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20 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
21 **FOR THE COUNTY OF ORANGE**

22 THE PEOPLE OF THE STATE OF
23 CALIFORNIA, acting by and through Orange
24 County District Attorney Tony Rackauckas,

25 Plaintiff,

26 vs.

27 BOEHRINGER INGELHEIM
28 PHARMACEUTICALS, INC.; BOEHRINGER
INGELHEIM PHARMA GmbH & CO. KG;
BOEHRINGER INGELHEIM
INTERNATIONAL GmbH; TEVA
PHARMACEUTICALS USA, INC.; BARR
PHARMACEUTICALS INC.; BARR
LABORATORIES, INC.; DURAMED
PHARMACEUTICALS, INC; DURAMED
PHARMACEUTICALS SALES CORP.; and
DOES 1 THROUGH 100, INCLUSIVE,

Defendants.

Case No. **30-2017-00914577-CU-BT-CXC**

**COMPLAINT FOR VIOLATIONS OF
CALIFORNIA UNFAIR
COMPETITION LAW, SEEKING
RESTITUTION, CIVIL PENALTIES
AND INJUNCTIVE RELIEF**

Judge: **Judge Thierry Patrick Colaw**
Dept.: CX-105

1 **COMPLAINT**

2 Plaintiff, the People of the State of California (“Plaintiff” or “the People”), by and through
3 Tony Rackauckas, District Attorney for the County of Orange (“District Attorney”), alleges the
4 following, on information and belief:

5 **I. INTRODUCTION**

6 1. This is an action brought by Tony Rackauckas, District Attorney of the County of
7 Orange for violations of California Business and Professions Code sections 17200 et seq., the Unfair
8 Competition Law (“UCL”), involving the purchases of, and reimbursements for, the prescription drug
9 Aggrenox occurring in California, including California Aggrenox users, their insurers, public
10 healthcare providers and other government payors. The defendants are Ingelheim Pharma GmbH &
11 Co. KG, Boehringer Ingelheim International GmbH, Boehringer Ingelheim Pharmaceuticals, Inc.
12 (“Boehringer”), Teva Pharmaceuticals USA, Inc. (“Teva”), Barr Pharmaceuticals Inc., Barr
13 Laboratories, Inc. (“Barr”), Duramed Pharmaceuticals Inc., and Duramed Pharmaceuticals Sales
14 Corp. (“Duramed”), (together, the “Defendants”). This action arises out of Defendants’ unlawful
15 agreements to allocate the market for 25 mg aspirin/200 mg extended-release dipyridamole capsules,
16 which is sold by Boehringer under the brand name Aggrenox. Aggrenox is a combination antiplatelet
17 agent used to reduce the risk of stroke in patients who have already suffered a “mini-stroke” (or
18 transient ischemic attack) or a completed ischemic stroke due to thrombosis (*i.e.*, blood clot).
19 Boehringer received approval to manufacture, market and sell Aggrenox in the United States from the
20 United States Food and Drug Administration (“FDA”) in 1999.

21 2. This is a law enforcement action which primarily seeks to protect the public safety and
22 welfare, brought by a governmental unit in the exercise of and to enforce its police power. *City &*
23 *Cnty. of San Francisco v. PG & E Corp.*, 433 F.3d 1115, 1124-25 (9th Cir. 2006); *California v.*
24 *Purdue Pharma L.P.* (C.D. Cal., Nov. 12, 2014, No. SACV 14-1080-JLS DFM) 2014 WL 6065907,
25 *4; *In re General Motors LLC Ignition Switch Litigation* (S.D.N.Y. 2014) 69 F. Supp. 3d 404, 416.

26 3. This case is based on several simple and provable facts: Defendants entered into an
27 unlawful “reverse payment agreement” through which Boehringer paid Barr more than \$120 million
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1 in cash and other valuable consideration in exchange for Barr’s agreement not to launch a less
2 expensive, bio-equivalent generic version of Aggrenox for up to seven years. No bio-equivalent
3 generic version of Aggrenox entered the market until July 2015 as a direct and proximate result of
4 Defendants unlawful market allocation agreement. This agreement not to compete prevented less
5 expensive generic versions of Aggrenox from entering the market earlier, causing Plaintiff to pay a
6 substantially higher price for Aggrenox than it otherwise would. From 1999 to 2015, Boehringer
7 charged supracompetitive prices and reaped a steady source of profits from Aggrenox, with annual
8 sales reaching approximately \$400 million.

9 4. On February 1, 2007, Barr sought regulatory approval to manufacture, market and sell
10 a generic version of Aggrenox before the expiration of any patents associated with Aggrenox by
11 filing an Abbreviated New Drug Application (“ANDA”) with the FDA. As the first filer of a
12 substantially complete generic Aggrenox ANDA, Barr was entitled to 180 days of market exclusivity
13 during which it was free from competition from other Aggrenox generics – with the exception of an
14 authorized generic marketed by the brand company, Boehringer.

15 5. Boehringer sued Barr, alleging that Barr’s generic Aggrenox product would infringe
16 Boehringer’s U.S. Patent No. 6,015,577 (the “577 Patent”)—even though the ‘577 Patent was
17 invalid and/or unenforceable and thus unlikely to prevent any generic Aggrenox product from coming
18 to market in advance of patent expiration in January 2017. Boehringer sued Barr solely to obtain an
19 automatic stay under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L.
20 No. 98-417, 98 Stat. 1585 (1984) (“Hatch-Waxman Act”) which prevented the FDA from approving
21 Barr’s generic Aggrenox product for up to thirty months.

22 6. Though temporarily stalled on account of the 30-month stay, Boehringer faced
23 imminent competition from Barr and other generic manufacturers due to the weakness of its ‘577
24 Patent, beginning either upon a ruling of patent invalidity or unenforceability, or at the latest upon the
25 end of the FDA issued stay.

26 7. As a sophisticated pharmaceutical manufacturer, Boehringer was well aware that
27 generic versions of brand drugs are typically priced significantly below brand versions. Because of
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1 the price differentials, and other institutional features of the pharmaceutical industry, generic versions
2 are liberally and substantially substituted for their brand counterparts. As a result, Boehringer knew
3 that the entry of one or more generic versions of Aggrenox would cause a drastic loss of its Aggrenox
4 monopoly profits.

5 8. To eliminate the risk that generic entry would devastate Aggrenox profits and to
6 ensure its monopoly, Boehringer elected to share its monopoly profits with Barr in exchange for
7 Barr's promise to drop its challenge to the '577 Patent and stay out of the market with a less
8 expensive, bioequivalent generic version of Aggrenox for approximately seven years. More
9 specifically, on or about August 11, 2008, Boehringer and Barr entered a non-competition agreement
10 (the "Exclusion Payment Agreement" or "Agreement").

11 9. Under this Agreement, Boehringer agreed to pay Barr in exchange for Barr's
12 commitment to delay marketing generic Aggrenox until as late as July 1, 2015. Boehringer's
13 payment took two forms: (a) cash payments provided under the guise of a co-promotion agreement –
14 an estimated \$120 million in one-time and yearly royalty payments – that far exceed the fair value of
15 the services provided by Barr; and (b) an agreement not to compete against Barr's generic Aggrenox
16 product with Boehringer's own generic Aggrenox product once generic entry belatedly occurs.

17 10. As a result of the Agreement, including the large unjustified payments from
18 Boehringer to Barr provided for therein, Barr (and its successor Teva) did in fact delay marketing less
19 expensive generic Aggrenox, despite having final FDA approval to market generic Aggrenox since
20 August 2009. And once generic entry finally occurred in 2015, Plaintiff still paid artificially inflated
21 prices because the Agreement eliminated inter-generic competition between Boehringer and Barr.
22 The purpose and effect of Boehringer's payments to Barr was to restrain competition in the market
23 for Aggrenox and its AB-rated generic equivalents from the time of possible generic entry through
24 the expiration of the '577 Patent.

25 11. But for the exclusion payments, less expensive, generic versions of Aggrenox would
26 have been available to Plaintiff as early as August 2008. Had Boehringer not paid Barr to drop its
27 challenge to the '577 Patent and stay out of the market, Barr would have launched its less expensive
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1 generic Aggrenox: (a) “at-risk” (*i.e.*, while the patent litigation was pending); (b) upon winning the
2 patent litigation; or (c) pursuant to a lawful settlement agreement without a large unjustified payment
3 from Boehringer to Barr. Absent the Agreement, immediately upon Barr’s launch, Boehringer, as a
4 rational economic actor seeking to recoup lost branded sales, would have launched an authorized
5 generic Aggrenox in competition with Barr, driving down prices even further.

6 12. The Agreement caused Plaintiff to pay substantially more for 25 mg aspirin/200mg
7 extended-release dipyridamole capsules than they would have absent Defendants’ anti-competitive
8 conduct. Defendants have shared in the illicit profits that have resulted from the artificially-inflated
9 prices Plaintiff paid for Aggrenox.

10 13. Defendants’ Exclusion Payment Agreement was designed to and did in fact: (a) delay
11 the entry of less expensive generic versions of Aggrenox; (b) fix, raise, maintain or stabilize the price
12 of 25 mg aspirin/200 mg extended-release dipyridamole capsules; and (c) allocate 100% of the
13 market for 25 mg aspirin/200 mg extended-release dipyridamole capsules to Boehringer for up to
14 seven years. Moreover, once generic Aggrenox entry finally occurred, the Agreement was designed
15 to and did allocate 100% of the generic segment to Barr during the 180-day exclusivity period (July
16 2015 to January 2016) and reduced inter-generic competition for the remainder of the 577 Patent’s
17 term.

18 14. Plaintiff brings this action with respect to its indirect purchases, payments and/or
19 reimbursements for Aggrenox, other than for resale, since August 14, 2008. As a direct and
20 proximate result of their unlawful scheme to keep generic versions of Aggrenox off the market, and
21 in violation of California’s consumer protection laws, Defendants: (a) illegally maintained monopoly
22 power in the market for Aggrenox in the United States since August 14, 2008, and sold Aggrenox at
23 supra-competitive prices; (b) illegally maintained the price of Aggrenox and generic Aggrenox at
24 supra-competitive levels; and (c) caused California users, their insurers, public healthcare providers
25 and other government payors to overpay millions of dollars by depriving them of the benefits of
26 access to less expensive generic versions of Aggrenox.

1 **II. PLAINTIFF'S AUTHORITY**

2 15. Tony Rackauckas, District Attorney of the County of Orange, acting to protect the
3 public as consumers from unlawful and unfair business practices, brings this action in the public
4 interest in the name of the People of the State of California pursuant to section 17200 of the
5 California Business and Professions Code. Plaintiff, by this action, seeks to enjoin Defendants from
6 engaging in the unlawful and unfair business practices alleged herein, and seeks civil penalties and
7 restitution for the Defendants' violations of the above statute.

8 **III. DEFENDANTS**

9 16. Defendant Teva USA, Inc. is a Delaware corporation with its principal place of
10 business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454. Teva USA is a
11 subsidiary of Teva Pharmaceutical Industries, Ltd., a corporation organized and existing under the
12 laws of Israel ("Teva Israel"). Teva USA is the largest generic drug company by sales volume in the
13 United States.

14 17. Defendant Barr Pharmaceuticals Inc. (n/k/a Barr Pharmaceuticals, LLC) is a limited
15 liability company organized under the laws of the state of Delaware, with its principal place of
16 business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Teva purchased Barr
17 Pharmaceuticals Inc. on December 23, 2008.

18 18. Defendant Barr Laboratories, Inc. is a corporation organized under the laws of the state
19 of Delaware, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New
20 Jersey.

21 19. On December 23, 2008, Barr became a wholly-owned subsidiary of Teva.

22 20. Defendant Duramed Pharmaceuticals Inc. is a corporation organized under the laws of
23 the state of Delaware, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff
24 Lake, New Jersey. Until 2008, Duramed was a subsidiary of Barr. In December 2008, when Teva
25 purchased Barr, Duramed became a subsidiary of Teva and is now known as Teva Women's Health
26 Inc.

1 21. Defendant Duramed Pharmaceuticals Sales Corp. is a corporation organized under the
2 laws of the state of Delaware, with a principal place of business at 400 Chestnut Ridge Road,
3 Woodcliff Lake, New Jersey. It was a subsidiary of Barr until December 2008, when it became a
4 subsidiary of Teva.

5 22. Defendant Boehringer Ingelheim Pharma GmbH & Co. KG is a limited partnership
6 organized and existing under the laws of Germany, with its principal place of business at Binger
7 Strasse 173, 55216 Ingelheim, Germany.

8 23. Defendant Boehringer Ingelheim International GmbH is a limited liability company
9 organized and existing under the laws of Germany, having a principal place of business at Binger
10 Strasse 173, 55216 Ingelheim, Germany.

11 24. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a Delaware corporation with
12 its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut.

13 25. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or
14 otherwise, of the defendants sued herein under the fictitious names DOES 1 through 100 inclusive,
15 and they are therefore sued herein pursuant to CCP § 474. Plaintiff will amend this Complaint to
16 show their true names and capacities if and when they are ascertained. Plaintiff is informed and
17 believes, and on such information and belief alleges, that each of the Defendants named as a DOE is
18 responsible in some manner for the events and occurrences alleged in this Complaint and is liable for
19 the relief sought herein.

20 26. All of the Defendants' actions described in this complaint are part of, and were in
21 furtherance of, the illegal restraint of trade alleged herein, and were authorized, ordered, and
22 performed by the Defendants' various officers, agents, employees, or other representatives while
23 actively engaged in the management of the Defendants' affairs, within the course and scope of their
24 duties and employment, and with the actual, apparent or ostensible authority of the Defendants.

25 27. Although not named as Defendants, various other individuals and entities may have
26 participated as co-conspirators with Defendants, and may have engaged in conduct and made
27 statements in furtherance of the conspiracy.

1 **IV. JURISDICTION AND VENUE**

2 28. This Court has jurisdiction over this matter pursuant to the California Constitution,
3 Article XI, Section 10 and California Code of Civil Procedure (“CCP”) section 410.10 because the
4 Defendants transact and have transacted business in California, and the violations of California law
5 complained of herein resulted in damages to consumers of Aggrenox in California, including in the
6 County of Orange.

7 29. Venue is proper in the County of Orange, California, pursuant to CCP section 395,
8 because the Defendants transact and have transacted business in this County, and some of the acts
9 complained of have occurred in this venue.

10 **V. REGULATORY BACKGROUND**

11 **A. Generic Drugs Benefit Purchasers**

12 30. Generic competition allows purchasers at all levels of the pharmaceutical supply chain
13 to purchase both the brand name drug and its generic equivalents at a reduced price. Generic
14 competition to a single branded drug can provide billions of dollars in savings to consumers, insurers,
15 pharmacies, and other drug purchasers.

16 31. Generics that meet all of the requirements for approval are assigned an “AB” rating by
17 the FDA. The AB rating permits the generic drug to be substituted for the brand name drug at the
18 pharmacy counter. All states permit, and some states require, pharmacists to automatically substitute
19 an AB-rated generic drug for the corresponding brand name drug unless the doctor has said that the
20 prescription for the brand name product must be dispensed as written.

21 32. Until a generic manufacturer enters the market, the brand name manufacturer
22 maintains a pure monopoly, and can charge monopoly prices without a material loss in sales volume
23 because the drug faces no competition. It is widely acknowledged that a monopolist’s profit
24 maximizing price exceeds the price that would prevail in a competitive market. With respect to the
25 market for branded pharmaceutical drugs and their AB-rated generic equivalents, the monopoly price
26 is typically far in excess of the competitive price. Brand name drug manufacturers therefore have a
27 strong interest in seeking to restrain generic competition.

1 33. Many third-party payors (such as health insurance plans and Medicaid programs) have
2 adopted policies to encourage the substitution of AB-rated generic drugs for their branded
3 counterparts. And many consumers routinely switch from a branded drug to an AB-rated generic
4 drug once the generic becomes available. AB-rated generic drugs therefore capture a significant
5 share of their branded counterparts' sales, causing a significant reduction in the branded drug's unit
6 and dollar sales.

7 34. The first AB-rated generic drug is typically priced significantly below its branded
8 counterpart. As more AB-rated generics enter the market, the brand and generic drug prices usually
9 continue to decline as the generics compete with one another and the brand name drug.

10 35. The first generic equivalent to reach the market often captures 80% or more of the
11 market within the first six months. Within one year of market entry, the generic often accounts for
12 90% of the branded drug's unit sales and sells for 15% of the price of the brand name drug.

13 **B. The FDA Approval Process**

14 36. Under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), manufacturers who
15 seek to market a new drug must apply for FDA approval to sell the drug by filing a New Drug
16 Application, or NDA. 21 U.S.C. §§ 301-392. NDAs must include specific data concerning the safety
17 and effectiveness of the drug and identify applicable patents. *Id.* at §§ 355(a) & (b).

18 37. When the FDA approves a brand manufacturer's NDA, the brand name manufacturer
19 lists any patents it contends apply to the approved drug in a publication called the "Approved Drug
20 Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21
21 U.S.C. §355(j)(7)(A)(iii). The FDA performs a ministerial duty in listing these patents, and does not
22 confirm the accuracy of the information supplied by the brand manufacturer. After the NDA is
23 approved, the brand manufacturer may list additional patents relating to the drug in the Orange Book.

24 **C. The Government Encourages and Facilitates the Approval of Generic Drugs**
25 **Through the Hatch-Waxman Amendments**

1 38. In 1984, Congress amended the FDCA with the enactment of the Drug Price
2 Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984),
3 known as the Hatch-Waxman Amendments.

4 39. The Hatch-Waxman Amendments simplify the regulatory hurdles that generic
5 manufacturers have to clear to enter the market. Instead of filing a lengthy and costly NDA, the
6 Hatch-Waxman Amendments allow generic manufacturers to seek FDA approval on an expedited
7 basis by filing an Abbreviated New Drug Application, or ANDA.

8 40. If an ANDA applicant shows that the generic drug is “bioequivalent” to the brand
9 name drug—that it contains the same active ingredient(s), dosage form, route of administration, and
10 strength as the brand name drug—then the ANDA may rely on the scientific safety and effectiveness
11 findings included in the brand name drug manufacturer’s original NDA. 21 U.S.C. § 355(j)(2)(A).
12 The FDA must approve an ANDA unless the information submitted in the ANDA is insufficient to
13 meet the Act’s requirements. 21 U.S.C. § 355(j)(4). The streamlined approval process under the
14 Hatch-Waxman Amendments makes it easier for manufacturers to bring competing generic products
15 to the market.

16 41. While Hatch-Waxman seeks to facilitate generic competition, the brand name
17 manufacturer retains the right to enforce any patents associated with the drug. To gain regulatory
18 approval, an ANDA application must also certify that the generic drug will not infringe the brand
19 name drug’s patents listed in the Orange Book, because either: (i) no patents exist on the brand name
20 product; (ii) the patents have expired; (iii) the patents will expire by the time the generic product
21 comes to market; or (iv) the patents are invalid or will not be infringed by the sale of the generic
22 product. See 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). The last certification, that the patents are invalid or
23 not infringed, is known as a “Paragraph IV certification.”

24 42. When a generic manufacturer files a Paragraph IV certification asserting that a patent
25 listed in the Orange Book is invalid or will not be infringed, it must promptly give notice of its
26 certification to both the brand manufacturer and the owner of the patent. If the brand manufacturer
27 files a patent infringement lawsuit against the ANDA filer within 45 days of receiving the Paragraph
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1 IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) 30 months
2 or (b) a court ruling that the patent is invalid or not infringed by the generic manufacturer's ANDA.
3 21 U.S.C. §355(j)(5)(B)(iii). During the 30-month stay, the FDA may grant "tentative approval" to
4 an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final
5 approval, but cannot authorize the generic manufacturer to market its drug before the 30-month stay
6 expires or a court rules on invalidity and infringement.

7 43. Congress also created incentives for drug manufacturers to seek approval of generic
8 alternatives to branded drugs and challenge weak patents. The Hatch-Waxman Amendments grant a
9 180-day period of market exclusivity to the first ANDA applicant to file a substantially complete
10 ANDA containing a Paragraph IV certification. During the 180-day exclusivity period the first filer
11 enjoys temporary freedom from competition from other generic versions of the drug, and is able to
12 sell the generic for a higher price than when multiple generics enter the market. The brand name
13 manufacturer may, however, market its own generic equivalent of the brand name drug (known as an
14 "authorized generic") during the 180-day period.

15 44. The first-filed generic manufacturer can forfeit its right to the 180-day period of
16 exclusivity. This can occur, for example, if the first-filer fails market its product under certain
17 circumstances or fails to receive tentative approval of its ANDA from the FDA within 30 months of
18 filing the ANDA, unless the failure is caused by a change in or review of the requirements for
19 approval of the ANDA.

20 **D. Pharmaceutical Manufacturers Game the Regulatory Structure**

21 45. Because the Hatch-Waxman regulatory scheme automatically delays approval of an
22 ANDA whenever a brand name manufacturer sues the potential generic competitor for patent
23 infringement, brand name manufacturers frequently take aggressive positions in listing patents in the
24 Orange Book, and then bring patent lawsuits against any generic competitor that files an ANDA with
25 a Paragraph IV certification. Brand name manufacturers often sue generics simply to delay generic
26 competition, rather than to enforce valid patents against infringing products.

1 46. In connection with the resolution of patent litigation arising out of Paragraph IV
2 Certifications, brand name manufacturers have also developed a practice of entering into
3 “settlements” in which brand name manufacturer pays off its generic competitors in exchange for a
4 delay in generic competition. These exclusion payment agreements among horizontal competitors
5 not to compete are commonly known as “pay-for-delay” or “reverse payment agreements.” Brand and
6 generic manufacturers execute exclusion payment agreements as purported settlements of patent
7 infringement lawsuits that brand manufacturers file against generic manufacturers. The brand name
8 manufacturer preserves increased profits by keeping its monopoly intact via a payment of some of the
9 monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product.
10 Initially these agreements took the form of a straight cash payment from the brand name
11 manufacturer to the generic competitor. As a result of regulatory scrutiny, congressional
12 investigations, and class action lawsuits, brand name manufacturers and generic competitors have
13 entered into increasingly elaborate agreements in an attempt to mask the fundamentally
14 anticompetitive character of their agreements. Because the profits to be gained by delaying generic
15 competition are so great, however, drug manufacturers retain the incentive to enter into such
16 agreements.

17 47. The first generic filer’s agreement to delay marketing its drug may also prevent other
18 manufacturers of generics from bringing their own products to market. If the first-filed generic
19 manufacturer is eligible for 180-days of marketing exclusivity, no other generic manufacturer can
20 enter the market until the end of the exclusivity period. This “bottlenecking” tactic is known as
21 exclusivity “parking.”

22 **E. Agreements Not to Compete Between the Brand’s Authorized Generic and the**
23 **First-Filing Generic’s Product**

24 48. The 180-day marketing exclusivity to which first-filer generics may be entitled does
25 not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during
26 that 180-day period. Such an authorized generic is chemically identical to the brand drug, but is sold
27 as a generic product through either the brand manufacturer’s subsidiary (if it has one) or through a
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1 third-party generic manufacturer. Boehringer has traditionally marketed its authorized generic
2 products in-house, through its wholly-owned subsidiary Roxane Laboratories, Inc. Competition from
3 an authorized generic during the 180-day exclusivity period substantially reduces the first-filer's
4 revenue, and substantially reduces drug prices for consumers.

5 49. In its recent study, *Authorized Generic Drugs: Short-Term Effects and Long-Term*
6 *Impact* (August 2011) (the "FTC Study"), the Federal Trade Commission ("FTC") found that
7 authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues
8 by approximately 50% on average during the 180-day exclusivity period. The first-filing generic
9 makes significantly less money when it faces competition from an authorized generic because: (a) the
10 authorized generic takes a large share of unit sales away from the first filer; and (b) the presence of an
11 additional generic in the market causes prices to decrease.

12 50. Although first-filing generic manufacturers make significantly less money when they
13 must compete with an authorized generic during the first 180 days, consumers and other drug
14 purchasers such as Plaintiff benefit from the lower prices caused by competition between the
15 authorized generic and the first-filing generic.

16 51. Given the significant negative effect of an authorized generic on the first-filing
17 generic's revenues, a brand manufacturer's agreement not to launch an authorized generic has
18 tremendous value to the generic manufacturer. Brand manufacturers have used such agreements as a
19 way to pay the first-filer to delay entering the market. Such non-competition agreements deprive
20 consumers and other drug purchasers such as Plaintiff of the lower prices resulting from two forms of
21 competition: (a) among the branded and the generic products; and (b) between the generic products.

22 52. Agreements not to compete with an authorized generic can take many forms.
23 According to the FTC Study, one such form includes agreements like the Agreement here whereby
24 the brand manufacturer agrees to exclusively supply the first-filing generic with the authorized
25 generic product. As confirmed by the FTC, the result is the same as if the brand agreed not to launch
26 any authorized generic: no competition between an authorized generic and the first-filing generic's
27 product for a period of time.

1 **VI. FACTS**

2 **A. Boehringer Starts Marketing Aggrenox in December 1999**

3 53. Boehringer developed Aggrenox as a treatment to lower the risk of stroke in people
4 who have had a transient ischemic attack (also known as a ‘mini stroke’) or stroke due to a blood clot.
5 A transient ischemic attack is similar to a stroke, except it usually lasts only a few minutes and does
6 not result in permanent damage. Aggrenox is a single gelatin capsule containing 200mg of extended-
7 release dipyridamole and 25mg of immediate-release acetylsalicylic acid (aspirin). Boehringer has
8 previously marketed dipyridamole as a stand-alone drug under the brand name Persantine to prevent
9 clots from forming after heart valve replacements and aspirin has previously been prescribed for the
10 prevention of strokes. Other drugs prescribed for the prevention of strokes are not AB-rated to
11 Aggrenox, cannot be automatically substituted for Aggrenox by pharmacists, do not exhibit
12 substantial cross-price elasticity of demand with respect to Aggrenox at competitive prices, and thus
13 are not economic substitutes for, nor reasonably interchangeable with, Aggrenox.

14 54. On December 15, 1998, Boehringer filed NDA 20-884 seeking FDA approval to
15 market Aggrenox to help reduce the risk of repeated strokes. The FDA approved the NDA on
16 November 22, 1999.

17 55. In connection with its Aggrenox NDA, Boehringer submitted Patent No. 6,015,577
18 (the ‘577 Patent) to the FDA for listing in the Orange Book. The purported invention described in the
19 ‘577 Patent is a composition of dipyridamole and acetylsalicylic acid for oral administration. The
20 ‘577 Patent is scheduled to expire on January 18, 2017.

21 56. Boehringer began marketing Aggrenox in December 1999. Aggrenox was the only
22 prescription drug for reducing the risk of subsequent stroke through a single aspirin and extended-
23 release dipyridamole capsule. Boehringer represented that studies submitted to the FDA by
24 Boehringer showed that Aggrenox’s combined dipyridamole-aspirin formulation is more effective at
25 reducing the risk of future stroke than administration of either ingredient on its own.

26 57. However, as described in Aggrenox’s FDA-approved labeling, because Aggrenox
27 contains aspirin, Aggrenox can cause fetal harm when administered to a pregnant or nursing woman.

1 Boehringer states on its Aggrenox website that “Aggrenox should be avoided during pregnancy,
2 especially in the third trimester.”

3 58. Aggrenox quickly became a steady source of profits for Boehringer. By 2008
4 Aggrenox sales in the United States had reached \$366 million.

5 **B. Barr Seeks FDA Approval to Market a Generic Equivalent to Aggrenox**

6 59. On February 1, 2007, Barr submitted ANDA 78-804 to the FDA, seeking approval to
7 manufacture, market and sell a generic, bioequivalent version of Aggrenox. Barr was the first
8 manufacturer to submit a substantially complete ANDA for generic Aggrenox with a Paragraph IV
9 certification for the ‘577 Patent. As the first-filing generic, Barr was entitled to 180-days of
10 marketing exclusivity, free from other ANDA-based generic Aggrenox competition.

11 60. On May 31, 2007, Barr notified Boehringer that it had submitted ANDA 78-804 with a
12 Paragraph IV certification regarding the ‘577 Patent, asserting that its generic would not infringe the
13 patent and/or that the patents was invalid or unenforceable.

14 61. On July 11, 2007, Boehringer sued Barr for patent infringement in the United States
15 District Court for the District of Delaware, alleging that Barr’s filing of its ANDA infringed the ‘577
16 patent. Boehringer’s lawsuit triggered an automatic 30-month stay that prohibited the FDA from
17 granting final approval of Barr’s ANDA until the stay expired in November 2009.

18 62. Barr denied the allegations in Boehringer’s complaint, and counterclaimed for
19 declaratory relief of non-infringement, invalidity, and unenforceability of the ‘577 Patent. Barr
20 argued that Boehringer had misrepresented to the United States Patent and Trademark Office the
21 nature and materiality of a prior patent, Patent No. 5,694,024, and its related reference DE-A1-
22 3,515,874. According to Barr, the properly disclosed patent and reference would have made the
23 claims of the ‘577 Patent obvious. In light of these allegations, Barr asked the District Court to find
24 the ‘577 Patent unenforceable.

25 63. The patent lawsuit continued until August 2008 without any substantive rulings.
26 Barr’s defenses and counterclaims, however, were strong. Absent a settlement, the ‘577 Patent was
27 likely to have been adjudicated invalid, unenforceable, and/or not infringed.

1 **C. Boehringer and Barr Enter Into the Exclusion Payment Agreement**

2 64. On August 11, 2008, Boehringer and Barr announced that they had settled the patent
3 litigation and on or about that same time, Boehringer and Barr entered the Exclusion Payment
4 Agreement.

5 65. Under the terms of the Agreement, Boehringer and Barr agreed that Barr would drop
6 its challenges to the ‘577 Patent, delay launching a generic equivalent of Aggrenox until as late as
7 July 1, 2015, and act to preserve its 180-day exclusivity, in order to block other generic
8 manufacturers from entering the market before Barr’s delayed entry. A generic launch date as late as
9 July 2015 effectively preserved 82% of the patent’s remaining life – for which Boehringer was
10 prepared to, and did, pay Barr handsomely.

11 66. As the *quid pro quo* for Barr’s agreement to drop its challenge to the ‘577 Patent and
12 stay out of the market for almost seven years, Boehringer agreed to make cash payments to Barr
13 estimated at \$120 million dollars and to pay other valuable consideration that was as good as cash to
14 Barr. Boehringer’s payments to Barr under the Agreement took at least two forms.

15 67. *First*, Boehringer agreed to pay Barr (through its subsidiary Duramed, now known as
16 Teva Women’s Health) under the guise of co-promotion services related to Aggrenox. For ostensibly
17 promoting anti-stroke drug Aggrenox to obstetricians, gynecologists, and women’s health care
18 professionals from April 2009 and continuing until generic entry in 2015, Boehringer agreed to pay
19 Barr millions in cash upfront plus substantial additional consideration, including annual, increasing
20 royalties on the total U.S. Aggrenox sales. The total value of these payments is an estimated \$120
21 million. The co-promotion agreement was part and parcel of Boehringer and Barr’s settlement, and
22 Boehringer would not have agreed to enter into the co-promotion agreement absent Barr’s agreement
23 to delay entry into the market with generic Aggrenox.

24 68. Boehringer’s continuing payments to Barr under the Co-Promotion Agreement vastly
25 exceeded the fair value of the services provided by Barr and its subsidiaries. Boehringer had no
26 expectation of receiving significant financial benefit during the seven-year delay period from Barr’s
27 promotion of a drug for patients who have suffered strokes to a target group consisting primarily of
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1 gynecologists and obstetricians. Indeed, Boehringer compensated Barr for ostensibly promoting
2 Aggrenox to obstetricians even though Boehringer warns pregnant and nursing women and the
3 doctors treating them not to take or prescribe Aggrenox because it poses a serious risk to fetal health.

4 69. Moreover, Boehringer's payments to Barr under the Agreement are based on a
5 percentage of total U.S. sales, not just on the far smaller percentage of sales resulting from Barr's
6 promotion of anti-stroke drug Aggrenox to obstetricians, gynecologists, and women's health care
7 professionals, as one would expect with a fair value for services promotion agreement. Thus, the vast
8 majority of Boehringer's multi-million dollar payments to Barr could have nothing whatsoever to do
9 with any services purportedly performed by Barr. Boehringer's payments to Barr were purely for
10 delay.

11 70. *Second*, the Agreement provides that Boehringer and Barr would not compete with
12 respect to generic Aggrenox once a generic Aggrenox product finally entered the market. Under the
13 Agreement, Boehringer agreed to exclusively supply Barr with Boehringer's own authorized generic
14 Aggrenox product at below-market rates, and not to supply any third-party with Boehringer's
15 authorized generic product, until the expiration of the '577 Patent. In return, Barr agreed not to
16 launch its own ANDA generic product (for which it received final FDA approval in August 2009)
17 until the expiration of the '577 Patent.

18 71. The purpose and effect of these covenants is (a) no competition between a Boehringer
19 authorized generic product and Barr's ANDA generic product for approximately one and a half years
20 (from generic entry on July 1, 2015 to the end of the patent term on January 18, 2017) and (b) no
21 competition between a Barr generic Aggrenox product and *any other* generic Aggrenox product
22 (including those sold by Boehringer and/or third parties) during Barr's 180-exclusivity period (from
23 generic entry until January 2016). This aspect of the Agreement provides substantial compensation—
24 many millions of dollars—to Barr, which could expect to make approximately double the unit sales,
25 at a much higher price, absent competition between Barr's ANDA generic and Boehringer's
26 authorized generic in the market, particularly during the 180-day exclusivity period. These higher
27 prices come at the expense of Plaintiff and others.

1 72. Boehringer’s large payment to Barr via the exclusive supply and non-competition
2 arrangement is unjustified and far exceeds the fair value of services (if any) provided by Barr.
3 Boehringer had no need to market its authorized generic Aggrenox product through Barr. Boehringer
4 has its own wholly-owned subsidiary, Roxane Laboratories, Inc., through which it has launched at
5 least seven authorized generic versions of its brand name products, including before the Agreement
6 with Barr. Absent Barr’s agreement to delay generic entry, Boehringer would not have agreed to
7 exclusively supply its authorized generic Aggrenox to its competitor Barr. Instead, Boehringer would
8 have launched its authorized generic in competition with Barr. And absent payment from
9 Boehringer, Barr would not have agreed to refrain from launching its ANDA product to market in
10 competition with Boehringer’s product. As Boehringer itself has said: “parties engaged in
11 contentious litigation would not otherwise be willing to do business with each other. . . .”

12 73. Nor was the supply agreement an independent business transaction. The face of the
13 Agreement makes plain that the supply agreement, like the co-promotion agreement, was an integral
14 part of the overall Agreement and consideration for Barr’s agreement to drop its challenge to the ‘577
15 Patent and delay generic entry.

16 74. Taken together, Boehringer’s payments to Barr under the Agreement guaranteed two
17 distinct periods of non-competition: (a) the period before generic competition, whereby Boehringer
18 and Barr agreed to allocate 100% of the market to Boehringer; and (b) the period after generic
19 competition, whereby Boehringer and Barr agreed not to sell competing generic versions of
20 Aggrenox, with the intent to allocate 100% of the generic segment to Barr during the 180-day
21 exclusivity period and reduce inter-generic competition for the duration of the patent term. Under the
22 Agreement, there was no period of unrestrained competition between possible generic entry and the
23 end of the patent term.

24 75. Defendants have no procompetitive explanation or justification for the payments. The
25 total payments flowing from Boehringer to Barr had a cash value far above \$120 million dollars and
26 had no explanation or justification other than to induce Barr to stay out of the Aggrenox market.
27 These large, unjustified payments had no rational connection to, and far exceeds, any approximation
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1 of the costs of continuing the patent litigation. The payment was not consideration for the fair value
2 of services provided from Barr to Boehringer.

3 **D. Teva Acquired Barr and Continued the Unlawful Agreement to Suppress**
4 **Generic Competition**

5 76. The Agreement contemplated that Barr might be acquired by Teva and bound Teva to
6 its terms in the event of such an acquisition.

7 77. On December 23, 2008, Teva acquired Barr by merging the two corporations, Teva, as
8 the surviving entity, assumed liability for the illegal conduct Barr engaged in before the merger and
9 stepped into Barr's shoes with respect to the Exclusion Payment Agreement. Teva had continued to
10 refrain from entering the market with a generic equivalent of Aggrenox. Teva thus joined the
11 ongoing unlawful course of conduct—and joined the unlawful agreements, collusion and
12 conspiracy—to suppress generic competition of Aggrenox. Teva did not withdraw from the
13 conspiracy, and instead continued to participate in it.

14 78. As a result of its merger with Barr, Teva would own (either directly or indirectly)
15 ANDA 78-804 and the 180-day exclusivity period that Barr was entitled to as the first filer.

16 79. Post-acquisition, Teva/Barr continued to pursue approval of ANDA 78-804. On
17 August 14, 2009 the FDA granted final approval of ANDA 78-804 for a generic equivalent of
18 Aggrenox. Because of the Exclusion Payment Agreement, no generic equivalent of Aggrenox was on
19 the market until July 1, 2015.

20 **E. The Unlawful Agreement to Suppress Generic Competition Caused Plaintiff**
21 **Substantial Harm**

22 80. Since the execution of the Agreement and continuing until July 1, 2015, Barr/Teva
23 continuously refused to enter the market with generic Aggrenox despite having FDA approval to do
24 so, and Boehringer continued to pay Barr/Teva for this delayed competition.

25 81. The former lack of generic competition is the direct result of the ongoing unlawful
26 Agreement that began in 2008, and continued through July 1, 2015. Until July 1, 2015, Boehringer
27 continued to sell brand name Aggrenox at artificially inflated prices, and Plaintiff was denied the
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1 lower prices that generic competition would have brought to the market. Moreover, even once a
2 generic, bioequivalent version of Aggrenox entered the market, the Agreement continued to harm
3 Plaintiff by depriving it of the benefits of inter-generic competition.

4 82. But for the anticompetitive and illegal conduct alleged in this complaint, Plaintiff
5 would have had access to less expensive versions of Aggrenox, and would have substituted its
6 purchases of branded Aggrenox with generic Aggrenox, much sooner than it did. The Defendants
7 have injured Plaintiff by causing it to pay substantial overcharges – potentially hundreds of millions
8 of dollars—each time it purchased Aggrenox at artificially inflated prices.

9 **F. Generic Equivalents to Aggrenox Make Delayed Entry into the Market**

10 83. On July 1, 2015, Barr launched its generic equivalent to Aggrenox.

11 84. Upon information and belief, Amneal Pharmaceuticals LLC received final approval for
12 and launched its generic equivalent of Aggrenox on or about March 18, 2016.

13 85. Upon further information and belief, Impax Laboratories Inc. received final approval
14 for and launched its generic equivalent of Aggrenox on or about January 18, 2017.

15 86. Upon further information and belief, Sandoz, Inc. received final approval for and
16 launched its generic equivalent of Aggrenox on or about January 18, 2017.

17 **G. The California Medicaid Program**

18 87. The California Medicaid program is a state-administered program with federal
19 matching funds that pays for medical care, including prescription drug benefits, for California’s low-
20 income and disabled citizens.

21 88. California Medicaid spending in FY 2014 alone was \$492.3 billion.

22 89. California Medicaid currently covers approximately 11,887,524 individuals.

23 90. Prescription drug benefits represent approximately 16% of California Medicaid’s
24 annual budget, or approximately \$78.8 billion.

25 91. California Medicaid reimburses medical providers, including physicians and
26 pharmacists, for drugs prescribed for, and dispensed to, California Medicaid recipients pursuant to
27 statutory and administrative formulas.

1 92. Reimbursement for pharmacy-dispensed prescription drugs under the California
2 Medicaid program is based on information supplied by Defendants. At all times relevant to this
3 action, Defendants were aware of the State of California’s Medicaid drug reimbursement formulas
4 and procedures for pharmacy-dispensed drugs, yet they continued their unlawful conduct in violation
5 of California’s antitrust and consumer protection laws.

6 93. Since August of 2009, Defendants have caused California’s medical assistance
7 programs to pay more for Aggrenox/generic Aggrenox products than they would otherwise have paid.
8 Defendants’ unlawful conduct deprived California’s medical assistance programs of the benefits of
9 competition that California’s antitrust and consumer protection laws are intended to preserve.

10 **VII. MARKET POWER AND MARKET DEFINITION**

11 94. At all relevant times, Boehringer had the power to maintain the price of Aggrenox at
12 supracompetitive levels without losing substantial sales to other products.

13 95. At all relevant times, Boehringer had the power to maintain the price of Aggrenox at
14 supracompetitive levels without losing substantial sales to other products.

15 96. Aggrenox does not exhibit significant, positive cross-elasticity of demand with respect
16 to price with any product other than an AB-rated generic equivalent of Aggrenox.

17 97. Because of its unique profile as a combined aspirin and extended-release dipyridamole
18 treatment for subsequent strokes, Aggrenox is differentiated from all products other than AB-rated
19 generic equivalents of Aggrenox. Aggrenox’s specific ratio of dipyridamole to aspirin and the release
20 formulations of those components also differentiate it from products aside from AB-rated generic
21 equivalents.

22 98. At all relevant times, Boehringer had the power to maintain the price of Aggrenox at
23 supracompetitive levels without losing substantial sales to other products.

24 99. Aggrenox does not exhibit significant, positive cross-elasticity of demand with respect
25 to price with any product other than an AB-rated generic equivalent of Aggrenox.

26 100. Because of its unique profile as a combined aspirin and extended-release
27 dipyridamole treatment for subsequent strokes, Aggrenox is differentiated from all products other
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1 than AB-rated generic equivalents of Aggrenox. Aggrenox’s specific ratio of dipyridamole to aspirin
2 and the release formulations of those components also differentiate it from products aside from AB-
3 rated generic equivalents.

4 101. Boehringer needed to control only Aggrenox (and any AB-rated generic equivalents to
5 Aggrenox), and no other products, to maintain the price of Aggrenox profitably at monopolistic
6 prices. Only the market entry of a competing AB-rated generic equivalent to Aggrenox rendered
7 Boehringer unable to profitably maintain monopoly prices of Aggrenox.

8 102. Boehringer also sold branded Aggrenox at prices well in excess of marginal costs and
9 the competitive price, and enjoyed high profit margins.

10 103. The Defendants had to exercise the power to exclude generic competition to branded
11 Aggrenox.

12 104. At all relevant times, the Defendants enjoyed high barriers to entry with respect to the
13 market for Aggrenox products.

14 105. To the extent that Plaintiff is legally required to define a relevant product market,
15 Plaintiff alleges that the relevant market is all Aggrenox products (i.e., 25 mg aspirin/200 mg
16 extended-release dipyridamole capsules), which includes Aggrenox and AB-rated bioequivalent
17 products.

18 106. Aggrenox is available only by doctor’s prescription. The doctor’s prescription defines
19 the relevant product market, since a prescription for a prescription drug may be filled only with the
20 brand name drug named in the prescription or its AB-rated, FDA-approved generic equivalent. So if a
21 doctor prescribes “Aggrenox,” the prescription could only be filled with brand Aggrenox until an AB-
22 rated bioequivalent became available.

23 107. During the relevant time period, the Defendants were able to profitably maintain the
24 price of Aggrenox well above competitive levels.

25 108. Without the power to exclude and restrict competition to 200 mg extended release
26 dipyridamole I 25 mg acetylsalicylic acid capsules (Aggrenox and AB-rated bioequivalent generics),
27 and ability to sell its own branded version of that drug, Aggrenox, at prices well over marginal costs,
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1 it would not have been economically rational for Boehringer to pay Barr up to \$120 million to delay
2 Barr's launch of its AB-rated generic Aggrenox.

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

4 110. Since 1999, Boehringer had a 100% market share in the relevant market, and
5 continued to have that market share until July 2015.

6 **VIII. MARKET EFFECTS**

7 111. Boehringer began marketing Aggrenox in December 1999. But, as a result of the
8 Agreement, no generic equivalent of Aggrenox was available for purchase in the United States until
9 July 2015.

10 112. Defendants' unlawful Exclusion Payment Agreement was designed to and did in fact:
11 (a) preclude the entry of less expensive generic versions of Aggrenox products in the United States
12 and its territories; (b) fix, raise, maintain or stabilize the price of 25 mg aspirin/200 mg extended-
13 release dipyridamole capsules; and (c) allocate 100% of the United States and its territories 25 mg
14 aspirin/200 mg extended-release dipyridamole capsules market to Boehringer. Moreover, once
15 generic Aggrenox entry finally occurred in July 2015, Defendants' Agreement was designed to and
16 did allocate 100% of the generic segment to Barr during the 180-day exclusivity period and reduced
17 inter-generic competition for the remainder of the 577 Patent's term.

18 113. Barr's generic Aggrenox ANDA received final FDA approval on August 14, 2009.
19 But for the unlawful Exclusion Payment Agreement, Barr would have entered the market as early as
20 August 11, 2008, or at the latest by November 30, 2009 through: (a) an "at risk" launch upon
21 receiving final FDA approval following the expiration of the 30-month stay; (b) earlier licensed entry
22 via a lawful agreement with Boehringer that did not include unlawful payments to Barr; or (c) by
23 winning the '577 Patent litigation.

24 114. It is well-known in the industry that due to its substantial resources Teva has a long
25 history of "at risk" launches, including thirteen such launches between 2004 and 2008 alone. Many
26 of Teva's "at risk" launches involved products with annual sales less than \$500 million. It is also
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1 well-known in the industry that “at risk” launches are particularly likely when, like here, a company
2 with a history of “at risk” launches is the first-filing generic.

3 115. Absent an “at risk” launch, but for the large unjustified payments Boehringer made to
4 Barr in exchange for Barr’s agreement to delay launching generic Aggrenox, Defendants would have
5 agreed to an unrestrained licensed entry date significantly earlier than July 1, 2015. Without the
6 payments, which were the *quid pro quo* for the delay (and absent an at risk launch or litigation
7 victory), Barr would have insisted on and received earlier, unrestrained licensed entry.

8 116. In addition, but for the Agreement, Boehringer, as a rational economic actor seeking to
9 recoup lost branded sales, would have launched an authorized, bioequivalent generic version of
10 Aggrenox simultaneously with the launch of Barr’s bioequivalent generic version of Aggrenox, as it
11 has done numerous times, pushing generic prices lower. Indeed, Boehringer, through its wholly-
12 owned subsidiary Roxane Laboratories, Inc., has launched authorized generic versions of at least
13 seven of its brand drug products, including before the Agreement. Boehringer’s launch of authorized
14 generic products through Roxane include, but are not limited to: Atrovent, Metaprel, Micardis,
15 Micardis HCT, Mobic, Persantine, and Viramune.

16 117. But for the Defendants’ illegal conduct, generic competition would have forced a
17 decrease in the price of branded Aggrenox, and price competition among the suppliers of branded and
18 generic Aggrenox would have been intense.

19 118. But for the Defendants’ illegal conduct, Plaintiff would have paid less for Aggrenox or
20 a generic equivalent. The Defendants’ conduct directly injured Plaintiff because it forced Plaintiff to
21 pay millions of dollars in overcharges on its Aggrenox purchases and has forced Plaintiff to pay
22 artificially inflated prices for generic Aggrenox as a result of the non-competition agreement between
23 Boehringer and Barr.

24 119. As a result of the delay in generic competition brought about by the Defendants’
25 anticompetitive scheme, Plaintiff paid more for Aggrenox products than they would have paid absent
26 the Defendants’ illegal conduct.

1 126. Defendants’ efforts to restrain competition in the market for Aggrenox have
2 substantially affected interstate and foreign commerce.

3 127. At all material times, Boehringer manufactured, promoted, distributed, and sold
4 substantial amounts of Aggrenox in a continuous and uninterrupted flow of commerce within
5 California.

6 128. Defendants’ anticompetitive conduct had substantial effects within California. Among
7 other things, retailers within each state were foreclosed from offering less expensive generic,
8 bioequivalent versions of Aggrenox to purchasers. This directly impacted commerce for consumers
9 and third-party payors, such as California purchasers.

10 129. At all material times, Defendants transmitted funds and contracts, invoices, and other
11 forms of business communications and transactions in a continuous and uninterrupted flow of
12 commerce across and within California in connection with the sale of Aggrenox.

13 130. General economic theory recognizes that any overcharge at a higher level of
14 distribution generally results in higher prices at every level below. *See* Hovenkamp, *Federal Antitrust*
15 *Policy: The Law of Competition and Its Practice* (1994) at 624. Professor Hovenkamp explains that
16 “[e]very person at every stage in the chain will be poorer” as a result of the anticompetitive price at
17 the top. He also says that “[t]heoretically, one can calculate the percentage of any overcharge that a
18 firm at one distribution level will pass on to those at the next level.”

19 131. The institutional structure of pricing and regulation in the pharmaceutical drug
20 industry ensures that overcharges at the higher level of distribution are passed on to end-payors.
21 Wholesalers and retailers passed on the inflated prices of Aggrenox to consumers and third-party
22 payors.

23 132. Defendants’ anticompetitive conduct enabled Defendants to indirectly charge
24 consumers and third-party payors prices in excess of what they otherwise would have been able to
25 charge absent the Defendants’ unlawful actions.

26 133. The prices were inflated as a direct and foreseeable result of Defendants’
27 anticompetitive conduct.

1 138. California Aggrenox users, their insurers, public healthcare providers and other
2 government payors could not, by the exercise of reasonable diligence, have discovered the wrongful
3 cause of the injuries at an earlier time because the injuries were caused without perceptible harm.
4 Without actual knowledge of the content and persistent effect of the anticompetitive agreements,
5 there was simply no way to discern that the price of Aggrenox was higher than it otherwise would or
6 should have been. Furthermore, even were the harm perceptible, its cause remained unknowable in
7 the absence of such actual knowledge. In addition, where Aggrenox consumers relied on other
8 healthcare providers, these providers had similarly relied upon both the proper functioning of the
9 pharmaceutical market and the defendants' misrepresentations regarding the patents.

10 139. California Aggrenox users, their insurers, public healthcare providers and other
11 government payors, as represented here by Tony Rackauckas, District Attorney of the County of
12 Orange, were not aware of the Defendants' wrongful conduct, the tortious and unlawful nature of the
13 conduct, and the harm to California consumers and others caused by Defendants' conduct, until
14 January 31, 2017 when the unlawful agreements and the facts which form the basis for Plaintiffs'
15 Complaint were first brought to the attention of the Office of the District Attorney's Consumer
16 Protection Unit.

17 **XI. CONTINUING VIOLATIONS**

18 140. This Complaint alleges a continuing course of conduct (including conduct within the
19 limitations periods), and Defendants' unlawful conduct has included continuing and accumulating
20 harm within the applicable statutes of limitations. Thus, Plaintiff can recover damages they suffered
21 during the applicable limitations periods.

22 141. The most obvious continuing violation is Defendants' charging of supracompetitive
23 prices to Plaintiff within the limitations periods. Every time Plaintiff was overcharged for branded
24 Aggrenox, Plaintiff suffered a cognizable injury. In addition to inflicting overcharges, Defendants
25 committed additional overt acts constituting continuing violations, including without limitation:

- 26 a. Teva/Barr's continuous refusal to enter the market until July 2015. Teva/Barr
27 continually adhered to the Exclusion Payment Agreement by refusing to launch generic
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1 Aggrenox before July 1, 2015. This continuous refusal to enter the market constitutes an
2 ongoing series of overt acts that continually re-set the statute of limitations.

3 b. Boehringer's refraining from launching a competing generic. Similar to
4 Teva/Barr's refusal to enter the market is Boehringer's refraining from launching a
5 competing generic. This refusal to enter with a competing generic results in Plaintiff
6 incurring additional overcharges.

7 c. Boehringer's continuing payments under the Co-Promotion Agreement. Each
8 payment to Teva/Barr pursuant to the Co-Promotion Agreement constitutes an overt act
9 justifying the application of the continuing violation doctrine. These payments, which
10 occur quarterly, are based on annual increasing royalties on the total U.S. Aggrenox sales
11 through July 1, 2015.

12 142. As co-conspirators, Defendants share responsibility for each of these continuing
13 violations.

14 **XII. CAUSES OF ACTION**

15 **FIRST CAUSE OF ACTION**

16 **UNFAIR COMPETITION**

17 **Violation of Business and Professions Code Section 17200, et seq.**

18 **(Against all Defendants)**

19 143. The People reallege and incorporate by reference each of the allegations contained in
20 the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

21 144. Business and Professions Code Section 17200 (Section 17200) prohibits any
22 "unlawful, unfair or fraudulent business act or practice[]." Defendants have engaged in unlawful and
23 unfair business practices in violation of Section 17200 as set forth above.

24 145. Defendants' business practices as described in this Complaint constitute unlawful
25 business acts and practices within the meaning of California Business and Professions Code section
26 17200. Defendants' unlawful business acts and practices as alleged herein have violated federal,
27 state, statutory and/or common laws - and said predicate acts are therefore per se violations of section
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1 17200. These predicate unlawful business acts and practices include, but are not limited to, the
2 following antitrust laws: California Business and Professions Code section 16700 et seq. (“the
3 Cartwright Act”), The Sherman Antitrust Act, 15 U.S.C. §§ 1–7, The Clayton Antitrust Act, 15
4 U.S.C. §§ 12-27, and the Federal Trade Commission Act, 15 U.S.C. § 45.

5 146. Defendants’ business practices as described in this Complaint are unfair and violate
6 Section 17200 because they offend established public policy, are substantially injurious to consumers,
7 and because the harm they cause to consumers and purchasers in California greatly outweighs any
8 benefits associated with those practices and the Defendants’ reasons, justifications, and motives for
9 the practices. The business acts and practices described above are also unfair in that they violate and
10 threaten incipient violations of the aforementioned antitrust laws and violate the policy or spirit of
11 these laws because their effects are comparable to or the same as a violation of these laws, and
12 significantly threaten and harm competition.

13 147. As a direct and proximate result of the foregoing acts and practices, Defendants have
14 received income, profits, and other benefits, which they would not have received if they had not
15 engaged in the violations of Section 17200 described in this Complaint. The People therefore seek
16 restitution from Defendants pursuant to Business & Professions Code Section 17203.

17 148. As a direct and proximate result of the foregoing acts and practices, Defendants have
18 obtained an unfair advantage over similar businesses that have not engaged in such practices.


19 149. Each sale of Aggrenox in violation of Section 17200 constitutes a separate violation.
20 Business & Professions Code § 17206(b). The People therefore seek civil penalties up to \$2,500 per
21 violation pursuant to Section 17206 for each violation of Section 17200. The People also seek civil
22 penalties up to \$2,500 per violation under Section 17206.1.

23 150. Each sale of Aggrenox in violation of Section 17200 constitutes a separate violation.
24 Business & Professions Code § 17206(b). The People therefore seek civil penalties up to \$2,500 per
25 violation pursuant to Section 17206 for each violation of Section 17200. The People also seek civil
26 penalties up to \$2,500 per violation under Section 17206.1.

- 1 F. Order Defendants to pay the cost of the suit, including attorneys' fees.
2 G. Provide such further and additional relief as the Court deems proper.
3

4 Dated: April 10, 2017

ORANGE COUNTY DISTRICT ATTORNEY

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