherwise engaging in the conduct more fully described herein with respect to TriCor, Abbott and Fournier, individually and jointly, are engaging in trade or commerce that directly or indirectly harmed consumers in this Commonwealth within the meaning of 73 P.S. §201-2(3).
 - 222. Abbott and Fournier violated the UTPCPL:
 - a. each time Abbott and/or Fournier prosecuted and obtained multiple patents through inequitable conduct; (b) each time Abbott and/or Fournier listed inequitably obtained patents in the Orange Book as maintained by the Food and Drug Administration; (c) each time Abbott and/or Fournier filed sham patent litigation for the purpose of foreclosing and delaying competition in the market for fenofibrate; (d) each time Abbott and/or Fournier reformulated TriCor to prevent generic entry; (e) each time Abbott and/or Fournier contacted a

prescribing physician to convert the market over to a new formulation of TriCor; (f) each time Abbott and/or Fournier contacted pharmacies to remove prior formulations of TriCor to make it commercially unavailable to prevent generic entry; (g) each time Abbott and/or Fournier interfered with the normal and customary channels of distribution used by generics; (h) each time a medical provider prescribed TriCor; (i) each time a request for reimbursement was made to a Commonwealth of Pennsylvania program for TriCor; (j) each time a patient and/or his or her insurer was charged for TriCor; and (k) each time Abbott and/or Fournier engaged in conduct actionable under the other counts of this Complaint brought by the Commonwealth of Pennsylvania and/or engaged in conduct in violation of the statute and laws of the Commonwealth of Pennsylvania.

- 223. Abbott's and Fournier's TriCor products reimbursed or purchased by the Commonwealth of Pennsylvania or purchased by Pennsylvania Consumers were used for personal, family or household use.
- 224. Abbott's and Fournier's conduct, as more fully described herein, constitutes unfair methods of competition and unfair or deceptive acts or practices within the meaning of 73 P.S. §201-2(4), including, but not limited to, the following:
 - a. causing likelihood of confusion or misunderstanding as to the source, sponsorship, approval or certification of goods or services, within the meaning of 73 P.S. §201-2(4) (ii); (b) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have; within the meaning of 73 P.S. §201-2(4) (v); (c)

engaging in any other fraudulent or deceptive conduct which creates the likelihood of confusion or of misunderstanding; within the meaning of 73 P.S. §201-2(4) (xxi).

- 225. The Commonwealth of Pennsylvania is empowered to bring this action on behalf of "persons" who have purchased TriCor at artificially-inflated prices and as a result, have suffered, are suffering and will continue to suffer irreparable harm as a result of Abbott's and Fournier's actions. "Persons" include, but are not limited to, natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations and any other legal entities within the meaning of 73 P.S. §201-2(2).
- 226. The Commonwealth of Pennsylvania also has standing to bring this claim in that the Commonwealth of Pennsylvania is both an end payor and purchaser/reimburser of TriCor through its Medicaid, PACE and state hospitals programs. The Commonwealth of Pennsylvania performs these functions, not for its own business purposes, but rather in its representative capacity on behalf and for the benefit of its constituents who, in turn, make use of TriCor primarily for personal, family and/or household purposes.
- 227. Defendants agreed to and did, in fact, act in restraint of trade or commerce in a market that includes Pennsylvania, by affecting, fixing, controlling and/or maintaining, at artificial and non-competitive levels, the prices at which fenofibrate was sold, distributed or obtained in Pennsylvania.
- 228. Defendants deliberately failed to disclose material facts to the Commonwealth of Pennsylvania and Pennsylvania Consumers concerning Defendants' unlawful activities and artificially-inflated prices for fenofibrate. Defendants owed a

duty to disclose such facts and considering the relative lack of sophistication of the average, non-business consumer, Defendants breached that duty by their silence.

Defendants misrepresented to all consumers during the relevant period that Defendants' fenofibrate prices were competitive and fair.

- 229. Defendants' unlawful conduct had the following effects: (1) fenofibrate price competition was restrained, suppressed and eliminated throughout Pennsylvania; (2) fenofibrate prices were raised, fixed, maintained and stabilized at artificially-high levels throughout Pennsylvania; (3) Commonwealth of Pennsylvania and Pennsylvania Consumers were deprived of free and open competition; and (4) Commonwealth of Pennsylvania and Pennsylvania Consumers paid supracompetitive, artificially inflated prices for fenofibrate.
- 230. As a direct and proximate result of the Defendants' violations of law, Commonwealth of Pennsylvania and Pennsylvania Consumers have and will continue to suffer an ascertainable loss of money or property as a result of Defendants' use or employment of unconscionable and deceptive commercial practices as set forth above. That loss has been caused by Defendants' willful and deceptive conduct, as described herein.
- 231. Defendants' deception, including its affirmative misrepresentation and omissions concerning the inequitable patent prosecution, improper FDA Orange Book listing and the price of fenofibrate, likely misled all consumers acting reasonably under the circumstances to believe that they were purchasing fenofibrate at prices borne by a free and fair market. Defendants' affirmative misrepresentations and omissions constitute information important to Commonwealth of Pennsylvania and Pennsylvania

Consumers as they related to the choice, efficacy and/or cost of fenofibrate they purchased. Defendants violated the UTPCPL under its "catch-all provision," 73 P.S. §201-2(4) (xxi), by engaging in deceptive conduct which created a likelihood of confusion or misunderstanding as alleged therein and Commonwealth of Pennsylvania seeks all relief available hereunder.

- 232. Abbott's and Fournier's conduct, individually and jointly, more fully described herein is, accordingly, proscribed and unlawful pursuant to 73 P. S. §201-3.
- 233. Abbott's and Fournier's conduct, individually and jointly, as more fully described herein, was willful within the meaning of 73 P.S. §201-8.
- 234. The Attorney General has determined that these proceedings to enjoin Abbott's and Fournier's conduct are in the public interest.
- 235. The Commonwealth of Pennsylvania therefore seeks the entry of a permanent injunction restraining Abbott's and Fournier's unlawful conduct and mandating corrective measures pursuant to 73 P.S. §201-4.
- 236. The Commonwealth of Pennsylvania also requests that the Court require Abbott and Fournier to restore to the Commonwealth of Pennsylvania and Pennsylvania Consumers monies acquired from the sale of its prescription drugs, TriCor, during the period of time Defendant's unlawful conduct took place, pursuant to 73 P.S. §201-4.1.
- 237. In addition, and in light of Abbott's and Fournier's willful and improper conduct as herein described, the Commonwealth of Pennsylvania requests that the Court award a civil penalty to the Commonwealth of Pennsylvania not exceeding:

- a. as to affected Pennsylvania Consumers under the age of sixty (60) years, \$1,000.00 per violation; (b) and as to affected Pennsylvania Consumers sixty (60) years of age or older, \$3,000.00 per violation.
- 238. Abbott is liable for its actions and the actions of its co-conspirators for each of these violations as independent unfair and deceptive acts in violation of the UTPCPL, and for its course of conduct comprising an unfair and deceptive practice in violation of the UTPCPL.
- 239. Fournier is liable for its actions and the actions of its co-conspirators for each of these violations as independent unfair and deceptive acts in violation of the UTPCPL, and for its course of conduct comprising an unfair and deceptive practice in violation of the UTPCPL.
- 240. As a result of Abbott's and Fournier's unfair and deceptive trade practices, the Commonwealth of Pennsylvania and Pennsylvania Consumers have suffered and will continue to suffer ascertainable loss and damages in an amount to be determined at trial.
- 241. Accordingly, the Commonwealth of Pennsylvania, on behalf of itself and Pennsylvania Consumers, seeks all relief available, including treble damages, restitution, disgorgement, and/or civil penalties, under the UTPCPL.
- 242. Defendants' combinations or conspiracies had the following effects: (1) fenofibrate price competition was restrained, suppressed and eliminated throughout Pennsylvania; (2) fenofibrate prices were raised, fixed, maintained and stabilized at artificially-high levels throughout Pennsylvania; (3) Commonwealth of Pennsylvania and Pennsylvania Consumers were deprived of free and open competition; and (4)

Commonwealth of Pennsylvania and Pennsylvania Consumers paid supracompetitive, artificially-inflated prices for fenofibrate.

- 243. During the relevant period, Defendants' illegal conduct had a substantial effect on Pennsylvania residents.
- 244. As a direct and proximate result of Defendants' unlawful conduct, the Commonwealth of Pennsylvania and Pennsylvania Consumers have been injured in their business and property and are threatened with further injury.
- 245. By reason of the foregoing, defendants have entered into agreements in restraint of trade and have monopolized in violation of Pennsylvania common law.

 Accordingly, the Commonwealth of Pennsylvania, on behalf of itself and Pennsylvania Consumers, seeks all relief available, including damages, restitution and/or disgorgement, under Pennsylvania common law proceeding pursuant to 73 P.S. §732-204 (c).
- 246. As set forth above, Abbott and Fournier, individually and jointly, have been unjustly enriched as a result of engaging in the following practices with respect to the Commonwealth of Pennsylvania and Pennsylvania Consumers.
 - a. obtaining multiple patents through inequitable conduct and improperly listing these patents with the Food and Drug Administration; (b) knowing they were obtained improperly and then filing sham patent litigation for the purpose of foreclosing and delaying competition in the market for fenofibrate; (c) forcing the market to convert to a new formulation before generic entry by reformulating TriCor with only minor changes to the form and dosage strength that did not provide any significant new clinical benefit for the purpose of eliminating the generic bioequivalent AB-rating for the prior formulation; (d)

creating an artificial product differentiation as a marketing tool to convince physicians to stop writing prescriptions for the old formulation and to write prescriptions only for the new formulation; (e) stopping promotion and sales of the previous TriCor formulation upon the introduction of the new formulation; (f) removing the old TriCor formulation from the market, so as to make it commercially unavailable by the time a generic competitor could enter the market; and (g) interfering with the normal and customary channels of distribution used by generics.

- 247. The Commonwealth of Pennsylvania and Pennsylvania Consumers were purchasers, reimbursers, and/or end payors of Abbott's and Fournier's drug, TriCor, and have paid amounts far in excess of the competitive price for TriCor and generic fenofibrate that would have prevailed in a competitive and fair market.
- 248. Abbott and Fournier, individually and jointly, knew of and has appreciated and retained, or used, the benefits of the Commonwealth of Pennsylvania and Pennsylvania Consumers' purchases of its drug, TriCor, at amounts far in excess of the competitive price. Defendants manipulated the patent process and the FDA Orange Book listing process and filed sham litigation to enforce the improperly obtained and listed patents to eliminate consumer choice of generic fenofibrate. Each of these acts was intended to increase the market share of TriCor thereby increasing its sales and profits.
- 249. For those customers that purchase directly or indirectly from Abbott at artificially-inflated and supra-competitive prices, Abbott's and Fournier's increases to prices that would have prevailed in a competitive and fair market directly benefit Abbott in the form of increased revenues.

- 250. Based upon Abbott's and Fournier's conduct set forth in this complaint, it would be inequitable and unjust for Abbott and Fournier, individually and jointly, to retain such benefits without payment of value.
- 251. Abbott and Fournier, individually and jointly, will be unjustly enriched if it is permitted to retain the direct or indirect benefits received or used resulting from the purchase of TriCor by the Commonwealth of Pennsylvania and Pennsylvania Consumers. The Commonwealth of Pennsylvania, on behalf of itself and Pennsylvania Consumers, seeks to recover the amounts that unjustly enriched Abbott and Fournier, individually and jointly.
- 252. The Commonwealth of Pennsylvania and Pennsylvania Consumers are therefore entitled to equitable relief in the form of an injunction, restitution and disgorgement, legal relief in the form of damages and any other relief the Court deems appropriate.

South Carolina

- 253. South Carolina realleges and incorporates all of the allegations above from paragraphs 1 through 154.
- 254. South Carolina incorporates by reference the foregoing allegations as if set forth at length herein.
- 255. South Carolina represents the South Carolina Medicaid Program ("South Carolina Medicaid"), the South Carolina Employee Insurance Program ("South Carolina EIP"), and South Carolina consumers in this action.

- 256. Abbott and Fournier's conduct constitutes "unfair methods of competition and unfair or deceptive acts or practices" under §39-5-20 of the South Carolina Code of Laws.
- 257. South Carolina Medicaid and South Carolina EIP are represented in an individual capacity pursuant to §39-5-140(a). Abbott and Fournier's conduct constitutes a "willful or knowing violation of §39-5-20" under §39-5-140(d), and thus South Carolina seeks to recover treble damages under §39-5-140(a) on behalf of South Carolina Medicaid and South Carolina EIP for all purchases of TriCor made by South Carolina Medicaid and South Carolina EIP during the relevant time period.
- 258. South Carolina consumers are represented in a statutory parens patriae capacity under §39-5-50 and a common law parens patriae capacity. Pursuant to §39-5-50(b), South Carolina seeks that this Court restore unto South Carolina consumers any ascertainable loss incurred in making any payments for purchases of TriCor. Pursuant to §39-5-50(a), South Carolina seeks injunctive relief to prohibit Abbott from engaging in the conduct described in this complaint.
- 259. Abbott and Fournier's conduct constitutes a "willful or knowing violation of §39-5-20" under §39-5-110(c). South Carolina seeks an award of civil penalties under §39-5-110(a) in the amount of \$5,000.00 per sale of TriCor made in South Carolina.

Washington

- 260. The State of Washington realleges and incorporates all of the allegations from paragraphs 1 through 154.
- 261. Defendants' acts violate Wash. Rev. Code 19.86, including Wash, Rev. Code 19.86.020, Wash. Rev. Code 19.86.030, and/or Wash. Rev. Code 19.86.040.

262. Plaintiff State of Washington on behalf of itself, its state agencies and as parens patriae for all natural persons who purchased defendants' fenofibrate-based drugs is entitled to recover damages and attorneys' fees under RCW 19.86.090, injunctive relief and restitution under RCW 19.86.080 and civil penalties under RCW 19.86.140.

West Virginia

- 263. Plaintiff State of West Virginia repeats and realleges each and every allegation contained in paragraphs 1 through 154 with the same force and effect as if here set forth in full.
- 264. The aforementioned practices by Defendants were in violation of the West Virginia Antitrust Act, W. Va. Codes 47-18-1 *et seq.*, and the West Virginia Consumer Credit and Protection Act, W. Va. Code s 46A-1-101 *et seq.*, and the State of West Virginia, its state agencies, and political subdivisions, and the natural persons it represents are entitled to relief there under.

Prayer for Relief

Accordingly, the Plaintiff States request that this Court:

- 1. Adjudge and decree that Abbott and Fournier violated sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1, 2;
- 2. Adjudge and decree that the foregoing activities violated each of the state statutes enumerated in this Complaint;
- 3. Enjoin and restrain, pursuant to federal and state law, Abbott and Fournier, their affiliates, assignees, subsidiaries, successors, and transferees, and their officers, directors, partners, agents and employees, and all other persons acting or claiming to act

on their behalf or in concert with them, from continuing to engage in any anticompetitive conduct and from adopting in the future any practice, plan, program, or device having a

similar purpose or effect to the anticompetitive actions set forth above;

4. Award to Plaintiff States any other equitable relief as the Court finds

appropriate to redress Defendants' violations of federal or state antitrust law or restore

competition;

5. Award to each Plaintiff State the maximum civil penalties allowed by law;

6. Award to each Plaintiff State treble damages for overcharges paid by State

entities or the State's purchasers of TriCor;

7. Award to each Plaintiff State any other statutory damages, restitution or

equitable disgorgement for the benefit of the state and its consumers as appropriate under

each state's law;

8. Award to each Plaintiff State its costs, including reasonable attorneys'

fees; and

9. Order any other relief that this Court deems proper.

Jury Trial Demanded

The Plaintiff States demand a trial by jury of all issues so triable in this cause.

Dated: March 18, 2008

Respectfully submitted,

THE PLAINTIFF STATES

BILL MCCOLLUM

Attorney General

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STATE OF FLORIDA

Patricia A. Conners

Associate Deputy Attorney General

R. Scott Palmer

Special Counsel-Assist. Attorney General

Elizabeth G. Arthur

Assistant Attorney General

PL-01, The Capitol

Tallahassee, Florida 32399-1050

Telephone: 850-414-3300 Facsimile: 850-488-9134

Elizabeth.Arthur@myfloridalegal.com

STATE OF ARIZONA

by Attorney General TERRY GODDARD

Nancy M. Bonnell

Antitrust Unit Chief

Public Advocacy Division

Office of the Attorney General

1275 West Washington

Phoenix, Arizona 85007-2926

Telephone: 602-542-7752

STATE OF ARKANSAS

by Attorney General DUSTIN McDANIEL;

Bart Dickinson

Assistant Attorney General

Office of the Attorney General

323 Center Street

Little Rock, Arkansas 72201

Telephone: 501-682-3561

STATE OF CALIFORNIA

by Attorney General EDMUND G. BROWN, JR.

Cheryl L. Johnson

Deputy Attorney General

300 S. Spring Street, Room 1702

Los Angeles, California 90013

Telephone: 213-897-2688

STATE OF CONNECTICUT

by Attorney General RICHARD BLUMENTHAL

Michael E. Cole

Chief, Antitrust Department

Arnold B. Feigin

Assistant Attorney General

55 Elm Street

Hartford, Connecticut 06106

Telephone: 860-808-5040

DISTRICT OF COLUMBIA

By Interim Attorney General PETER J. NICKLES

Bennett Rushkoff

Senior Division Counsel

Public Advocacy Division

Don Allen Resnikoff

Senior Assistant Attorney General

Craig Farringer

Assistant Attorney General

Susan Phan

Assistant Attorney General

Consumer and Trade Protection Section

441 Fourth Street, NW, Suite 1130N

Washington, District of Columbia 20001

Telephone: 202-727-3225

STATE OF IOWA

by Attorney General THOMAS J. MILLER

John F. Dwyer

Attorney

Layne M. Lindebak

Assistant Attorney General

2nd Floor, Hoover Office Building

East 13th & Walnut Street

Des Moines, Iowa 50319

Telephone: 515-281-7054

STATE OF KANSAS

by Attorney General STEPHEN N. SIX

Lynette R. Baker

Assistant Attorney General

Consumer Protection/Antitrust

120 SW 10th Avenue, 2nd Floor

Topeka, Kansas 66212

Telephone: 785-368-8451

STATE OF MAINE

by Attorney General G. STEVEN ROWE

Christina Moylan

Assistant Attorney General

6 State House Station

Augusta, Maine 04333-0006

Telephone: 207-626-8800

STATE OF MARYLAND

by Attorney General DOUGLAS F. GANSLER

Ellen S. Cooper

Assistant Attorney General

Chief, Antitrust Division

Alan M. Barr

Assistant Attorney General

Deputy Chief, Antitrust Division

Schonette J. Walker

Assistant Attorney General

200 St. Paul Place, 19th Floor

Baltimore, Maryland 21202

Telephone: 410-576-6470

STATE OF MINNESOTA

by Attorney General LORI SWANSON

Matthew P. Reinsmoen

Assistant Attorney General

445 Minnesota Street, Suite 1200

St. Paul, Minnesota 55101-2130

Telephone: 651-215-1564

STATE OF MISSOURI

by Attorney General JEREMIAH (JAY) W. NIXON

Anne E. Schneider

Assistant Attorney General

Antitrust Counsel

P.O. Box 899

Jefferson City, Missouri 65102

Telephone: 573-751-8455

STATE OF NEVADA

by Attorney General CATHERINE CORTEZ MASTO

Eric Witkoski

Chief Deputy Attorney General and Consumer Advocate

Marie Martin-Kerr

Senior Deputy Attorney General

100 N. Carson Street

Carson City, Nevada 89701

Telephone: 775-684-1100

STATE OF NEW YORK

by Attorney General ANDREW M. CUOMO

Elinor Hoffman

Assistant Attorney General Margaret Martin Assistant Attorney General Antitrust Bureau New York State Department of Law 120 Broadway, Suite 26C New York, New York 10271-0332 Telephone: 212-416-8269

STATE OF OREGON
by Attorney General HARDY MYERS
Tim D. Nord
Assistant Attorney General
Chin See Ming
Assistant Attorney General
Oregon Department of Justice
1162 Court Street NE
Salem, Oregon 97301-4096
Telephone: 503-934-4400

COMMONWEALTH OF PENNSYLVANIA by Attorney General TOM CORBETT James A. Donahue, III Chief Deputy Attorney General Joseph S. Betsko Deputy Attorney General Antitrust Section 14th Floor, Strawberry Square Harrisburg, PA 17120 Telephone: 717-787-4530 Facsimile: 717-705-7110

STATE OF SOUTH CAROLINA by Attorney General HENRY D. McMASTER C. Havird Jones, Jr. Senior Assistant Attorney General P. O. Box 11549 Columbia, South Carolina 29211 Telephone: 803-734-3680

STATE OF WASHINGTON by Attorney General ROB McKENNA Mark O. Brevard Assistant Attorney General 800 5th Avenue, Suite 2000 Seattle, Washington 98104-6338 Telephone: 206-464-7030 Facsimile: 206-464-6338

STATE OF WEST VIRGINIA
by Attorney General DARRELL V. McGRAW, JR.
Douglas Davis
Assistant Attorney General
Christopher Hedges
Assistant Attorney General
Consumer Protection and Antitrust Division
812 Quarrier Street
Charleston, West Virginia 25301