UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA

In Re: CELEBREX (CELECOXIB) ANTITRUST LITIGATION This Document Relates To: ALL END-PAYOR ACTIONS	*Lead Case* 2:14-cv-00395

CONSOLIDATED AMENDED COMPLAINT

I. INTRODUCTION

1. In 2008, the United States Court of Appeals for the Federal Circuit ruled that a Pfizer patent for its blockbuster painkiller Celebrex (U.S. Patent No. 5,760,068 – the "'068 patent" or the "'068 method-of-use patent") was invalid. The court ruled that the '068 patent, for methods of using the active pharmaceutical ingredient celecoxib to treat inflammation-related disorders, was not patentably distinct from two earlier Pfizer patents – U.S. Patent No. 5,466,823 ("the '823 patent") covering the celecoxib compound and U.S. Patent No. 5,563,165 ("the '165 patent") covering formulations – that already disclosed the use of celecoxib to reduce inflammation. Since the '068 patent was invalid, patent exclusivity for Celebrex would not extend beyond expiration of the '823 and '165 patents on May 30, 2014.

2. To avoid the consequences of the Federal Circuit ruling invalidating the '068 patent and allowing earlier generic competition into the market for Celebrex, Pfizer implemented a scheme to unlawfully prolong patent protection for celecoxib beyond May 30, 2014.

3. First, Pfizer sought from the United States Patent and Trademark Office ("PTO") reissuance of the invalid '068 method-of-use patent by claiming that its earlier applications for the patent contained unintentional "errors" needing "correction" in light of the Federal Circuit ruling. This was false and Pfizer knew it. And for over four years – from September of 2008

until March of 2013 – Pfizer bombarded the PTO with false information, deflective arguments and voluminous irrelevant materials. After the PTO's repeated rejections, Pfizer made further submissions to hide the true purpose of the reissue claim. Pfizer's onslaught of false information and deceit caused the PTO to be duped and to mistakenly grant allowance of the reissue patent (U.S. Reissue Patent No. RE44, 048 – "the '048 reissue patent").

4. Second, in 2013 Pfizer used the fraudulently obtained '048 reissue patent to prosecute sham litigation against would-be makers of generic Celebrex. Not only did Pfizer know that it had procured the '048 reissue patent by fraud, it also knew that (independent of the fraud it had committed before the PTO) a court would eventually conclude in later patent litigation that the '048 reissue patent had been erroneously granted and was invalid for "obviousness-type double-patenting" over Pfizer's two earlier celecoxib patents (the '823 and '165 patents). But Pfizer's goal was not to win this sham litigation; it was simply to use the lawsuit to delay would-be generic makers' entry efforts, and to have a lawsuit pending to serve as a vehicle for later settlements that would buy Pfizer additional exclusivity beyond May 30, 2014.

5. Pfizer's deliberate scheme worked as planned. It procured the '048 reissue patent through fraud and deceit, and used it to file sham litigation in March 2013. In that lawsuit the court granted summary judgment against Pfizer. Before the actual judgment was entered Pfizer used the pending sham lawsuit to "settle" with first-to-file, would-be generic manufacturer Teva Pharmaceuticals USA, Inc. ("Teva"). Under the terms of the settlement, Teva would not launch its competing generic product until December 2014 (six months after expiration of the '823 and '165 patents on May 30, 2014).

6. As a result, until generic launch in 2014, purchasers of Celebrex paid supracompetitive prices for Celebrex, incurring antitrust overcharges on purchases of many hundreds of millions of dollars even though there was no valid patent covering Celebrex.

7. This antitrust suit is brought on behalf of a proposed End-Payor Class that has purchased, paid for, or reimbursed for Celebrex at supracompetitive prices. The Class seeks to hold Pfizer accountable for its strategic manipulation of the patent review and judicial processes in violation of federal and state antitrust and consumer protection laws, as well as state common laws of unjust enrichment.

II. PARTIES

8. Plaintiff United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") is an employee welfare benefit plan. UFCW's office, from which it pays medical benefits including benefits for prescription drugs, is located in Cook County, Illinois. UFCW purchased Celebrex, other than for re-sale (and will purchase generic Celebrex other than for re-sale as it becomes available), at supra-competitive prices during the Class Period (as defined herein) and has thereby been injured. UFCW has paid for Celebrex prescriptions in at least the following states: Illinois, Indiana, Oklahoma, Michigan and Florida.

9. Plaintiff Wisconsin Masons' Health Care Fund ("Masons") is a self-funded, multi-employer health and welfare plan governed by the Employee Retirement Income Security Act of 1974 (ERISA). Masons is administered by Benefit Plan Administration of Wisconsin, whose offices are at 2901 W. Beltline Highway, Suite 100, Madison, WI 53713-4226. Masons purchased Celebrex, other than for re-sale (and will purchase generic Celebrex other than for re-sale as it becomes available), at supra-competitive prices during the Class Period (as defined herein) and has thereby been injured. Masons has paid for Celebrex prescriptions in at least the following states: Indiana, Nevada and Wisconsin.

10. Plaintiff Ironworkers Local 383 Health Care Plan ("Ironworkers") is a self-funded, multi-employer health and welfare plan governed by the ERISA. The Plan is administered by Benefit Plan Administration of Wisconsin, whose offices are at 2901 W. Beltline Highway, Suite 100, Madison, WI 57313-4226. Ironworkers purchased Celebrex, other than for re-sale (and will purchase generic Celebrex other than for re-sale as it becomes available), at supra-competitive prices during the Class Period (as defined herein) and has thereby been injured. Ironworkers has paid for Celebrex prescriptions in at least the following states: Wisconsin.

11. Plaintiff AFSCME Health and Welfare Fund ("AFSCME") is an employee welfare benefit plan. AFSCME's office, from which it pays prescription drug, dental and vision benefits, is located at 150 South 43rd Street, Harrisburg, Pennsylvania 17111. AFSCME has purchased Celebrex, other than for re-sale (and will purchase generic Celebrex other than for re-sale as it becomes available), at supra-competitive prices during the Class Period (as defined herein), and has thereby been injured. AFSCME has paid for Celebrex prescriptions in at least the following states: New Jersey and Pennsylvania.

12. Plaintiff International Union of Operating Engineers Local 49 Health & Welfare Fund ("IUOE Local 49") is an employee welfare benefit plan. IUOE Local 49's office, from which it pays medical benefits for prescription drugs, is located at 3001 Metro Drive, Suite 500, Bloomington, MN 55425. IUOE Local 49 has purchased Celebrex, other than for re-sale (and will purchase generic Celebrex other than for re-sale as it becomes available), at supra-competitive prices during the Class Period (as defined herein) and has thereby been injured. IUOE Local 49 has paid for Celebrex prescriptions in at least the following states: Arizona, Florida, Minnesota, North Dakota, Ohio, South Dakota, Texas and Wisconsin.

13. Plaintiff A.F. of L. – A.G.C. Building Trades Welfare Plan ("Building Trades Plan") is located in Mobile, Alabama. Building Trades Plan is a self-insured welfare plan that provides health care and prescription drug benefits to eligible members and their families. During the Class Period, Building Trades Plan purchased Celebrex, other than for re-sale (and will purchase generic Celebrex other than for re-sale as it becomes available), at supra-competitive prices during the Class Period (as defined herein) and has thereby been injured. Building Trades Plan has paid for Celebrex prescriptions in at least the following states: Mississippi and North Carolina.

14. Plaintiff International Association of Heat and Frost Insulators and Asbestos Workers Local #6 Health and Welfare Fund ("Insulators") is based in Dorchester, Massachusetts and provides health and welfare benefits to active and retired members in Massachusetts and other states. During the Class period, Insulators purchased Celebrex, other than for re-sale (and will purchase generic Celebrex other than for re-sale as it becomes available), at supra-competitive prices during the Class Period (as defined herein) and has thereby been injured. Insulators has paid for Celebrex prescriptions in at least the following states: New Jersey and Rhode Island.

15. Plaintiff Central Pennsylvania and Regional Health and Welfare Fund ("CPRHSW") maintains its principal place of business at 3013 B Walton Road, Plymouth Meeting, Pennsylvania 19462. CPRHSW has purchased Celebrex, other than for re-sale (and will purchase generic Celebrex other than for re-sale as it becomes available), at supra-competitive prices during the Class Period (as defined herein) and has thereby been injured. CPRHSW has paid for Celebrex prescriptions in at least the following states: Pennsylvania.

16. Plaintiff International Union of Engineers Local 138 Health & Welfare Fund ("IUOE Local 138") is a self-insured health and welfare benefit with its principal place of business in Farmingdale, New York. IUOE Local 138 has purchased Celebrex, other than for re-sale (and will purchase generic Celebrex other than for re-sale as it becomes available), at supra-competitive prices during the Class Period (as defined herein) and has thereby been injured. IUOE Local 138 has paid for Celebrex prescriptions in at least the following states: Florida, New York, North Carolina and Pennsylvania.

17. Plaintiff Barbara Stanley ("Stanley") is an adult individual residing in Broward County, Florida. During the Class Period, as defined below, Ms. Stanley purchased Celebrex, other than for re-sale (and will purchase generic Celebrex other than for re-sale as it becomes available), at supra-competitive prices during the Class Period (as defined herein) and has thereby been injured. Ms. Stanley has paid for Celebrex prescriptions in Florida.

18. Defendant Pfizer Inc. is a Delaware corporation, having its principal place of business at 235 East 42 Street, New York, New York, 10017.

19. Defendant G.D. Searle LLC ("Searle") is a Delaware limited liability company with its principal place of business at 235 East 42 Street, New York, New York, 10017. Searle LLC is a wholly-owned indirect subsidiary of Pfizer Inc. Searle holds an approved New Drug Application, NDA No. 20-998, for celecoxib capsules, 50 mg, 100 mg, 200 mg, and 400 mg dosage strengths, which it sells under the name Celebrex. Searle is the named assignee of the '048 patent.

20. Defendant Pfizer Asia Pacific Pte. Ltd. ("PAP") is a private limited company organized and existing under the laws of Singapore, with its principal place of business at 31 Tuas South Avenue 6, Singapore 637578. PAP is a wholly-owned indirect subsidiary of Pfizer

Inc. PAP is the holder of certain rights under the '048 patent, including an exclusive license to manufacture and sell Celebrex.

21. Defendants Pfizer Inc., Searle and PAP are referred to collectively herein as "Pfizer" or "Defendants." Pfizer is engaged in the worldwide marketing, production, and distribution of pharmaceutical products, including in this district.

22. All of Pfizer's actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Pfizer's officers, agents, employees, or other representatives while actively engaged in the management of Pfizer's affairs (or that of its predecessors-in-interest) within the course and scope of their duties and employment, and/or with Pfizer's actual, apparent, and/or ostensible authority.

III. JURISDICTION AND VENUE

23. This action arises under state antitrust law, section 2 of the Sherman Act, 15 U.S.C. § 2, and section 16 of the Clayton Act, 15 U.S.C. § 26, and seeks to recover multiple damages (where allowed by state statute), interest, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiffs and members of the Class (defined below) resulting from Pfizer's unlawful foreclosure of the United States market for celecoxib. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a) and 1407, and 15 U.S.C. § 26.

24. Venue is proper in this district pursuant to 15 U.S.C. §§ 26, 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because during the Class Period, each of the Defendants resided, transacted business, were found, or had agents in this district, and a substantial portion of the alleged activity affected interstate and intrastate trade and commerce discussed below has been carried out in this district.

25. Pfizer's conduct, as described in this complaint, was within the flow of, was intended to have a substantial effect on, and did have a substantial effect on, the interstate

commerce of the United States, including in this district, as well as the intrastate commerce of each state where purchases of Celebrex were made by class members at supracompetitive prices. Retailers in each state were foreclosed from buying and offering for sale to End Payors cheaper generic Celebrex.

26. During the Class Period, Pfizer manufactured, sold and shipped Celebrex in a continuous and uninterrupted flow of interstate commerce, which included sales of Celebrex in this district, advertisement of Celebrex in media in this district, monitoring prescriptions of Celebrex by prescribers within this district, and employment of product detailers in this district, who as agents of Pfizer, marketed Celebrex to prescribers in this district. Pfizer's conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce and on intrastate commerce in each class state, including commerce in this district and state.

27. This Court has personal jurisdiction over each Defendant. Each Defendant – throughout the United States and including in this district – has transacted business, maintained substantial contacts, or committed overt acts in furtherance of Defendants' illegal scheme. The scheme has been directed at, and has had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY BACKGROUND

28. Brand drug companies can, and do, obtain valid patents that cover their new prescription drug products. Such patents are meant to encourage discovery and development of new medicines, providing protection from competition by other drug companies for a length of time set under a statute by Congress.

29. Once the lawful periods of exclusivity expire on brand products, generic companies can seek Food and Drug Administration ("FDA") approval to sell generic versions of the brand, allowing the generic companies to manufacture generic products that are just as safe

and effective, but far less expensive than, the brand.[1] The medication becomes affordable for all, and purchasers are no longer burdened by the high cost of the brand drug.

30. At root, then, is a basic principle in the American system of access to prescription drugs that addresses these goals and paves the way for both new and more affordable drugs. The basic principle is this: brand name drugs have a statutory period of time to charge very high prices for medications that, in fact, cost little to manufacture, but it is a limited period, after which generic companies can compete with low-cost substitutes. And from this basic principle emerges a basic rule: a brand company should not deceive the PTO in order to illegally extend its monopoly period by procuring an invalid patent to delay entry of less expensive, but therapeutically equivalent, generic medications, and then use the invalid patent as the bases to prosecute infringement lawsuits that have no reasonable likelihood of succeeding.

31. Pfizer breached this basic rule.

A. The Competitive Effects of AB-Rated Generic Competition

32. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between generic drugs and their corresponding brand name versions is their price. Because generic versions of a corresponding brand drug product are commodities that cannot be differentiated, the primary basis for generic competition is price. Typically, generics are at least 25% less expensive than their brand name counterpart when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings to all drug purchasers.

[1] The FDA can grant final approval before patent expiration under the Hatch Waxman Amendments, as discussed below.

33. Since passage of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"), which amended the Federal Food, Drug, and Cosmetic Act ("FDCA"), every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents when filling prescriptions for the brand (unless the prescribing physician has specifically directed otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic equivalent hits the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the market within the first six months. This results in a loss of revenue for the brand drug company, but dramatic savings for the American public. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85%. As a result, competition from generic drugs is viewed by brand name drug companies, such as Pfizer, as a grave threat to their bottom lines.

34. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

35. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as Pfizer, are well aware of generics' rapid erosion of their brand sales.

Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to illegal means.

1. The first AB-rated generic is priced below the brand

36. Experience and economic research show that the first generic manufacturer to launch sets its prices below the prices of its branded counterpart. Every state either requires or permits a prescription written for the brand drug to be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the branded form of the molecule. Consequently, there is a reduction in average price paid for a prescription for the molecule.

37. Pursuant to the Hatch-Waxman Amendments, the first generic manufacturer to file an abbreviated new drug application ("ANDA") containing a Paragraph IV certification (discussed below) is eligible to receive 180 days of market exclusivity ("exclusivity period"). This means that other generic manufacturers filing ANDAs will not be approved by FDA to launch their own generic products for at least six months after the first generic – known as the "first filer" – launches its product.

38. During the exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market. As recognized by the Supreme Court, it is often the case that most of a first filer's profits with respect to an ANDA product are earned during the exclusivity period.[2]

39. When the only versions of a drug on the market are the brand and the first filer's product, the first filer typically prices its product below the brand product, but not as low as if it were facing competition from other generics. Since in these circumstances the first filer's

[2] *See Federal Trade Comm'n v. Actavis*, 133 S.Ct. 2223, 2229 (2013).

product may compete only with the brand, and because the brand company rarely drops the brand price to match the first filer, the first filer does not face the kind of price competition it will when additional generic products are available.

2. Later generics drive prices down further

40. When multiple generic competitors enter the market, competition accelerates and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.

41. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic launch results in a near term retail price reduction of at least 10%, but that with two generic entrants near term retail price reduction is about 50%.

42. Soon after generic competition begins, the vast majority of the sales formerly enjoyed by the brand shift to generic sellers. In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry. Although generic drugs are chemically identical to their brand counterparts, they are typically sold at substantial discounts from the brand price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 billion to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.

B. The regulatory structure for approval of new drugs.

43. Under the FDCA, drug companies who wish to sell a new drug product must file a New Drug Application ("NDA") with the FDA. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

44. The FDA may not approve an NDA if the data and test results provided fail to show that the drug is safe or if there is a lack of substantial evidence that the drug will be effective to treat the conditions suggested in the proposed labeling. The FDA approves new drugs based on their ability to satisfy the minimum regulatory requirements; namely, show that they are safe and effective to treat a particular indication. New drug applicants are not required to, and usually do not try to, show that their new drug product is better than other similar, already approved, products.

C. Patent protection for brand drugs.

1. Patent portfolios for blockbuster drugs.

45. There is a predictable pattern to the way brand drug companies develop their patent portfolios for blockbuster drugs. The first group of patents in the brand drug company's portfolio for the drug may reflect a genuine technological breakthrough that may later contribute to the success of the drug; these initial patents usually cover the active compound in a prescription drug or a particular pharmaceutical composition and may be correspondingly robust.

46. After filing applications for the original patents, the company continues its research and development efforts in the hopes of developing a drug product that could, eventually, be approved by the FDA. As the company's research matures, the patent filings continue, often for narrow modifications relating to specific formulations, methods of using the drug, or processes for creating the drug product disclosed in the original patent filings. But the original patent filings are now in the "prior art" and thus limit the scope of follow on patents that can be obtained. New patents can be obtained for features of the drug only if the brand drug company can show that the new features are non-obvious distinctions over the growing body of prior art, which includes patents and printed publications, among other things. And often methods of using earlier inventions are disclosed by earlier compound or composition patents.

Over time, as the number of patent filings for the drug grows, so does the volume of prior art beyond which the brand drug company must show non-obvious distinctions.

47. Patents present, at minimum, obstacles for would-be generic competitors to design around. Some patents broadly cover a drug's active ingredient and – if valid and enforceable – may prove impossible to design around while meeting the FDA's criteria for equivalent generics. While generic versions of the brand product may be able to obtain FDA approval and enter the market before all patents expire, once all the valid patents covering its blockbuster drug have expired, the brand drug company has no lawful means of preventing competitors from entering the market.

48. Therefore, a typical patent portfolio for a brand drug has its most significant patents issuing first; over time, the later- issued patents generally become increasingly narrow and more difficult to obtain. Even if the narrower coverage is obtained, these later-issuing patents are more vulnerable to attack as invalid for covering subject matter that is old or obvious, and the narrower coverage is more easily designed around by would-be generics, thus preventing the brand from satisfying its burden of proving patent infringement to keep generics out of the market.

2. Types of patents and patent applications.

49. If a drug company desires a United States patent, then it must file an initial patent application with the PTO. Patents may be granted by the PTO anywhere along the development lifeline of a drug and a patent portfolio can encompass a wide range of claims.

a. Continuing patent application.

50. Often a drug company will come up with additional inventions that are related to the material in an initial patent application. However, generally, each patent should cover only one invention or kind of invention. Thus, for these additional inventions, the applicant may file a

continuing patent application. A continuing patent application is a patent application that follows and claims the "priority date" of an earlier-filed patent application (often referred to as the "parent application").

51. The "priority date" is critical in the world of patents; being able to claim the priority date of an earlier-filed patent application can be invaluable to a patent applicant/holder. The priority date, sometimes called the "effective filing date," is the date used to establish the novelty and/or obviousness of a particular invention relative to other art. Applicants often file continuing patent applications to claim additional inventions related to an earlier patent application (*i.e.*, the parent application) and receive the benefit of the priority date of the parent application.

52. There are three different types of continuing patent application: (1) continuation, (2) divisional, and (3) continuation-in-part.

53. A continuation is a continuing application filed by an applicant who wants to pursue additional claims to an invention disclosed in the parent application. The continuation uses the same specification (*i.e.*, written description of the invention) as the parent application, claims the priority date of the parent, and generally names at least one of the same inventors as in the parent.

54. A divisional is a continuing application filed by an applicant when the parent application contains more than one distinct invention. If multiple inventions are disclosed in a single application, the applicant may pursue claims to one of the inventions in the parent application, and pursue the other inventions in one or more subsequent divisional applications. A divisional application uses the same specification as the parent application and claims the priority date of the parent, but has a different set of claims. Importantly, a divisional may claim

only subject matter disclosed in the parent application. While a divisional application may depart from the phraseology used in the parent application, there may be no departure in substance or variation in the disclosure that would amount to "new matter." As discussed below, divisional applications are often (but not always) pursued in response to a PTO "restriction requirement."[3]

55. A continuation-in-part application (or "CIP application"), is an application to which the applicant has provided substantially the same specification as the parent application, but *has disclosed additional subject matter that was not included in the parent*. For a CIP application, claims to subject matter that were also disclosed in the parent are entitled to the parent's priority date, while claims to the additional subject matter are entitled only to the filing date of the CIP application. CIP applications are generally used to claim enhancements that were developed after the parent patent application was filed.

56. The key difference between a divisional application and a CIP application is whether the application claims something new.

b. Restriction requirements.

57. If, after reviewing a patent application, the PTO believes that one application claims two or more independent and distinct inventions, the PTO may require that the application be restricted to only one invention (*i.e.*, issue a restriction requirement). Restriction is the practice of requiring an applicant to choose a single invention for examination when two or more independent inventions and/or two or more distinct inventions are claimed in an application.

[3] A divisional application that is not filed as a result of a restriction requirement made by the patent examiner is sometimes referred to as a "voluntary divisional." A voluntary divisional differs from a divisional filed in response to a restriction requirement because, *inter alia*, a voluntary divisional is not entitled to the same safe harbor protection from claims of obviousness-type double patenting (the § 121 safe harbor discussed *infra* at ¶ 53).

58. To respond to a restriction requirement, an applicant must decide which invention to pursue in the current application and whether to pursue the other inventions in new applications. If an applicant decides to file separate applications for the other inventions, the applicant must decide what type of application to file: divisional, continuation, or CIP. Depending on the choice, there are different advantages and consequences.

59. As noted above, a divisional application literally claims some of the exact same subject matter that was "restricted out" by the applicant's decision to pursue other subject matter in the original application. The divisional application claims the benefit of the parent patent application. As a result, because the divisional application states no new matter, the priority date of filing the predecessor application is the priority date of the claimed invention. The divisional application should set forth at least the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application.

60. One advantage to choosing to file a divisional application in response to a restriction requirement is that divisional applications filed in response to a PTO restriction requirement ordinarily cannot be rejected as obvious in light of an earlier patent application by the same applicant (called an "obviousness-type double patenting rejection"). An applicant cannot obtain additional patent protection based on claims in a later patent unless those claims are "patentably distinct" from claims in the applicant's earlier patent(s).[4] A later patent claim is not "patentably distinct" from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.[5] As an example, a claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing an identical use.

[4] *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001).

[5] *Id.* (citing *In re Longi*, 759 F.2d 887, 896 (Fed. Cir. 1985)).

61. Congress created an exception for divisional applications that are filed in response to a restriction requirement in 35 U.S.C.§ 121:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a *divisional* application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. A patent issuing on *an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement*, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the *divisional* application is filed before the issuance of the patent on the other application. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention. (emphasis added).

62. An application is not entitled to this "safe harbor" provision unless the patent examiner "require[s] the application to be restricted to one of the inventions" (*i.e.*, unless the application is in response to a restriction requirement by the patent examiner).

63. The party seeking to invoke the protection of this safe harbor bears the burden of showing that § 121 applies.

64. Thus, in terms of choosing how to respond to a restriction requirement, each type of continuing patent application has its own advantage and patent law requires the patent applicant to carefully consider which continuing patent application represents the best strategic choice. Filing a CIP application may allow the applicant to put his arms around (*i.e.*, obtain patent protection for) more material, but it leaves the applicant open to potential obviousness-type double patenting rejections based on the original application. In contrast, filing a divisional application restricts the applicant to only the matter identified in the original application, but may

eliminate the threat of an obviousness-type double patenting rejection based on an earlier patent issued to the patentee.

c. Original versus reissued patents.

65. A reissue application may be filed pursuant to 35 U.S.C. § 251 after the grant of an original patent to correct "errors" of inadvertence, accident, or mistake in the original patent.[6] A strategic choice made during prosecution of the original patent is not an "error" that can be corrected under § 251.[7]

66. Reissuance is based on fundamental principles of equity and fairness, but it is "not without limits" and "not every event or circumstance that might be labeled 'error' is correctable by reissue."[8] Section 251 was neither enacted "as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute *de novo* his original application."[9]

67. Once a reissue application is filed, the original patent must be surrendered.

68. Section 251(a) provides:

> *Whenever any patent is, through error, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent,* the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue. (emphasis added).

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[6] *In re Serenkin*, 479 F.3d 1359, 1365 (Fed. Cir. 2007); *In re Mead*, 581 F.2d 251, 256-57 (C.C.P.A. 1978); *see also In re Weiler*, 790 F.2d 1576, 1583 n.4 (Fed. Cir. 1986).

[7] *In re Serenkin*, 479 F.3d at 1365; *In re Mead*, 581 F.2d at 256-57; *see also In re Weiler*, 790 F.2d at 1583 n.4.

[8] *In re Serenkin*, 479 F.3d at 1362 (citing *In re Weiler*, 790 F.2d 1579).

[9] *Id.*

69. An application for reissue must satisfy the same procedural and substantive patentability requirements as an original patent application.

70. As reflected in the language of section 251, the permissible bases for filing a reissue application are: (a) the claims are too narrow or too broad; (b) the disclosure contains inaccuracies; (c) applicant failed to or incorrectly claimed foreign priority; and (d) applicant failed to make reference to or incorrectly made reference to prior co-pending applications.

3. Brand companies list patents (original or reissued) covering brand drugs in the Orange Book.

71. To notify other drug manufacturers, a manufacturer of a new drug product must tell the FDA about patents that it believes cover its drug products. The FDA publishes a list of those patents in the publicly available "Orange Book." Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. Once patents are listed in the Orange Book, potential generic competitors are on notice regarding the patents that are claimed to relate to the brand name drug.

72. The brand name drug manufacturer can list its patents in the Orange Book by filing a Form 3542 with the FDA. Under the FDA rules, the branded manufacturer is only permitted to list patents that are *reasonably enforceable*. Form 3542 expressly asks the applicant whether the drug presents a "No Relevant Patent" situation (*i.e.*, a situation where there are no patents that could be *reasonably asserted* in an infringement lawsuit). Form 3542 likewise requires the signatory to affirm, under penalty of perjury, that all the patent information submitted to the FDA on each patent that claims the drug substance, drug product, or method of use that is the subject of the approved NDA or supplement is complete and accurate.

73. The FDA relies completely on the manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the

manufacturer's representations. The FDA performs only a ministerial act in listing the patents identified by the manufacturer in the Orange Book.

D. The regulatory approval process for generic drugs.

1. The Hatch-Waxman Amendments sought to expedite introduction of generic drugs.

74. In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments were designed to speed the introduction of low-cost generic drugs to market by permitting generic manufacturers to file Abbreviated New Drug Applications (ANDAs) that rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, requiring only a showing that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. The premise – codified by Congress and implemented by the FDA for the past thirty years – is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, and are absorbed into the blood stream at a similar rate over a similar period of time are expected to be equally safe and effective.

75. At the same time, the Hatch-Waxman Amendments also sought to protect pharmaceutical companies' incentives to create new and innovative products, by, among other things, permitting a brand company to file a *legitimate* patent infringement lawsuit against a generic before the generic actually brought its product to market.

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

generic drugs accounting for 18.6% of prescriptions. By 2013, total prescription drug revenue had soared to over $329 billion, with generic drugs accounting for 84% of prescriptions.

2. Hatch-Waxman encourages generics to challenge questionable patents.

77. The Hatch-Waxman Amendments also created a mechanism to potentially resolve patent disputes between brand and generic manufacturers before generic products launched, although the Amendments do not require such disputes to be resolved before generic launch.

78. Once one or more brand manufacturer patents are listed in the Orange Book, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any of those patents (or that the patents are invalid or unenforceable) to obtain FDA approval of an ANDA. A generic manufacturer can make one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA;

ii. that the patent for the brand name drug has expired;

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

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

79. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has standing to sue the ANDA applicant for patent infringement, even though the generic had not launched. If the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months (commonly called the "30-month stay"), or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA cannot authorize the

generic manufacturer to go to market with its product. But the FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay or other regulatory exclusivity.

80. The brand manufacturer may file patent infringement claims more than 45 days after receiving the Paragraph IV certification, but a suit filed after the 45-day period would not trigger the automatic stay of approval of the generic's ANDA. And for patents listed in the Orange Book after an ANDA is filed, no 30-month stay is available.

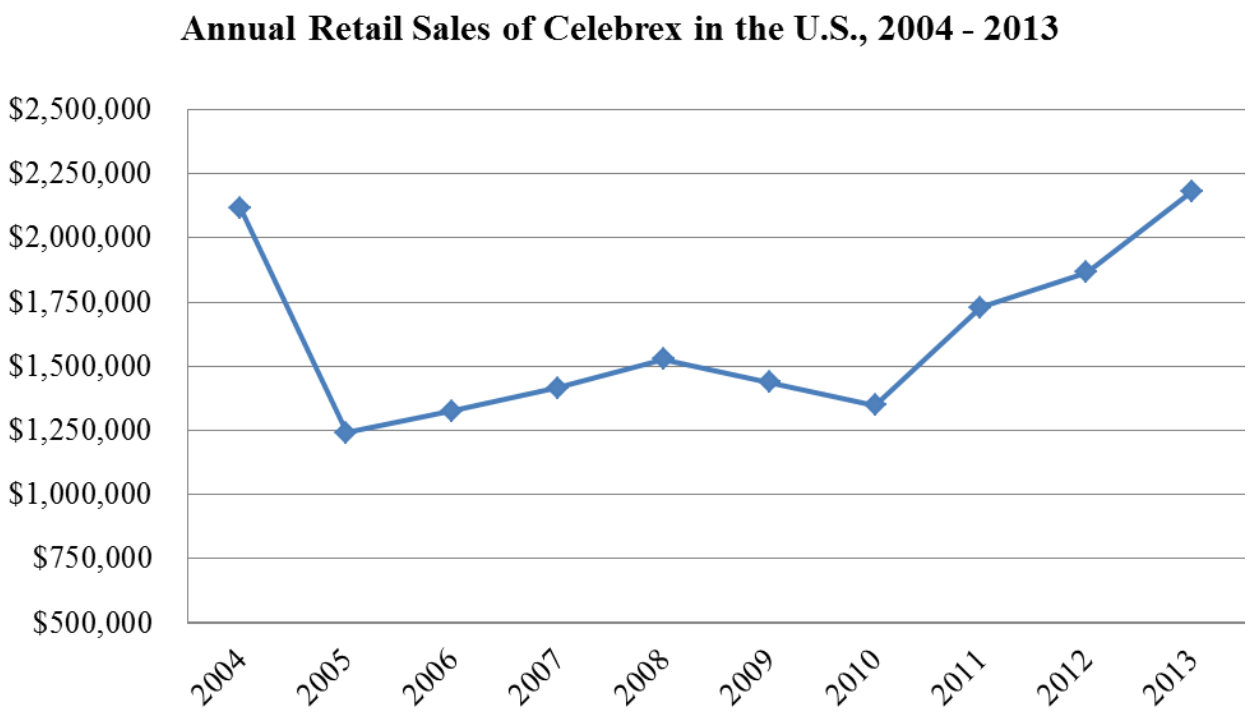
V. FACTUAL ALLEGATIONS

A. The FDA approves Pfizer's Celebrex.

81. Pfizer manufactures and sells the prescription drug celecoxib under the brand name Celebrex, a non-steroidal anti-inflammatory drug ("NSAID") approved to treat osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, acute pain, and primary dysmenorrhea. Celebrex is one of the most widely prescribed drugs in the world. Last year, U.S. sales of Celebrex topped $2 billion.

Year	Annual Retail Sales[10]
2004	$ 2,114,734
2005	$ 1,241,574
2006	$ 1,326,177
2007	$ 1,416,084
2008	$ 1,526,818
2009	$ 1,437,539
2010	$ 1,349,833
2011	$ 1,728,618
2012	$ 1,866,967
2013	$ 2,183,246

[10] In thousands.



82. Pfizer first applied for approval to market Celebrex on June 29, 1998. Pfizer submitted NDA 20-998 seeking FDA approval to manufacture, market, and sell celecoxib capsules in 100 mg and 200 mg strengths. The FDA approved 100 mg and 200 mg strengths of Celebrex for the relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis in adults on December 31, 1998.

83. The FDA later approved Pfizer's supplemental NDAs to manufacture, market, and sell Celebrex for the management of acute pain in adults and the treatment of primary dysmenorrhea (on October 10, 2001) and for the relief of signs and symptoms of ankylosing spondylitis (on July 29, 2005). The FDA also approved 400 mg capsules (on August 29, 2002) and 50 mg capsules (on December 15, 2006).

84. Pfizer submitted an additional NDA for Celebrex, NDA 21-156, on June 24, 1999, seeking approval to market Celebrex for the reduction of the number of adenomatous colorectal polyps in familial adenomatous polyposis ("FAP") patients. The FDA approved that

indication on December 23, 1999. On or about February 2011, the FDA requested that Pfizer voluntarily withdraw the FAP indication for Celebrex and Pfizer complied. The FDA withdrew its approval of that indication effective June 8, 2012.

B. Pfizer lists three patents in the Orange Book as covering Celebrex.

85. Shortly after approval, Pfizer listed three patents in the Orange Book as covering Celebrex – the ’823, ’165, and ’068 patents. These three patents encompass a broad genus of non-steroidal anti-inflammatory compounds, formulations using those compounds, and (ostensibly) methods of using those formulations. The claims of these patents include celecoxib – the active compound in Celebrex – or formulations and (ostensibly) methods of using celecoxib.

86. The ’823 patent covers a number of compounds, including celecoxib.

87. The ’165 patent covers pharmaceutical formulations using celecoxib.

88. Both the ’823 compound and ’165 composition patents expired on November 30, 2013. The FDA gave Pfizer six more months of exclusivity because Pfizer had tested Celebrex in children (so-called “pediatric exclusivity”). The compound and composition patents (with pediatric exclusivity added) thus shielded Pfizer from competition with Celebrex until May 30, 2014.

89. Pfizer later obtained a third patent (the ’068 patent) that ostensibly covered methods of using the already patented celecoxib compounds and formulations to treat inflammation and inflammation disorders.

90. The ’068 method-of-use patent stemmed from a CIP application chain. Because the ’068 patent stemmed from a CIP application chain that asserted new matter, when the ’068 patent eventually issued from that chain it was scheduled to expire about a year and a half later

than the ’823 and ’165 celecoxib patents (*i.e.*, it was scheduled to expire on June 2, 2015, with pediatric exclusivity six months later, on December 2, 2015).

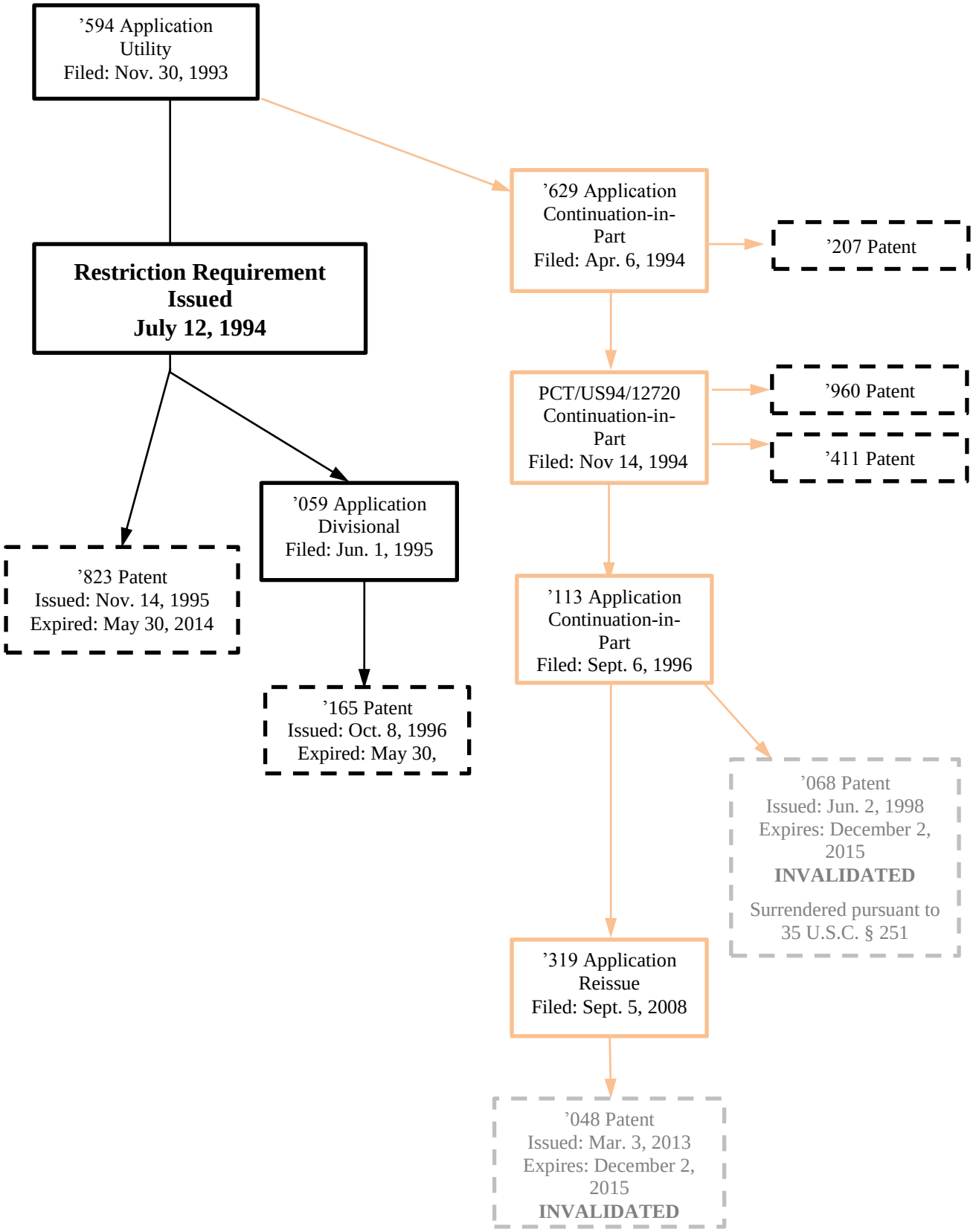
91. In 2008, the Federal Circuit ruled that the ’068 patent was invalid because a method of using an already-patented compound cannot extend patent life by claiming methods of using the compound that were disclosed in the original compound patent (*i.e.*, obviousness-type double patenting).

92. After the Federal Circuit ruled the ’068 patent to be invalid, Pfizer sought, eventually obtained, and listed a fourth patent – the ’048 reissue patent, a reissue of the invalid ’068 patent. It is the ’048 reissue patent that Pfizer used for its sham litigation.

93. The patents, with issuance and expiry dates (“PED Expiry” refers to the expiration of pediatric exclusivity) are set forth below.

Patent No.	**Issue Date**	**Patent Expiry**	**PED Expiry**
5,466,823	Nov. 14, 1995	Nov. 30, 2013	May 30, 2014
5,563,165	Oct. 9, 1996	Nov. 30, 2013	May 30, 2014
5,760,068	June 2, 1998	June 2, 2015	Dec. 2, 2015
RE44,048	Mar. 5, 2013	June 2, 2015	Dec. 2, 2015

94. The patent application tree showing the applications, patent issuances and where restriction requirement were (and were not) imposed appears below.


'594 Application
Utility
Filed: Nov. 30, 1993
Restriction Requirement
Issued
July 12, 1994
'823 Patent
Issued: Nov. 14, 1995
Expired: May 30, 2014
'059 Application
Divisional
Filed: Jun. 1, 1995
'165 Patent
Issued: Oct. 8, 1996
Expired: May 30,
'629 Application
Continuation-in-
Part
Filed: Apr. 6, 1994
'207 Patent
PCT/US94/12720
Continuation-in-
Part
Filed: Nov 14, 1994
'960 Patent
'411 Patent
'113 Application
Continuation-in-
Part
Filed: Sept. 6, 1996
'068 Patent
Issued: Jun. 2, 1998
Expires: December 2,
2015
INVALIDATED
Surrendered pursuant to
35 U.S.C. § 251
'319 Application
Reissue
Filed: Sept. 5, 2008
'048 Patent
Issued: Mar. 3, 2013
Expires: December 2,
2015
INVALIDATED

1. The 1993-94 patent prosecution efforts led to two later CIP applications adding new matter to the original application.

95. All of the Celebrex patents (the ’823, ’165, and ’068 patents and the ’048 reissue patent) stem from the same parent U.S. Patent Application No. 08/160,594 (“the ’594 application”).

96. On November 30, 1993, Pfizer filed the ’594 application, claiming compounds, pharmaceutical formulations, and methods of use.

97. Four months later, on April 6, 1994, Pfizer filed U.S. Patent Application No. 08/223,629 (the “’629 application”) as a CIP to the ’594 application. The ’629 application was the first in a series of CIP applications (“the ’629 application chain”).

98. Pfizer filed the ’629 application on its own initiative, *i.e.*, it did not file the application in response to any action by the PTO. In doing so, Pfizer chose to file the application as a CIP of the ’594 application, stating, “[t]his amendment is filed along with a CIP Application (filed April 6, 1994) of US Patent Application Serial No. 08/160,594 (filed November 30, 1993).” Pfizer asked the PTO to amend the ’629 patent application specification to state: “This is a CIP application of application Serial No. 08/160,594 filed in November 30, 1993.” One of Pfizer’s lawyers who prosecuted the Celebrex patent applications, Philip Polster II (“Polster”), testified under oath during the *Teva I* litigation (discussed below) that the ’629 application was a CIP application.

99. The ’629 CIP application added new subject matter not found in the ’594 application. An August 1994 preliminary amendment amended ten claims and added four new claims. However, because the ’629 CIP application claimed new matter, it could not have been designated as a divisional application (*i.e.*, Pfizer made the strategic choice to add new matter and give up the benefit of the earlier ’594 patent application’s priority date). Pfizer’s attorney,

Polster, testified under oath that new matter could not be added to a divisional application. Even if the '629 application had not included new matter and had been designated as a divisional application, it would have been a voluntary divisional, *i.e.*, it was not filed as a result of a restriction requirement.

100. The '629 application ultimately issued as U.S. Patent No. 5,521,207 (the "'207 patent"), with claims directed to a compound known as deracoxib. The deracoxib compound was part of the new matter that was added to the '629 application. The '207 patent covers an approved veterinary product called Deramaxx chewable tablets.

2. Prosecution of the International PCT application.

101. On November 14, 1994, Pfizer filed International Application No. PCT/US94/12720 ("the PCT application") as a CIP of the '629 application, claiming priority to the '629 application (which itself was a CIP of the '594 application). "PCT" stands for Patent Cooperation Treaty. The PCT allows individuals or corporations in signatory countries to file a PCT patent application (sometimes also referred to as an "international patent application"). A PCT application may, as Pfizer's application did here, claim priority to an earlier United States patent application. A PCT application speeds up the process of applying for patents in multiple countries at once but does not directly lead to a patent in any country. For a PCT application to lead to a United States patent it must enter the so-called "national stage" whereby a patent application is filed pursuant to United States patent procedures and claiming benefit to the PCT application.

102. Pfizer also added new matter to the PCT application. Because it added new matter, the PCT application could not have been filed as a divisional application (*i.e.*, Pfizer again made the strategic choice to add new matter and give up the benefit of the earlier patent application's priority date). The PCT application was not filed as the result of a restriction

requirement. When the PCT application was filed in November 1994, the applicants were challenging a restriction requirement that, in the meantime, had issued from the PTO in the '594 application. The PTO Examiner did not reject the applicants' arguments and make the restriction requirement "final" until January 12, 1995. This was months after the filing of the PCT application.

103. Pfizer ultimately obtained two other patents (not covering Celebrex) that claim priority to the PCT application and claim subject matter that was added to the PCT CIP application.

3. The PCT application enters the U.S. national stage as the '113 application, leading to the '068 method-of-use patent.

104. The PCT application entered the U.S. national stage as U.S. Patent Application No. 08/648,113 ("the '113 application") under 35 U.S.C. § 371(a) and was given a filing date of September 6, 1996. But because the filing date of the international stage application is also the filing date for the national stage application, the filing date of the '113 application was November 14, 1994.

105. Pfizer filed the '113 application as a CIP of the '629 application (itself a CIP of the '594 application). By definition, the CIP application contained new matter (*i.e.*, Pfizer again made the strategic choice to add new matter and give up the benefit of the earlier '594 patent application's priority date). Specifically, Pfizer added new subject matter not included in the '594 or the '629 application. Among other things, it added claim 22, which was directed towards a "method for the prevention of colorectal cancer."

106. The '113 application was not filed as the result of any restriction requirement (whether on the '594 application, the '629 application, or the PCT application) and was not intended to be a divisional application. Because the '113 application added new matter, it could

not have been designated as a divisional application. Even if the '113 application had not included new matter and had been designated a divisional application, it would have been a voluntary divisional (*i.e.*, it was not filed as a result of a restriction requirement.

107. In addition, the '113 application was not a direct descendent of the '594 application. Instead, the '113 application descended from a CIP application (*i.e.*, the '629 application) from the '594 application.

108. In fact, the Federal Circuit has already found "the '068 patent, though it derived from the application that led to the '823 patent, was filed as a CIP and not a divisional application."

109. On June 2, 1998 the '113 application ultimately issued as the '068 patent. Although stemming from an application tree that spawned more specific patents, the '068 patent had broad independent claims directed to methods of treating inflammation or an inflammation-associated disorder with celecoxib. Claims 1, 6, 9, and 11 all started with, "a method of treating inflammation or an inflammation-associated disorder in a subject . . ." using celecoxib.

110. Because the '068 patent was granted on an international application filed before June 8, 1995 (that itself had entered the national stage under 35 U.S.C. § 371 before, on or after June 8, 1995), the term of the '068 patent was the greater of seventeen years from the date of grant or twenty years from the international filing date or any earlier filing date relied upon under 35 U.S.C. 120, 121 or 365(c). For the '068 patent, the later date was seventeen years after issuance, or June 2, 2015 (prior to a six-month extension for pediatric testing).

111. Likely because the '068 patent issued from a series of CIP applications that added new matter from the original '594 application (*e.g.*, veterinary products, colorectal cancer, etc.), a terminal disclaimer that would have limited the term of the '068 patent to the length of two,

prior issued celecoxib patents from the same patent tree was not imposed. As a result, the '068 patent – ostensibly claiming methods of using celecoxib to treat inflammation related disorders – was set to expire about a year and a half later than two other, earlier issued celecoxib patents (the '823 and '165 patents.

4. Prosecution of the '059 application, leading to the formulation patent.

112. Back on July 12, 1994, several months after Pfizer filed the '629 CIP application, the PTO had issued a restriction requirement in the '594 application, requiring Pfizer to decide whether it would pursue compounds, compositions (*i.e.*, formulations), or methods of use. The PTO stated:

> Restriction to one of the following inventions is required under 35 U.S.C. 121:
>
> I. Claims 1-20, compounds.
>
> II. Claims 21-26, compositions.
>
> III. Claims 27-37, methods of use.

113. It is important to note that the PTO issued the restriction requirement for the '594 application *more than three months after* Pfizer had filed the '629 CIP application. As a result, Pfizer could not have filed the '629 CIP application in response to a restriction requirement. Pfizer made a strategic decision to pursue the subject matter presented in the '629 application – including new matter – in a separate CIP application and later applications that claimed priority to the '629 CIP application before any restriction requirement existed.

114. On September 14, 1994, Pfizer filed an amendment and response to the restriction and election requirements regarding the '594 application. Pfizer challenged the PTO's restriction requirement, arguing in a traverse to the restriction and election requirement that the composition claims and the method-of-use claims "are directed to a single inventive entity and

restriction among these claims would be improper." After the examiner considered and issued a final rejection to Pfizer's traverse to the restriction requirement on January 12, 1995, Pfizer then elected in its February 6, 1995 response to the PTO office action to select compound claims for prosecution in the '594 application.

115. The '594 application resulted in the issuance of the '823 patent, covering various compounds (including celecoxib).

116. Because the '823 patent was granted on an application filed before June 8, 1995, the term of the '823 patent was the greater of seventeen years from the date of grant or twenty years from the filing date or any earlier filing date relied upon under 35 U.S.C. §§ 120, 121 or § 365(c). For the '823 patent, the later date was November 30, 2013 (before a six-month extension for pediatric testing that expired on May 30, 2014).

117. On June 1, 1995, Pfizer filed U.S. Application No. 08/457059 ("the '059 application), claiming the pharmaceutical formulations restricted from the '594 application.

118. Pfizer filed the '059 application as a divisional application of the '594 application. A June 1, 1995 preliminary amendment stated, "this is a divisional of U.S. application 08/160,594, filed November 30, 1993."

119. In October, 1996 the '059 application issued as the '165 formulation patent. The '165 formulation patent issued a year and a half before the '068 method-of-use patent.

120. Claim 5 of the '165 patent claims compositions (or formulations) selected from compounds including celecoxib. The '165 patent specification discloses methods of using celecoxib: "Compounds of Formula I would be useful for the treatment of inflammation in a subject, and for treatment of other inflammation-associated disorders…"; "The compounds are

useful as anti-inflammatory agents, such as for the treatment of arthritis…"; "compounds of Formula I would be useful to treat arthritis…."

121. Because the '165 patent was granted on a divisional application filed before June 8, 1995, the term of the '165 patent was the greater of seventeen years from the date of grant or twenty years from the filing date or any earlier filing date relied upon under 35 U.S.C. §§ 120, 121 or 365(c). The '165 patent claimed priority to the '594 application. For the '165 patent, the later date was November 30, 2013 (before a six-month extension for pediatric testing that expired on May 30, 2014.

122. For both the '823 and the '165 patents, the expiration date winds up being 20 years from the filing of the original utility '594 application. The '823 and the '165 patents thus both expire on the same day.

C. The Federal Circuit invalidates the '068 method-of-use patent and confirms that patent protection for Celebrex ends on May 30, 2014.

123. On or about November 13, 2003, Teva submitted the first celecoxib ANDA, ANDA No. 076898, to the FDA, seeking approval to manufacture, market, and sell a generic version of Celebrex in 100 mg, 200 mg, and 400 mg strengths. Teva's ANDA contained Paragraph IV certifications with respect to all three Celebrex patents (the '823, '165, and '068 patents).

124. On or about January 6, 2004, Teva notified Pfizer that Teva had filed ANDA No. 076898 containing Paragraph IV certifications to the '823, '165 and '068 patents. The Teva notice letter asserted that the claims of the '823, '165 and '068 patents were invalid, unenforceable and/or not infringed.

125. On February 19, 2004, Pfizer filed suit against Teva pursuant to Hatch-Waxman in the United States District Court for the District of New Jersey, Case No. 2:04-cv-00754-GEB-

MCA, alleging that Teva's generic celecoxib product would infringe each of the three Celebrex patents ("*Teva I* litigation").

126. On March 20, 2007, following a bench trial, the United States District Court for the District of New Jersey ruled that each of the compound, formulations, and method-of-use patents were valid and infringed.[11] The court entered final judgment on April 10, 2007.

127. Teva subsequently appealed to the Federal Circuit. On March 7, 2008, the Federal Circuit affirmed the district court's finding that the '823 and '165 (the compound and composition) patents were valid and infringed by Teva's ANDA product. However, the Federal Circuit held that the '068 (method-of-use) patent was invalid, and that Pfizer was not entitled to patent protection beyond May 30, 2014, the expiration of exclusivities provided by the other patents.[12]

128. In its decision, the Federal Circuit determined that the method-of-use patent was invalid for "obviousness-type double patenting," meaning that the method-of-use claims in the '068 patent were not patentably distinct from the claims in Pfizer's '165 composition patent.

129. Federal law had long held that a claim to a method of using a composition is not patentably distinct if an earlier patent claimed the same composition and disclosed an identical use for it. The Federal Circuit noted that a statutory exception to this rule did not apply under the circumstances of the '068 patent.

130. Under the § 121 safe harbor, a patent stemming from a divisional application filed *in response to a PTO restriction requirement* will not be held to be obvious over art in the earlier, parent patent application. But the exception is limited to divisional applications filed in

[11] *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 482 F. Supp. 2d 390 (D.N.J. 2007) ("*Teva I* D.N.J.").

[12] *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008) ("*Teva II* Fed. Cir.").

response to a PTO restriction requirement and the exception does *not* apply to CIP applications or so-called voluntary divisional applications.[13]

131. Sound reasons support the clear distinction as CIP applications add additional matter and have later expiration dates, and the "new matter" is not entitled to the priority date of the predecessor application.

132. The court's invalidity decision thus turned on whether Pfizer submitted a divisional application in response to a PTO restriction requirement or a CIP application for the method-of-use patent. In the case of the '068 patent, that patent stemmed from a CIP application. The exception, therefore, did not apply. The '068 patent was declared invalid.

133. Pfizer's *en banc* request was denied.

D. Pfizer obtains the reissued method-of-use patent by fraud.

134. To avoid the consequences of the Federal Circuit's invalidity determination, that Celebrex would become subject to generic competition on May 30, 2014, Pfizer committed a series of fraudulent acts that caused the PTO to reissue a bogus patent (the '048 reissue patent) as part of Pfizer's plan to prevent generic competition.

135. Federal law has long held that failure to file a divisional application cannot be corrected by reissue. Similarly, an intentional act (such as filing a CIP application or, as Pfizer did here, a series of CIP applications) is not a mistake that can be corrected by reissue. Nevertheless, Pfizer applied for reissue to retroactively change the underlying CIP application to a divisional application. Although the PTO repeatedly took the position that the failure to file a divisional application was not correctable via reissue, Pfizer: (i) misrepresented to the PTO the

[13] *Pfizer II*, 518 F.3d at 1361-62 ("If the [safe harbor provision, 35 U.S.C. §121] had included CIPs, which by definition contain new matter, the section might be read as providing the earlier priority date even as to the new matter, contrary to the usual rule that new matter is not entitled to the priority date of the original application. There was no possible reason for protecting the new matter from double patenting rejections.") (citation omitted).

circumstances of its CIP applications; and (ii) misdirected the PTO to address other, unrelated, purported errors "in the patent – errors" of the type that, setting aside the fatal CIP versus divisional distinction and the lack of an earlier restriction requirement, could be corrected through reissue. In reliance on Pfizer's material misrepresentations, the PTO granted reissuance.

1. Pfizer falsely stated to the PTO that the '113 application was mistakenly filed as a CIP application.

136. Throughout prosecution of the reissue application, Pfizer repeatedly stated that the '113 application had originally been filed in response to a restriction requirement. These material representations to the PTO were intentionally deceptive.

137. The invalid '068 method-of-use patent issued as a result of the following patent application chain: (i) the '594 application; the '629 application (filed as a CIP application of the '594 application); (ii) the PCT application (filed as a CIP and claiming priority to the '629 application); and (iii) the '113 application (the national stage entry for the PCT application and a CIP of the '629 application). *See* Patent Application Tree, p. 25.

138. Pfizer filed the '594 application on November 30, 1993. Pfizer filed the '629 application on April 6, 1994 as a CIP of the '594 application. Pfizer filed the '629 application as a CIP application, and did not intend for it to be a divisional application. Indeed, because the '629 application included new matter, it could not have been a divisional application.

139. At the time Pfizer filed the '629 application, the PTO had *not* issued any restriction requirement during the prosecution of the '594 application. It was only later, three months *after* Pfizer filed the '629 application, that the PTO initially required Pfizer to restrict the subject matter pursued in the '594 application, and that restriction requirement was made final only after the examiner rejected Pfizer's traverse in January 1995.

140. On September 5, 2008, soon after the Federal Circuit invalidated the '068 patent, Pfizer filed Reissue Application Serial No. 12/205,319 ("the reissue application"). Pfizer asked the PTO to reissue the '068 patent to "correct" the "error" that the '113 application had been filed as a CIP application rather than a divisional one.

141. In the September 5, 2008 Preliminary Amendment filed with the reissue application, Scott A. Williams ("Williams"), in his capacity as attorney for Pfizer, stated that Pfizer was amending the claims and specification "so that the '113 Application from which the '068 Patent issued qualifies as a divisional application in compliance with the recent Federal Circuit opinion." Williams stated:

> During the examination of the United States Application Serial No. 08/160,594 (the "'594 application"), filed on November 30, 1993, which issued as United States Patent No. 5,466,823 (the "'823 Patent"), the Examiner issued a three-way restriction requirement described further below among various compounds, pharmaceutical compositions and methods of use.

142. He further stated: "At least one error upon which reissue is based is described as follows:

> The United States Court of Appeals for the Federal Circuit in a March 7, 2008 opinion, *Pfizer Inc. v. Teva Pharmaceuticals USA Inc.*, 86 U.S.P.Q.2d 1001 (Fed. Cir. 2008) [*Teva I* Fed. Cir.], determined that the application from which U.S. Patent No. 5,760,068 issued failed to qualify as a divisional application entitled to protection under 35 U.S.C. § 121. As a result, the Federal Circuit further held that claims 1-4 and 11-17 of the patent were invalid for obviousness-type double patenting based on the issued claims of a related family member, U.S. Patent No. 5,563,165. Applicant therefore is requesting reissue of U.S. Patent No. 5,760,068 to correct those errors that prevented the application from which the patent issued from complying with the definition of a divisional application pursuant to M.P.E.P. 201.06 entitled to protection under 35 U.S.C. § 121 as recently enunciated by the Federal Circuit.

143. Williams deceptively quoted the following portion of the Federal Circuit decision concerning the restriction requirement:

> *Subsequent to the restriction requirement* but before the '594 application issued, Pfizer filed a series of continuation applications claiming priority to the '594 application and covering the non-elected subject matter which it had elected not to prosecute in the original '594 application. In particular, Pfizer filed a divisional application, which ultimately issued as the '165 patent, that included the restricted-out composition claims, and a continuation-in-part application ("CIP"), which ultimately issued as the '068 patent, that included the restricted-out method claims. (emphasis added)

144. The strategically quoted summary from the Federal Circuit's opinion is inaccurate, and Pfizer knew it. As described above, the restriction requirement issued for the '594 application came *after* Pfizer filed the '629 CIP application.

145. On December 3, 2009, the examiner issued a non-final rejection on the grounds of "obviousness-type double patenting" over the '165 patent. In the May 27, 2010 Reply to Office Action, Polster, in his capacity as attorney for Pfizer, stated, "Applicants request correction of an error in the specification of the original patent resulting in it being denominated a CIP instead of a divisional, and deletion of unnecessary portions of the specification and claims." Polster also stated:

> Further, to deny the protection under 35 U.S.C. § 121 to Applicants solely because the Federal Circuit held that Applicants did not file a proper divisional application, when Applicants are trying to correct that defect through the present reissue proceeding by conforming their application---which was timely filed---to the proper divisional application form precisely because of the Federal Circuit holding, results in a circular trap that belies the whole purpose of the reissue statute. Applicants acknowledge that the application that issued as the '068 Patent in 1998 does not comply with the definition of a divisional application entitled to protection under 35 U.S.C. § 121 as enunciated by the Federal Circuit ten years later in [*Teva I*]. The correction of that defective application to a proper divisional application form is exactly the 'error' that

> Applicants are appropriately attempting to correct through the reissue process.

146. Polster further stated, "The Applicants did timely file the '113 Application but failed to properly denominate it as a divisional application by satisfying the requirements set forth in the subsequent [*Teva I* Fed. Cir.] decision."

147. These statements were completely untrue. The '113 application was, in fact, "properly denominated" at the time it was filed as a CIP application because it contained new matter. There was no error in the specification of the original patent resulting in it being denominated a CIP instead of a divisional application; the specification of the '068 patent disclosed the correct claims of priority as strategically chosen and intended by Pfizer. And even if Pfizer could go back in time and change the '113 application to a divisional application, it would have been a voluntary divisional application because it was not filed in response to a restriction requirement and stemmed from a series of CIP applications, the first of which was filed months before a restriction requirement was imposed in the '594 application and thus would not have been entitled to the safe harbor provided by § 121.

148. Pfizer sought to mislead the PTO by suggesting it had simply made "errors" in the denomination of the '113 application. But Pfizer had deliberately filed the '113 application (and '629 and PCT applications) as a CIP. Its assertion that the '113 application was filed erroneously as a CIP rather than a divisional application was a misrepresentation made to the PTO with a specific intent to deceive. Pfizer's sole reason for the alleged "correction" of the so-called "error" was to remove the '165 patent as a "double-patenting" prior art reference – to undo an intentional act that was originally done to garner extended patent protection.

149. The '068 patent was purposefully filed as a continuation-in-part application, rather than as a continuation application or as a divisional application. At the time the '694 PCT,

and ’113 CIP applications were filed, Pfizer sought patent protection for new matter beyond what had been set out in the original ’594 application. Filing CIP applications was Pfizer’s attempt to capture this new matter. Thus, Pfizer obtained the fruits of the CIP process — additional United States and foreign patents resulting from the new matter that it could only add in a CIP and later expiry dates from later issued patents (under the pre-twenty year regime).

150. Pfizer’s belated effort to designate the ’048 reissue patent as stemming from a divisional of the ’594 application was done for the purpose of removing the ’165 patent as a “double-patenting” prior art reference, not because it was required to “correctly” describe the relationship between the two applications.

151. An “error” under Section 251 requires an error in the patent and an error in conduct. The preliminary amendment filed with Pfizer’s reissue application did not identify an error in the patent or an error in conduct with respect to the ’113 application. Pfizer’s purported correction of an error was “ultimately no more than a statement of a now-regretted choice, because [Pfizer] identif[ied] no cognizable false or deficient understanding of fact or law that underlay the choice. This is not ‘error’ as required by section 251.” These material misrepresentations to the PTO were made by Pfizer with specific intent to deceive the PTO regarding the original posture of the ’113 application and whether the application was protected under 35 U.S.C. § 121.

152. In response to the PTO’s September 22, 2010 rejection, Pfizer, through A. Dean Olson (“Olson”) in his capacity as attorney for Pfizer, requested continued examination in a Response Accompanying Request for Continued Examination (“RCE”) dated March 9, 2011, stating, “[t]he identification of this application as a divisional application rather than as a CIP application now is not only proper, but is *required to correctly describe the relationship between*

the two applications." (emphasis added). Pfizer knew at the time it made this statement that there was no restriction requirement during the prosecution of the '068 patent application chain. Pfizer also knew that none of the applications in the '068 patent application chain was a divisional application subject to the protection of 35 U.S.C. § 121 since none of these applications was filed in response to a restriction requirement; even if they could have been classified as divisionals, they would be voluntary divisionals outside the ambit of § 121's safe harbor.

153. In a December 29, 2011 Office Action, the patent examiner again issued a non-final rejection and stated: "[t]he reissue oath/declaration filed with this application is defective because the error which is relied upon to support the reissue application is not an error upon which a reissue can be based. *See* 37 CFR 1.175(a)(1) and MPEP § 1414." The examiner further maintained that the claims "were already found to be unpatentable by United States Court of Appeals for the Federal Circuit in a [sic] March 07, 2008."

154. In its June 6, 2012 Response, Olson, in his capacity as attorney for Pfizer, stated that "prior to the CAFC [Federal Circuit] decision, Applicants could not have reissued their patent based on what was later determined to be erroneous (the filing of a C-I-P) because the district court held there was no double-patenting." Not only did this statement perpetuate Pfizer's improper suggestions that the '113 application was initially filed in response to a restriction requirement, it also mischaracterized the district court's opinion in the *Teva I* D.N.J. litigation. The district court did not hold that there was no "double-patenting"; rather, it refused to consider Teva's double-patenting arguments because they were not timely raised.[14]

[14] *Teva I*, D.N.J., 482 F. Supp. 2d at 475-476.

155. Pfizer repeatedly misrepresented to the PTO during the reissue proceedings that it committed an "error" by filing a CIP instead of a divisional application during the prosecution of the '068 patent, and this "error" led to the invalidation of claims of the '068 patent by the Federal Circuit because a CIP does not fall within the "safe harbor" of 35 U.S.C. § 121.

156. These misrepresentations were intentionally deceptive because Pfizer omitted the fact that there was no restriction requirement during the prosecution of the '068 patent application chain. Thus, Pfizer could not have filed a divisional application that fell within the ambit of the "safe harbor" provision of 35 U.S.C. § 121.

157. During the prosecution of the '048 patent, Pfizer consistently and systematically concealed the fact that it could not have filed a divisional application that complied with the "safe harbor" provision of 35 U.S.C. § 121 in the '068 patent application chain.

158. Pfizer's misrepresentations to the PTO during the reissue proceedings were made to the PTO with the specific intent of deceiving the PTO.

159. Pfizer's misrepresentations to the PTO during the reissue proceedings were material to the PTO and directly resulted in the issuance of the '048 reissue patent. In other words, but for Pfizer's misrepresentation, the '048 reissue patent would not have issued.

160. Had the patent examiner reviewing the reissue application been told by Pfizer, as required under the duty of candor, that the application was not filed as a result of a restriction requirement, the examiner would not have removed the double-patenting rejection and would not have allowed the '048 reissue patent to issue.

2. Pfizer made further false misrepresentations and deliberately omitted facts during the reissue proceedings that the PTO relied upon in issuing the '048 reissue patent.

161. Pfizer, including the applicants for the '048 reissue patent, their attorneys, agents, and others substantively involved in the prosecution of the application for the '048 reissue

patent, engaged in a pattern of fraud during the prosecution of the application. Pfizer intentionally misrepresented the facts surrounding the prosecution history of related patents, including: (i) misrepresenting the true basis for the reissue request; and (ii) averring that claims in the ’068 patent previously asserted against Teva were indefinite.

a. Pfizer intentionally misrepresented the actual basis for the reissue application and the PTO relied upon Pfizer’s misrepresentation.

162. In the face of the PTO repeatedly rejecting Pfizer’s efforts to recharacterize the CIP application a divisional application, Pfizer took a desperate change of course. Pfizer fabricated errors of the type that were capable of being corrected through reissue proceedings. Pfizer then packaged those faux errors as though they had occurred in the context of a different application, one that included an earlier restriction requirement. In doing so, Pfizer selectively re-wrote patent prosecution history, functionally erasing two CIP applications that led to the ’113 CIP application. Pfizer did not, however, relinquish the patents it obtained from those “erased” CIP applications.

163. In its March 9, 2011 Response Accompanying RCE, Pfizer listed various errors in the claims of the ’068 patent that purportedly rendered the claims indefinite or otherwise improper. Specifically, Olson, in his capacity as attorney for Pfizer, stated that the ’068 patent, in claim 1, included “several substituents that make indefinite the meaning of the claim” which resulted in “an indefinite claim scope.” Olson also pointed to other alleged errors in Claims 2, 3, 7, 8, and 12. Olson then stated that, on the basis of any of those errors, Pfizer may properly request reissue of the ’068 patent.

164. Pfizer intended to mislead the examiner to believe that the identification of one correctable error would permit amendment of any aspect of the patent application (including the designation of the application as a divisional instead of as CIP).

165. Olson then stated that "the current Reissue Application is now correctly designated a divisional application of U.S. Patent Application Serial no. 08/160,594." This was false, and intended to mislead the examiner to believe that the application could now properly be designated as a divisional application.

166. Olson also stated "[t]he identification of this application as a divisional application rather than as a CIP application now is not only proper, but is required to correctly describe the relationship between the two applications." This was false, and intended to mislead the examiner to believe the relationship between the applications was a divisional application.

167. Olson further stated that because the '068 patent "claimed methods of use that were restricted from the claims of the parent application, [the '594 application], it is respectfully submitted that U.S. Patent No. 5,563,165 (which was also a divisional of [the '594 application]) should be removed as a reference by operation of 35 U.S.C. § 121." This was false and intended to mislead the examiner to believe that the '113 application was filed in response to a restriction requirement.

168. Pfizer first raised this purported indefiniteness problem and/or problems with Claims 1, 2, 3, 7, 8, and 12 in March 2011, two-and-a-half years after it applied for reissuance. Pfizer raised these purported problems only after the PTO had twice rejected its efforts to "correct" the '113 CIP application to a divisional application.

169. Pfizer did not raise any concerns about indefiniteness in the claims of the '068 patent during the *Teva I* litigation. In fact, in *Teva I*, Pfizer took the position that the asserted claims of the '068 patent were definite. There, Pfizer submitted an expert report from Dr. Jim McGinty in support of definiteness. Pfizer is judicially estopped from now asserting a contradictory position.

170. In *Teva I*, Pfizer asserted infringement of claims 1-4 and 11-17 of the ’068 patent against Teva. In doing so, pursuant to Rule 11 of the Federal Rules of Civil Procedure, Pfizer represented that the claims of the ’068 patent were valid and infringed.

171. Neither the Federal Circuit nor the district court presiding over the *Teva I* litigation identified any indefiniteness or any of the problems raised by Pfizer in its March 2011 submission with respect to claims 1, 2, 3, 7, 8, and 12 in their opinions addressing the ’068 patent. The Federal Circuit reviewed the asserted claims of the ’068 patent (1-4, 11-17) and found them to be not patentably distinct from the claims of the ’165 patent.

172. Pfizer’s sole basis for raising these purported errors on March 9, 2011 was to present purportedly correctable errors to the PTO to overcome the final rejection of the reissue application and to disguise its true motivation for seeking reissue of the invalidated ’068 patent.

173. Rather than correct the purported errors in the claims that were listed in the March 9, 2011 Response Accompanying RCE, on July 19, 2011, Pfizer simply cancelled all of the claims of the ’068 patent (specifically, claims 1-18) and drafted new claims with the benefit of over ten years of hindsight and knowledge concerning the commercial embodiment of the ’068 patent. Pfizer also deleted the reference to the ’113 application being a CIP application, added language stating that the ’113 application was a divisional application, and added language stating that the ’113 application was a divisional of the ’594 application. Pfizer functionally rewrote history to erase the ’629 CIP application and the PCT CIP application that the ’113 application *actually* derived from in order to falsely claim that the ’113 application stemmed directly from the ’529 application.

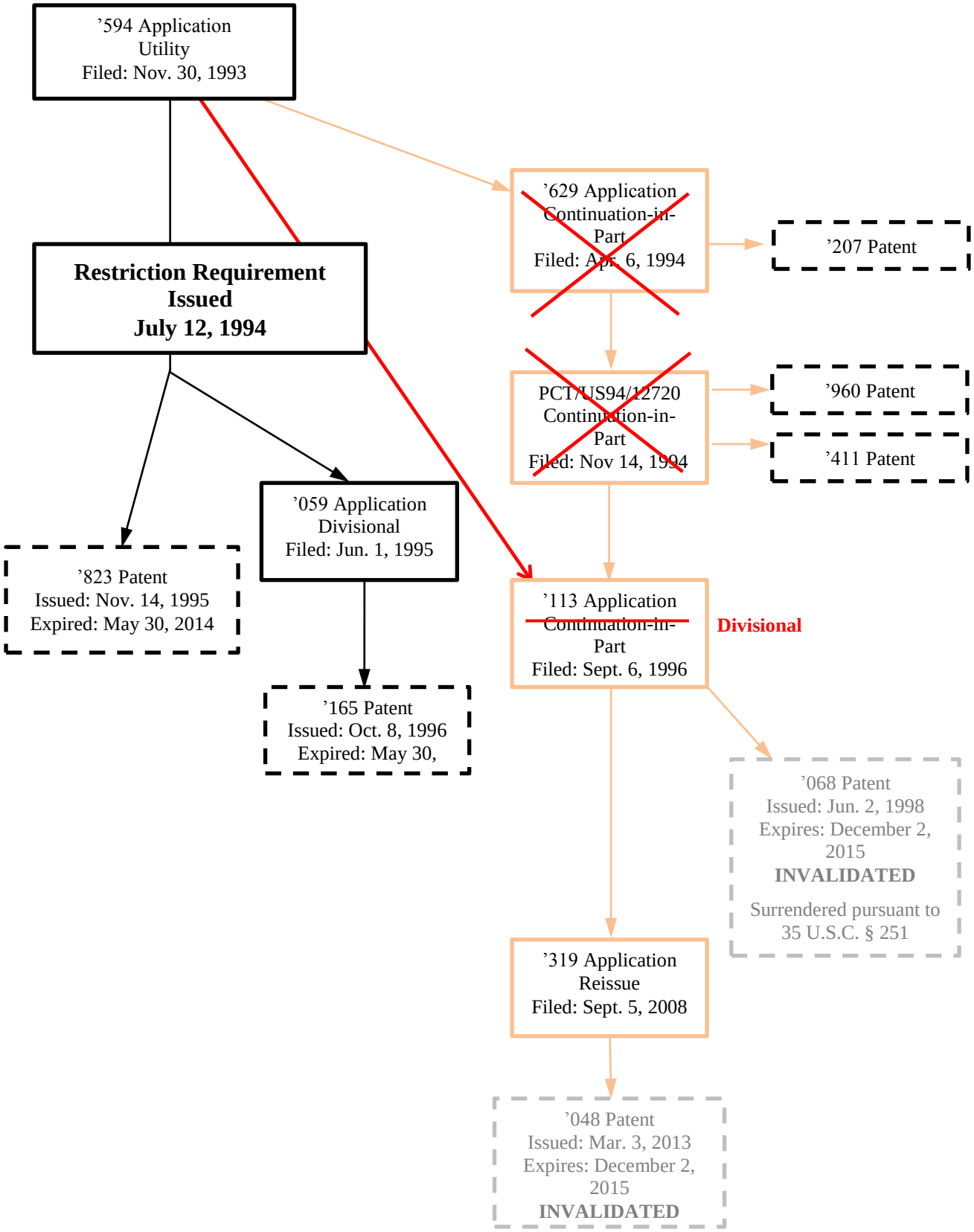
174. In selectively rewriting history, Pfizer did not give up the three patents it had obtained from those CIP applications. The ’629 CIP application resulted in the ’207 patent,

which included claims drawn to deracoxib, commercialized in an animal product. And two other Pfizer patents, U.S. Patent No. 6,413,960 ("the '960 patent") and U.S. Patent No. 6,942,411 ("the '411 patent"), also claim priority to the PCT application as a CIP of the '629 application.

175. Nor, in selectively rewriting history, did Pfizer give up the extra period of patent protection that it obtained by including new matter in the '068 patent. If the '113 application had been promptly filed as a divisional application (claiming no new matter) from the '594 application, then there were only two possible results, both of which lead to the reissued patent expiring no later than May 30, 2014.

176. First, the '113 application would have been diligently prosecuted, and its expiration date would have been May 30, 2014 (*i.e.*, twenty years from the filing of its patent '594 application, plus six months for pediatric exclusivity). Alternatively, if, for whatever reason the '113 application was not diligently prosecuted – and thus the resulting '068 patent did not issue for some considerable time – the later termination date that might otherwise apply from the 17 year rule would have been cut back by reason of a terminal disclaimer. The bottom line is that, at all times, method of use claims would never extend the patent life of celecoxib beyond May 30, 2014.

177. **Pfizer's Selective Revisionist History**



178. On August 4, 2011, the PTO rejected new claims 24-30 of the reissue application for failure to include an oath or declaration that the errors in the patent arose without any deceptive intention on the part of the applicant. However, the PTO stated "[t]he amendments presented in the reissue application to remove U.S. Patent No. 5,563,165 as a double patenting reference are now accepted because Applicants identified at least one error that is correctable in reissue under 35 U.S.C. 251. Therefore, the double patenting rejection is hereby withdrawn."

179. On October 11, 2011, Olson, in his capacity as attorney for Pfizer, submitted the requested supplemental declaration stating that "[e]very error in the patent which was corrected in the present reissue application and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the Applicants." This was false. The errors "arose" only as a result of Pfizer's effort to deceive the PTO into allowing Pfizer to change the status of the '113 application from a CIP to a divisional.

180. The PTO rejected Pfizer's application yet again in December 2011 noting that PTO could not reissue the patent based upon any purported error in characterizing the '113 application as a CIP instead of as a divisional.

181. In Pfizer's June 6, 2012 Response, Olson, in his capacity as attorney for Pfizer, stated that the August 4, 2011 PTO action "appropriately recognized these errors as correctable through reissue." Olson further stated that the current rejection "conflicts with the longstanding practice of the PTO… to permit reissue applications where claims have previously been held invalid. This practice is mandated by the statute's requirement '**the Director shall … reissue the patent'** if 'inoperative or invalid' because of 'a defective specification' or claiming 'less than he had a right to claim' '[w]henever' the applicant surrenders the patent and submits a 'new

and amended application.'" (emphasis in original). These statements were intended to and did mislead the PTO as to the issue presented.

182. While Pfizer was pointing to purported errors in the body of the patent that, standing alone, may have been otherwise correctible, Pfizer was deceitfully sweeping within the ambit of alleged errors that could be corrected the designation of the '113 application as a divisional application instead of as a CIP application, which is *not* a correctable error. As the PTO had stated: "[f]ailure to 'timely' file a divisional application prior to issuance of original patent is not correctable in reissue under 35 U.S.C. 251." Pfizer misled the PTO by characterizing the issue as whether reissue is permitted on another basis instead of whether a CIP application could be reissued as having been filed as a divisional application.

183. In an Office Action dated July 10, 2012, the PTO withdrew its rejections with regard to claims 24-30 "because Applicants[] argument was found to be persuasive." Pfizer's declaration "has been accepted because it identifies at least one error, which is relied upon to support the reissue Application."

184. Pfizer's misrepresentations to the PTO during the prosecution of the reissue application were made with the specific intent of deceiving the PTO.

185. Pfizer's misrepresentations to the PTO during the prosecution of the reissue application were material to the PTO and directly resulted in the issuance of the '048 reissue patent. In other words, but for Pfizer's misrepresentations to the PTO during the prosecution of the reissue application, the '048 reissue patent would not have issued.

E. Pfizer lists the reissue patent in the Orange Book and files baseless litigation against its would-be generic competitors.

186. On March 5, 2013, the reissue application issued as the '048 reissue patent. On the same day the '048 patent issued, Pfizer requested that the FDA list the '048 patent in the

Orange Book. The ’048 patent was listed in the Orange Book on March 7, 2013. Pfizer thus falsely represented under oath that the ’048 patent was reasonably enforceable.

187. At the time, generic companies had been lining up for years to launch generic celecoxib products. In addition to Teva, at least four additional generic manufacturers submitted ANDAs to the FDA seeking approval to market generic celecoxib capsules:

Applicant	**ANDA**	**Date Submitted**	**Tentatively Approved**
Teva	076898	Nov. 13, 2003	Apr. 27, 2012
Mylan Pharmaceuticals, Inc. (“Mylan”)	078857	Mar. 2, 2007	Apr. 29, 2011
Watson Laboratories, Inc. (“Watson”)	200562	Oct. 23, 2009	Sept. 21, 2012
Lupin Pharmaceuticals, Inc. (“Lupin”)	202240	by Dec. 30, 2010	none reported
Apotex Inc. / Apotex Corp. (“Apotex”)	204197	by July 12, 2012	none reported

188. Before the ’048 patent was reissued, three ANDAs for generic celecoxib capsules had received tentative approval from the FDA: ANDA No. 076898, submitted by Teva; ANDA No. 078857, submitted by Mylan; and ANDA No. 200562, submitted by Watson. Thus, but for Pfizer’s conduct in procuring and enforcing the ’048 reissue patent, these ANDAs would have been eligible for final FDA approval on May 30, 2014 (*i.e.*, upon expiration of the pediatric exclusivity associated with the ’823 and ’165 patents) and all of these ANDAs would have received final FDA approval as early as May 30, 2014 and before December 2014.

189. On March 5, 2013, the same day that the PTO issued the ’048 reissue patent, Pfizer filed suit against the five ANDA applicants - Teva, Mylan, Watson, Lupin and Apotex - in the United States District Court for the Eastern District of Virginia under the caption *G.D. Searle LLC v. Lupin Pharm., Inc.*, No. 13-cv-00121 (“*Teva II* litigation”), alleging that each of the ANDA sponsor’s generic Celebrex products would infringe the ’048 reissue patent.

190. The *Teva II* litigation was a sham. The litigations were objectively baseless because no reasonable litigant would realistically have expected Pfizer to succeed on the merits of any of the infringement claims against Teva, Mylan, Watson, Lupin or Apotex because the '048 reissue patent was manifestly invalid. Pfizer filed the *Teva II* lawsuit for the purpose of frustrating lawful competition and not for any valid, lawful purpose. The litigations were subjectively baseless because Pfizer's intent was to file the sham suit and use it as a platform to prolong market exclusivity longer than that to which it was lawfully entitled.

191. Regardless of whether Pfizer committed inequitable conduct or intentionally deceived the PTO, the stark light of patent infringement litigation would reveal that the '048 reissue patent was, at the very least, unenforceable. Pfizer, like any reasonable pharmaceutical manufacturer litigant, recognized the weakness in the reissue patent, but asserted it against generic competitors in patent infringement litigation nonetheless.

192. For purposes of this antitrust claim, the relevant question is whether the law was sufficiently clear at the time Pfizer asserted the '048 reissue patent against its generic competitors, in 2013. At that time, given the Federal Circuit's 2008 decision and other case law, no reasonable pharmaceutical manufacturer would have realistically expected to succeed on the merits of Pfizer's infringement suits (*i.e.*, no reasonable pharmaceutical manufacturers would have realistically expected that a court would find the '048 patent valid and infringed).

193. The Federal Circuit had already ruled that validating the kind of method-of-use claims sought in these circumstances for celecoxib would be shocking, and it quoted a long held principle:

> It would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then

> prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted.[15]

194. Any reasonable litigant would expect a district court to follow accepted law. Accepted law has long held that the reissue process is not available to "correct" the failure to file a divisional application. Accepted law has also long held that the reissue process is not available to "correct" intentional acts. There was no factual issue that: (i) the '113 application had been filed as a CIP application; and (ii) that Pfizer's doing so was entirely intentional. Pfizer had intentionally sought and received the benefits of a CIP application; it could not later seek to undo those intentional acts through the reissue process.

195. Any reasonable litigant would also expect that (even if for some reason existing law were not followed, and Pfizer could resurrect the '068 patent as stemming from a divisional application that was not invalid for obviousness double patenting in light of the earlier '823 and '165 celecoxib patents) any reissue patent issuing in these circumstances would at least require a terminal disclaimer limiting the term of this revamped, reissue patent to May 30, 2014, *i.e.*, the expiry date for the '823 and '165 patents – since the Federal Circuit had already held that the claims of the '068 were not patentably distinct from the claims of the '823 and '165 patents.

196. In short, no reasonable pharmaceutical company or person in the industry could expect to prevail in patent litigation to extend exclusivity for celecoxib beyond May 30, 2014 using a reissued method-of-use patent for celecoxib. Pfizer knew at all times it was never entitled to a valid reissuance of the '068 patent given its intentional prosecution history. And even if Pfizer could have gotten a valid reissuance of the '068 patent (a circumstance completely

[15] *Teva I* Fed. Cir., 518 F.3d at 1363 (quoting *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1386 (Fed. Cir. 2003)).

contrary to the facts and the law), such a patent would need to be limited in its term to May 30, 2014.

197. On November 22, 2013, Mylan, Watson, Lupin and Apotex moved for summary judgment against Pfizer, asserting that the '048 patent was invalid. Teva did not move for summary judgment against Pfizer.

F. The District Court invalidates the '048 reissue patent.

198. On March 12, 2014, Judge Allen of this Court ruled that the '048 patent was invalid. Judge Allen held that:

> [T]he '048 patent is invalid under 35 U.S.C. § 251 because, even if other errors supported the reissue application under § 251, the failure to file a divisional is not an error correctable under 35 U.S.C. § 251, and is not a narrowing change to the patent's claims. Additionally, because the applicant intentionally filed a CIP application as opposed to a divisional, and intentional acts are not correctable via reissue, the '048 patent violates § 251 of the reissue statute as a matter of law and is invalid.[16]

199. The court also held that the claims of the '048 patent are not patentably distinct from the claims of the '165 patent, and that as a result, the '048 patent is invalid on the basis of "obviousness-type double patenting."

200. The court's recognition that failure to file a divisional application is not an error correctable under 35 U.S.C. § 251 is what a reasonable patent litigant would have expected. Federal law had long held that "the deliberate action of an inventor or attorney during prosecution generally fails to qualify as a correctable error under §251."[17] Federal law had also long held that that failure to file a divisional application cannot be corrected by reissue.[18]

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[16] *Teva II*, No. 13-cv-121, Doc. No. 351, at 13 (E.D. Va. Mar. 12, 2014).

[17] *In re Serenkin*, 479 F.3d at 1261.

[18] *See, e.g.*, *In re Watkinson*, 900 F.2d at 231.

201. Although this court acted with dispatch in ruling on the invalid '048 reissue patent, Pfizer used its sham lawsuits as a platform to "settle" its sham claims with the would-be generic entrants, thereby illegally prolonging Pfizer's Celebrex exclusivity beyond May 30, 2014.

G. Pfizer settles with Teva, Watson, and Mylan.

202. On April 17, 2014, after the court granted summary judgment but before the district court entered a final judgment, Teva announced that it had entered into a settlement agreement with Pfizer to settle the Teva claims in *Teva II*. According to Teva, "[u]nder the terms of the settlement, Teva may launch its generic versions in December 2014, or earlier under certain circumstances." The terms of the settlement agreement between Pfizer and Teva have not otherwise been publicly disclosed.[19]

203. One week later, on April 24, 2014, Watson announced that it, too, had entered into a settlement agreement with Pfizer to settle the patent litigation. According to Watson, "[u]nder the terms of the agreement, Pfizer will grant [Watson] a license to market its generic Celebrex® beginning in December 2014, or earlier under certain circumstances. Other details of the settlement were not disclosed."

204. Pfizer subsequently confirmed its settlement agreements with Teva and Watson, stating that it "has entered into settlement agreements with certain . . . generic drug companies granting them licenses to launch their generic versions of celecoxib in the U.S. beginning in December 2014, or earlier under certain circumstances. Under certain conditions, the licenses may be royalty-bearing through the remaining term of the reissue patent."

[19] Pursuant to an Order of this Court, Pfizer produced settlement agreements to counsel as "Highly Confidential – Outside Counsel's Eyes Only." This complaint cites only publicly available information and does not refer to, or rely on, confidential information contained in those agreements.

205. On June 2, 2014, Mylan announced that it had entered into a settlement agreement with Pfizer to settle the Celebrex patent litigation. According to Mylan, "[u]nder the terms of the agreement, Mylan will begin selling product at the earliest market formation, however in any case not later than December 2014. All other terms and conditions of the settlement and license agreement are confidential…."

206. Together, the settlement agreements with Teva, Watson, and Mylan, appear to permit the three generics to come to market in December 2014 under conditions specified in the agreements, which is a full six months after all three would have been able to come to market simultaneously (without any of the terms or conditions in the agreements with Pfizer) but for Pfizer's anticompetitive conduct.

207. Indeed, on December 10, 2014 Teva, Actavis (formerly Watson) and Mylan each announced that they were launching generic versions of Celebrex, in 50, 100, 200 and 400mg capsules. Lupin Pharmaceuticals announced its launch the next day.

H. The District Court for the Northern District of West Virginia upholds the FDA's determination that Teva is entitled to 180-day exclusivity as the first ANDA filer.

208. On April 24, 2014, the FDA sent a letter addressed to "Dear Celecoxib ANDA Applicant" that provided the FDA's position on the eligibility of ANDA applicants for 180-day exclusivity under the pre-Medicare Prescription Drug, Improvement, and Modernization Act ("Medicare Modernization Act" or "MMA") version of the FDCA in a situation involving a reissued patent.[20]

[20] The FDA sent this letter because the eligibility of ANDA applicants for pre-MMA180-day exclusivity in a situation involving a reissue patent was a novel issue. On December 8, 2003, the MMA was enacted. The MMA created a new regime for 180-day generic drug marketing exclusivity, but did not retroactively change how 180-day exclusivity worked before the MMA. Under the pre-MMA version of 180-day exclusivity, 180-day exclusivity is patent-based, such that an ANDA applicant is eligible for 180-day exclusivity with respect to different Orange Book listed patents covering the brand drug product. Pre-MMA 180-day exclusivity was triggered by the earlier of the first commercial marketing of a generic

209. Because Teva submitted its ANDA as to the '823, '165, and '068 patents on November 13, 2003, 180-day exclusivity was subject to the pre-MMA rules. Thus, the question arose concerning what consequence, if any, the issuance of the '048 reissue patent had on Teva's status as the first filer entitled to 180-day exclusivity.

210. The FDA concluded that:

> [F]or purposes of 180-day exclusivity, upon the listing of a reissued patent, a prior court decision on the original patent is not regarded as having triggered 180-day exclusivity for the single bundle of patent rights represented by the original and reissued patent. In such a case, eligibility for 180-day exclusivity is only available to the applicant that first filed a paragraph IV certification to the original patent, and that applicant must make a timely submission of a paragraph IV certification to the reissued patent to remain eligible for 180-day exclusivity.

211. While the FDA noted in its April 24 letter that it was "not making a determination with respect to 180-day exclusivity in a particular case," the practical result of the FDA's stated position on eligibility for exclusivity in situations involving a reissued patent was that Teva, and only Teva, would be eligible for 180-day exclusivity with respect to generic celecoxib capsules in 100 mg, 200 mg and 400 mg strengths. Absent the issuance of the '048 reissue patent, Teva's exclusivity period would have begun after the Federal Circuit decision invalidating the '068 patent in 2008, and would have long since lapsed before May 30, 2014. Thus, the FDA's decision ensured that Teva would still have 180-day exclusivity upon its launch.

212. On April 25, 2014, Mylan filed suit against the FDA in the United States District Court for the Northern District of West Virginia, Case No. 1:14-cv-00075-IMK, challenging the

product or by a court decision favorable to an ANDA applicant (with respect to a particular patent). Pre-MMA 180-day exclusivity could also lapse or be forfeited in various ways laid out by statute.

FDA's April 24 decision regarding exclusivity.[21] Mylan sought a preliminary injunction enjoining the FDA from withholding final approval to any celecoxib ANDA applicant that submitted a Paragraph IV certification to the '048 patent on March 7, 2013 (the day the '048 patent was listed in the Orange Book) and compelling the FDA to grant final approval to Mylan's celecoxib ANDA on May 30, 2014.

213. On May 29, 2014, the District Court for the Northern District of West Virginia denied Mylan's motion for a preliminary injunction. The district court found that "the FDA's decision to treat an original and its reissued patent as having a single bundle of rights is reasonable and allows the agency to administer the Hatch-Waxman Act in a predictable manner."

214. However the Fourth Circuit reversed the District Court's ruling in an unpublished Opinion on December 16, 2014.[22] The Fourth Circuit found that the relevant statute gave Teva a 180 day exclusivity starting from its victory in the Federal Circuit in 2008, and thus long since expired.

I. The FDA gives Teva's celecoxib ANDA final approval.

215. On May 30, 2014, the FDA granted Teva final ANDA approval, stating that Teva "received approval to market celecoxib capsules in 50 milligram, 100 mg, 200 mg, and 400 mg strengths, and has 180-day exclusivity on the 100 mg, 200 mg, and 400 mg strength products." Even though Teva had *final* FDA approval to market its celecoxib product, Teva did not launch a generic product. Why? Because Pfizer's scheme had worked. Pfizer procured the '048 reissue patent by fraud and trickery, filed the reissue patent in the Orange Book knowing it could not be

[21] Lupin and Watson also sued the FDA in the United States District Court for the District of Maryland and the United States District Court for the District of Columbia, respectively. Lupin and Watson later intervened in the Mylan proceeding in the United States District Court for the Northern District of West Virginia and Lupin and Watson voluntarily dismissed their other actions.

[22] *Mylan Pharmaceuticals v. FDA*, No 14-1522, Docket # 61(4th Cir Dec. 16, 2014).

reasonably enforced against generics, filed the sham *Teva II* lawsuit against Teva, and then used that sham lawsuit to negotiate a delayed entry date out of Teva. As a result, Teva did not launch generic celecoxib until December, 2014, causing the Class to continue paying hundreds of millions in overcharges.

VI. MONOPOLY POWER AND MARKET DEFINITION

216. At all relevant times, Pfizer had monopoly power in the market for celecoxib capsules, *i.e.*, Celebrex and its AB-rated generic equivalents, because it had the power to maintain the price of the drug it sold as Celebrex at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Celebrex, with the exception of AB-rated generic celecoxib capsules.

217. NSAIDs are a group of drugs used to temporarily relieve pain and inflammation. They work by blocking the production of prostaglandins, or chemicals believed to be associated with pain and inflammation.

218. Some NSAIDs act by blocking the action of two different enzymes, Cyclooxygenase-1 and Cyclooxygenase-2 (COX-1 and COX-2), which the body uses to make prostaglandins. These NSAIDs, such as ibuprofen and naproxen, are known as "nonselective" NSAIDs.

219. While the use of a nonselective NSAID may reduce pain and inflammation, they may also result in serious gastrointestinal bleeding, heart attacks, and strokes. The gastrointestinal bleeding problems have been traced specifically to the blocking of COX-1. Some of the prostaglandins produced by the COX-1 enzyme help protect the lining of the stomach from acid, so blocking this enzyme increases the risk of stomach upset, stomach bleeding and ulcers.

220. Selective COX-2 inhibitors are a newer type of NSAID that primarily block the COX-2 enzyme, and not the COX-1 enzyme. The theory with selective COX-2 inhibitors is that they might provide similar relief from pain and inflammation-related disorders than non-selective ones, but with less gastrointestinal side effects.

221. Over the years, the FDA has only approved three selective COX-2 inhibitors: (i) rofecoxib, sold under the name Vioxx; (ii) valdecoxib, sold under the name Bextra; and (iii) celecoxib, sold under the name Celebrex. Vioxx was withdrawn from the market in 2004 because it was linked to an increased risk of heart attacks and strokes. Bextra was withdrawn in 2005 because it was associated with an increased risk of serious cardiovascular problems in people who had undergone coronary artery bypass graft surgery as well as a higher risk of life-threatening skin reactions than other NSAIDs. For many years Celebrex has been the only selective COX-2 inhibitor on the market in the United States.

222. Pfizer differentiates Celebrex from other medications used to treat the indications for which it is approved, *i.e.*, osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, acute pain, and primary dysmenorrhea. Among other things, Pfizer has differentiated Celebrex from other drugs based on its reports of the results of clinical studies that indicate that a lower percentage of patients taking Celebrex report stomach discomfort (including indigestion, abdominal pain, and nausea) versus those taking prescription ibuprofen and naproxen.

223. It has become generally accepted by many that celecoxib has shown an advantage in lowering the risk of serious ulcer complications in the short-term (six months or less) compared with other NSAIDs. Studies also indicate that Celebrex is effective at reducing the risk of ulcers with longer-term use.

224. Manufacturers attempt to differentiate brand name drugs like Celebrex based on features and benefits (including safety and efficacy), and not based on price. Physicians who prescribe drugs such as Celebrex do not pay for them (unlike typical products which are both selected and paid for by consumers), and insurance bears much of the cost of prescriptions. Different patients may respond differently to different drugs and even drugs within the same therapeutic class as Celebrex do not constrain the pricing of Celebrex.

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

226. Less expensive generic versions of other NSAIDs are available (including a generic version of Relafen (nabumeton)) but those less expensive products do not exhibit cross price elasticity with (and therefore do not constrain the price of) Celebrex.

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

228. Indeed, the impact of generic competition has been stark and predictable. In the one month generics have been available (starting on December 10, 2014), prices of generic celecoxib are far below the prices for brand name Celebrex.

229. A search of local pharmacy prices in Norfolk, VA using the goodrx.com website reveals that generic prices are 66% below brand Celebrex. Thus, for a prescription of 60 200 mg

capsules, generic celecoxib is available for approximately $143, while the cheapest price for Celebrex (brand) capsules is $440.[23]

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

231. Pfizer has had, and exercised, the power to exclude and restrict competition to Celebrex and AB-rated bioequivalents.

232. Pfizer, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market of celecoxib capsules due, in large part, to legally and illegally created patent protections, legally and illegally created regulatory bars to FDA approval of AB-rated generic competitors, and high costs of entry and expansion.

233. To the extent the Plaintiffs are legally required to prove monopoly power through circumstantial evidence by first defining a relevant product market, Plaintiffs allege that the relevant market is all celecoxib capsules (*i.e.*, Celebrex in all its dosage strengths, and its AB-rated generic equivalents). During the period relevant to this case, Pfizer has been able to profitably maintain the price of celecoxib capsules well above competitive levels.

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

235. At all relevant times, Pfizer's market share in the relevant market was 100%.

VII. MARKET EFFECTS AND DAMAGES TO THE CLASS

236. But for the anticompetitive conduct alleged above, multiple generic manufacturers would have entered the market with their generic celecoxib products as early as May 31, 2014, when the pediatric exclusivities associated with the '823 and '165 patents expired.

[23] Based on a search of the goodrx.com website on January 12, 2014, using zip code 23510.

237. Pfizer willfully and unlawfully maintained its monopoly power in the market for celecoxib through a scheme to exclude competition. The scheme unlawfully forestalled generic competition and maintained supra-competitive prices for Celebrex.

238. Pfizer implemented its scheme by fraudulently obtaining the ’048 reissue patent, prosecuting a sham patent infringement lawsuit against the generic manufacturers, and abusing the Hatch-Waxman framework. These acts, in combination and individually, were anticompetitive.

239. If Pfizer had not defrauded the PTO: (i) the ’048 reissue patent would never have been issued; (ii) it could never have been used as a vehicle to bring suits against would-be makers of generic celecoxib products; and (iii) those makers would have been able to launch generic celecoxib by May 31, 2014. Moreover, if the ’048 reissue patent had not issued, then Teva would not have had a basis by which to argue that it was entitled to resurrect its first-to-file status for celecoxib (because the sole basis by which it has been able to do so is that the PTO’s reissuance of the ’048 reissue patent is a part of the bundle of rights upon which Teva had been the first to file); absent the ’048 reissue patent, multiple generic makers would have been able to launch by May 31, 2014 without waiting for a sole Teva exclusivity to lapse or be forfeited.

240. If Pfizer had not filed and prosecuted the sham litigation claiming infringement of the invalid ’048 reissue patent, generic competitors would have been able to launch generic celecoxib by May 31, 2014. Moreover, even if the PTO fraud allegations of this complaint fail at trial, the sham litigation against Teva would alone have caused delay of the entry generic celecoxib. Absent the sham *Teva II* litigation: (i) there would have been no settlement of *Teva* litigation; (ii) Teva would not have made an agreement to delay its market entry; (iii) it would

have entered the market on or about May 30, 2014; and (iv) other generics (if stalled by Teva's resurrected first-to-file status) would still enter six months thereafter.

241. Teva received final FDA approval of its ANDA for generic celecoxib capsules on May 30, 2014. Even though Teva had final FDA approval, Teva did not launch its generic product until December 10, 2014. Pfizer's wrongful conduct in procuring and litigating the '048 reissue patent is a "but for" cause of Teva's delay in the marketing of generic celecoxib capsules.

242. Mylan received *tentative* FDA approval of its ANDA for generic celecoxib capsules on April 29, 2011 (three years ago). Mylan would have received *final* FDA approval on or about May 30, 2014 had it not been for the fraudulent procurement of the '048 reissue patent; it is the existence of the '048 patent that serves as the only reason that the FDA has ruled that Teva entitled to sole first-to-file exclusivity, and it was only Teva's sole first-to-file status, and Pfizer's prosecution and settlement of sham litigation, that prevented FDA final approval of Mylan's generic product, and it was only the lack of FDA final approval that prevented Mylan's immediate launch of generic celecoxib.

243. Watson received *tentative* FDA approval of its ANDA for generic celecoxib capsules on September 21, 2012 (almost two years ago). Watson would have received *final* FDA approval on or about May 30, 2014 had it not been for the fraudulent procurement of the '048 reissue patent; that patent is the only reason that the FDA has ruled Teva entitled to sole first-to-file exclusivity, and it was only Teva's sole first-to-file status, and Pfizer's prosecution and settlement of sham litigation, that prevented FDA final approval of Watson's generic product, and it was only FDA final approval that prevented Watson's immediate launch of generic celecoxib.

244. Even putting Pfizer's fraudulent procurement of the '048 reissue patent aside, Pfizer's prosecution of the *Teva II* patent litigation would remain a sham and has caused significant delay of the launch of Teva's first-to-file generic product and delayed FDA approval of other ANDAs during Teva's first-to-file exclusivity period.

245. Pfizer's unlawful conduct has delayed generic entry of celecoxib and will continue to cause overcharges until prices have dropped to their competitive level such that prices in the actual world and "but for" world are the same.

246. Pfizer's anticompetitive conduct had the purpose and effect of unreasonably restraining and injuring competition by protecting Celebrex from generic competition. Pfizer's actions allowed it to unlawfully maintain a monopoly and exclude competition in the market for celecoxib capsules, *i.e.*, Celebrex and its AB-rated generic equivalents.

247. Pfizer's exclusionary conduct has unlawfully delayed generic competition and unlawfully enabled it to sell Celebrex without generic competition. But for the illegal conduct of Pfizer, Teva and one or more generic competitors would have begun marketing AB-rated generic versions of Celebrex before December 10, 2014. By way of examples and not limitation: (i) if there had been no fraud upon the PTO, the '048 patent would not have issued, the patent would never have been listed in the Orange Book, and thus the patent would never have been the subject of infringement litigation; (ii) with no lawsuit, there would have been no settlements, which acted to further delay generic launch; and (iii) if the settlement agreement had not occurred, Teva would have entered the market on May 30, 2014, and other generics would have launched at that time or followed after Teva's sole 180-day exclusivity expired.

248. The generic manufacturers seeking to sell generic Celebrex have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs,

marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand, and at least several of these generic manufacturers would have been ready, willing and able to launch its generic version of Celebrex by May 30, 2014 were it not for Pfizer's unlawful acts.

249. Pfizer's anticompetitive conduct, which delayed the introduction into the U.S. marketplace of any generic version of Celebrex, has caused and will cause Plaintiffs and the Class to pay more than they would have paid for celecoxib capsules.

250. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding reference listed drug ("RLD") brand counterpart as to which they are AB-rated. As a result, upon generic entry, Class members' purchases of brand drugs are rapidly substituted for generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generic versions of the drug.

251. The standard price decline has happened here. As noted above, current generic prices are approximately 66% lower than brand Celebrex prices.[24]

252. This price competition enables all purchasers of the drug to: (i) purchase generic versions of a drug at substantially lower prices than the brand; (ii) purchase generic equivalents of the drug at a lower price, sooner; and/or (iii) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

[24] Based on a search of the goodrx.com website on January 12, 2014, using zip code 23510.

253. If generic competitors had not been unlawfully prevented from entering the market earlier and competing with Pfizer, end-payor purchasers, such as Plaintiffs and members of the Class, would have paid less for celecoxib capsules by: (i) substituting purchases of less-expensive AB-rated generic Celebrex for their purchases of more-expensive brand Celebrex, (ii) receiving discounts on their remaining brand Celebrex purchases, and/or (iii) purchasing Celebrex at lower prices sooner.

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

VIII. ANTITRUST IMPACT

255. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Celebrex indirectly from Pfizer. As a result Pfizer's illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for their celecoxib capsule requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Celebrex was artificially inflated by the defendants' illegal conduct, and (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Celebrex sooner.

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

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

258. The prices were inflated as a direct and foreseeable result of Pfizer's anticompetitive conduct.

259. The inflated prices the Class paid are traceable to, and the foreseeable result of, the overcharges by Pfizer.

260. At all relevant times, Pfizer manufactured, promoted, distributed, and sold substantial amounts of Celebrex met in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

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

262. In furtherance of their efforts to monopolize and restrain competition, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of, and have substantially affected (and will continue to substantially effect), interstate commerce.

263. Defendants' anticompetitive conduct also had substantial intrastate effects in that, *inter alia*, retailers within each state were foreclosed from offering cheaper generic Celebrex to end-payors inside each respective state. The complete foreclosure of generic Celebrex directly impacted and disrupted commerce for end-payors within each state (and will continue to do so).

264. General economic theory recognizes that any overcharge at a higher level of distribution in the chain of distribution for Celebrex results in higher prices at every level below. Herbert Hovenkamp, *FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE* p. 624 (1994). Professor Herbert Hovenkamp goes on to state that "[e]very

person at every stage in the chain will be poorer as a result of the monopoly price at the top." He also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

IX. CLASS ALLEGATIONS

265. Plaintiffs, on behalf of themselves and all members of the Class, seek damages, measured as overcharges, against Pfizer based on allegations of anticompetitive conduct in the market for Celebrex.

266. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), as representatives of the below-defined Class (the "Class" or the "End-Payor Class") defined as follows:[25]

> All persons or entities who purchased and/or paid for some or all of the purchase price for Celebrex and/or its AB-rated generic equivalents in Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, and the District of Columbia and Puerto Rico (the "Class States"), in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period May 31, 2014, through and until the anticompetitive effects of Defendants' unlawful conduct ceases (the "Class Period").

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

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

[25] For purposes of the class definitions, persons or entities "purchased" Celebrex or its generic equivalent if they paid or reimbursed some or all of the purchase price.

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

c. All persons or entities who purchased Celebrex for purposes of resale or directly from Defendants or their affiliates;

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

e. Pharmacy benefit managers without capitation contracts; and

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

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

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

270. Plaintiffs will fairly and adequately protect and represent the interests of the End-Payor Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the End-Payor Class.

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

272. Questions of law and fact common to the members of the End-Payor Class predominate over questions that may affect only individual Class members because Pfizer has

acted on grounds generally applicable to the entire End-Payor Class, thereby making overcharge damages with respect to the End-Payor Class as a whole appropriate.

273. Questions of law and fact common to the End-Payor Class include, but are not limited to:

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

b. whether Prizer obtained the '048 reissue patent by fraud;

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

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

e. whether Pfizer maintained monopoly power, itself and/or in conspiracy with Teva and/or Watson, by delaying generic entry;

f. whether the Defendants entered into an illegal contract, combination, conspiracy and/or other agreement in restraint of trade;

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

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

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

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

k. whether the Defendants were unjustly enriched by the activities alleged herein; and

l. the amount the Defendants have been unjustly enriched.

274. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the

unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

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

X. CLAIMS FOR RELIEF

COUNT I
FOR MONOPOLIZATION UNDER STATE LAW
(Asserted Against Pfizer)

276. Plaintiffs repeat and incorporate by reference all preceding paragraphs and allegations.

277. As described above, from January 1999 until December 2014, and with effects that will continue, Pfizer possessed monopoly power in the market for celecoxib capsules. No other manufacturer sold a competing version of celecoxib in the United States.

278. Pfizer has willfully and unlawfully maintained its monopoly power in the celecoxib capsule market from May 30, 2014 through December 2014 by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

279. Pfizer knowingly and intentionally engaged in an anticompetitive scheme deliberately designed to block and delay entry of AB-rated generic versions of Celebrex to maintain its monopoly power. This scheme included:

a. obtaining the ’048 patent by fraud through misleading the PTO and failing to exercise the duty of good faith;

b. improperly listing the ’048 patent in the Orange Book;

c. engaging in sham litigation; and

d. prolonging the impact of its sham litigation through settlement arrangements requiring, by definition, reciprocal and concerted activity with others, that further delayed generic entry.

280. By engaging in the foregoing conduct, Pfizer has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 16700, 17200, *et seq.*, with respect to purchases in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, and §542.19, with respect to purchases in Florida by members of the Class.

e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases in Illinois by members of the Class.

f. Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Class.

g. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases in Maine by members of the Class.

h. Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class.

i. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by members of the Class.

j. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

k. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

l. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

m. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class.

n. N.H. Rev. Stat. Ann. §§ 356.1, *et seq.*, with respect to purchases in New Hampshire by members of the Class.

o. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Class.

p. New York General Business Law § 340, *et seq.*, with respect to purchases in New York by members of the Class.

q. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

r. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by members of the Class.

s. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases in Oregon by members of the Class.

t. R.I. Gen. Laws §§ 6-36-5, *et seq.*, with respect to purchases in Rhode Island by members of the Class.

u. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

v. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class.

w. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases in Utah by members of the Class who are either citizens of Utah or residents of Utah.

x. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

y. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by members of the Class.

z. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

281. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Celebrex products, and (2) paying higher prices for Celebrex products than they would have paid in the absence of

Defendants' conduct. These injuries are of the type the laws of the above States were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

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

COUNT II
UNJUST ENRICHMENT
(Asserted Against Pfizer)

283. Plaintiffs repeat and incorporate by reference all preceding paragraphs and allegations.

284. It would be inequitable under the laws of the District of Columbia, Puerto Rico, and all states within the United States, except Indiana and Ohio for Defendants to retain any of the overcharges for Celebrex derived from Defendant's unfair and unconscionable methods, acts, and trade practices alleged herein.

285. Pfizer has benefited from the monopoly profits on their sales of Celebrex resulting from the unlawful and inequitable acts alleged in this Complaint.

286. Pfizer's financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Celebrex by Plaintiff and members of the Class.

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

288. The economic benefit of overcharges and unlawful monopoly profits derived by Pfizer through charging supracompetitive and artificially inflated prices for Celebrex is a direct and proximate result of Pfizer's unlawful practices.

289. The financial benefits derived by Pfizer rightfully belong to Plaintiffs and the Class, as Plaintiffs and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to Pfizer's benefit.

290. It would be inequitable for the Pfizer to be permitted to retain any of the overcharges for Celebrex derived from Pfizer's unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

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

292. To the extent the Court finds that Plaintiffs and the Class members have no adequate remedy at law, a constructive trust should be imposed upon all unlawful or inequitable sums received by Pfizer traceable to Plaintiffs and the Class.

COUNT III
DECLARATORY AND INJUNCTIVE RELIEF
(Asserted Against Pfizer)

293. Plaintiffs repeat and incorporate by reference all preceding paragraphs and allegations.

294. Plaintiffs' allegations described herein and in the preceding Counts comprise violations of Section 2 of the Sherman Act, in addition to the state laws *supra*.

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

296. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the

anticompetitive market effects caused by the unlawful conduct of Pfizer, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future

XI. DEMAND FOR JUDGMENT

297. WHEREFORE, Plaintiffs, on behalf of themselves and the Class, respectfully request that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class; find Plaintiffs to be adequate representatives of the class; and appoint the undersigned attorneys as Class Counsel;

B. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;

C. Enter joint and several judgments against the Defendants and in favor of Plaintiffs and the Class;

D. Award the Class damages (*i.e.*, three times overcharges, to the extent allowed by applicable law) in an amount to be determined at trial, plus interest in accordance with law;

E. Award the Class damages in the amount of the overcharges resulting from Defendants' conduct by which they were unjustly enriched;

F. Award Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

G. Award such further and additional relief as is necessary to correct for the anticompetitive market effects caused by Pfizer's unlawful conduct, as the Court may deem just and proper under the circumstances.

XII. JURY DEMAND

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

Dated: January 14, 2015

Respectfully submitted,

/s/ Wyatt B. Durrette, Jr.

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CERTIFICATE OF SERVICE

I hereby certify that on January 14, 2015, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will automatically e-mail notification of such filing to all counsel of record.

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