UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

IN RE: SENSIPAR (CINACALCET HYDROCHLORIDE TABLETS) ANTITRUST LITIGATION	C.A. No. 19-md-02895-LPS
THIS DOCUMENT RELATES TO: ALL DIRECT PURCHASER ACTIONS	 C.A. No. 19-396-LPS C.A. No. 19-1460-LPS **CONSOLIDATED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED** **CONFIDENTIAL FILED UNDER SEAL**

CONSOLIDATED CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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I. INTRODUCTION

1. Plaintiffs César Castillo, Inc. ("CCI") and KPH Healthcare Services, Inc., a/k/a. Kinney Drugs, Inc. ("KPH") (together, "Plaintiffs"), bring this action on behalf of themselves and all others similarly situated, against Amgen Inc. ("Amgen"), Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., and Actavis Pharma, Inc. (collectively, "Teva" and together with Amgen, the "Defendants"),[1] based on personal knowledge as to themselves and upon information and belief as to all other allegations, and allege as follows.

II. NATURE OF THE ACTION

2. This is a civil antitrust action seeking treble damages arising out of the Defendants' unlawful scheme to allocate the market for cinacalcet hydrochloride tablets that Amgen sells under the brand name "Sensipar." As described below, Defendant Amgen and the Teva Defendants engaged in an anticompetitive scheme that had the purpose and effect of delaying the entry of lower-priced generic cinacalcet hydrochloride into the market (as defined in this Complaint). The Defendants' market-allocation scheme injured Plaintiffs and the class of direct purchasers that Plaintiffs seek to represent, causing them to pay overcharges.

3. Cinacalcet hydrochloride is a calcium-sensing receptor agonist indicated for secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease on dialysis. It is also indicated for the treatment of hypercalcemia in adult patients with parathyroid carcinoma, and for treating severe hypercalcemia in adult patients with primary HPT who are

[1] Watson Laboratories, Inc. and Actavis Pharma, Inc. are referred to herein, collectively, as "Watson." Watson was acquired by Teva in 2016.

unable to undergo parathyroidectomy. Cinacalcet hydrochloride is available as an oral therapy in 30 mg, 60 mg, and 90 mg strength tablets.[2]

4. Amgen has sold cinacalcet hydrochloride under the brand name "Sensipar" in the United States since 2004.

5. Sensipar is a blockbuster drug – one of Amgen's top-selling drugs and one of the top-selling drugs in the United States – with U.S. brand sales for Amgen of over $1 billion annually since 2015.

6. Generic competition was likely to begin immediately after Amgen's drug substance patent – U.S. Patent No. 6,011,068 ("the '068 Patent") – expired on March 8, 2018.

7. Generic manufacturers were eager to bring a generic version of cinacalcet hydrochloride to market upon the expiry of the '068 patent. Indeed, by January 2016, at least seven generic drug manufacturers had filed Abbreviated New Drug Applications ("ANDAs") with the U.S. Food and Drug Administration ("FDA") seeking regulatory approval to manufacture, use and/or sell generic versions of Sensipar in the United States;

8. In June 2016, Amgen obtained a new patent purportedly covering Sensipar, U.S. Patent No. 9,375,405 ("the '405 patent"). This patent could theoretically (if it was found valid, enforceable and infringed), provide Amgen with market protection for Sensipar until September 22, 2026. But the '405 patent had problems, and generics quickly set about designing around it.

9. Between August 3, 2016 and June 9, 2017, at least eighteen generic manufacturers' ANDAs provided certifications ("Paragraph IV certifications") to the FDA and Amgen that the '405 patent was invalid, unenforceable, or would not be infringed by the commercial manufacture, use, or sale of the respective generic manufacturers' cinacalcet

[2] *See* Poon G. "Cinacalcet hydrochloride (Sensipar)." *Proc. (Bayl. Univ. Med. Cent.)* 2005;18(2), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1200722/.

hydrochloride generic products. By June 2017 over twenty ANDAs were pending, and all were challenging the '405 patent.[3]

10. Amgen was (and is) highly motivated to quash all generic competition for Sensipar. Beginning in September 2016, to avoid its potential loss of market exclusivity for cinacalcet hydrochloride on March 8, 2018 (when its '068 patent would expire), Amgen filed patent infringement lawsuits in federal district courts against each of 20 generic drug manufacturers vying for FDA approval to bring their generic versions of cinacalcet hydrochloride to market.

11. Amgen's lawsuits alleged that each of the generic manufacturers' generic cinacalcet hydrochloride products would infringe its '405 patent. Amgen sought to enjoin every defendant generic cinacalcet hydrochloride manufacturer from bringing its generic product to market prior to 2026 – the expiry date for the '405 patent.

12. Each of the generic manufacturers responded seeking, among other relief, invalidity and non-infringement rulings. Under the circumstances here, no potential generic

[3] Those generic drug manufacturers include: Accord Healthcare and Intas Pharmaceuticals ("Accord"); Ajanta Pharma, Ltd. and Ajanta Pharma USA, Inc. ("Ajanta"); Alkem Laboratories Ltd ("Alkem"); Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Co. India Private Ltd. ("Amneal"); Apotex Inc. and Apotex Corp. ("Apotex"); Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. ("Aurobindo"); Breckenridge Pharmaceutical, Inc. ("Breckinridge"); Cipla Limited and Cipla USA, Inc. ("Cipla"); Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's"); Emcure Pharmaceuticals Ltd. ("Emcure"); Heritage Pharmaceuticals Inc. and Heritage Pharma Labs, Inc. ("Heritage"); Hetero USA Inc., Hetero Labs Ltd. and Hetero Labs Ltd. Unit V ("Hetero"); Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin"); Macleods Pharmaceuticals Ltd., Macleods, and Macleods Pharma USA Inc. ("Macleods"); Micro Labs Ltd. and Micro Labs USA Inc. ("Micro Labs"); Mylan Pharmaceuticals, Inc. and Mylan, Inc.; Piramal Healthcare UK Ltd. "Mylan"); Strides Pharma Global PTE Ltd. and Strides Pharma, Inc. ("Strides"); Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. ("Sun Pharma"); Teva Pharmaceuticals, USA, Inc. and Barr Pharmaceuticals; Watson Laboratories, Inc., Actavis, Inc., and Actavis Pharma, Inc.; Torrent Pharmaceuticals Ltd.; and Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. ("Zydus").

entrant had first-to-file exclusivity (which would require other generics to await the expiration of a 180-day exclusivity period). As a result, given the large numbers of potential generic makers and if acting independently, each of the potential generic entrants had the self-interested incentive to enter the market at the earliest potential time, ahead of as many of the others as it could. Doing so would enable it to enter before others, gain more market share, and compete with fewer generics on price than they otherwise would. However, if incentives to do so were undermined—for example, [redacted]—then efforts by generics to gain early market entry would diminish.

13. But a year later (in the fall of 2017), Amgen strategically began settling with some, typically smaller generic manufacturers under terms that were designed to, and did, have the effect of undermining incentives for other generic makers to enter the market for cinacalcet hydrochloride. The settlements contained two features that enabled Amgen to use the settlements—then and with future generic cinacalcet hydrochloride efforts—in an anticompetitive manner.

14. First, Amgen repeatedly incorporated clauses in the agreed entry date provisions of the [redacted]—was sufficient to undermine

the incentives for any individual generic manufacturer to do so, and for each to be content to accept an industry-coordinated, later entry date.

15. These clauses are sometimes called [redacted] While the clause allowed a generic [redacted] They were instead designed to deter generic drug manufacturers from entering the market before Amgen's preferred entry dates. [redacted] so as to enter the market and commence true generic competition.

16. Second, [redacted]

17. During the same period, Amgen received unfavorable rulings concerning the '405 patent. In February 2018, the FDA denied Amgen's application for an additional six months of pediatric exclusivity.

18. Also in February 2018, a federal district court rejected certain of Amgen's requested constructions of its '405 patent claims.

19. With billions of dollars in sales revenue dependent on maintaining its market exclusivity, Amgen continued to enter into delay agreements, [redacted]

20. Amgen structured its settlements so as to diminish the incentive for any single generic manufacturer to enter the market and trigger full generic competition. Instead, the settlements were designed to ensure that full generic competition would not begin until a delayed agreed-upon date, regardless of when any generic obtained FDA Final Approval.

21. In July 2018, after a bench trial on Amgen's '405 infringement claims against four generic manufacturers, Judge Mitchell Goldberg ruled that three generic manufacturers' generic products – Watson, Piramal and Amneal – did not infringe the '405 patent ("Non-Infringement Judgments"). Judge Goldberg also ruled that the generic product of a fourth manufacturer, Zydus, infringed some, but not all, of the '405 patent claims at issue. Appeals of these rulings by Amgen and Zydus are pending.

22. On December 27, 2018, Teva – which owned the rights to Watson's non-infringing ANDA and had not settled with Amgen – received FDA Final Approval for a generic cinacalcet hydrochloride product.

23. Teva immediately launched its generic cinacalcet hydrochloride product, including products with the label below. The launch was at-risk (*i.e.*, while the litigation was still pending) due to Amgen's pending appeal.

24. During the week that followed its launch, Teva flooded the market with [redacted] worth of product sales, reaping over [redacted] in revenue in just seven days. With Teva now competing in the market, Amgen had a choice; (1) it could follow the law by either accepting the entry and [redacted] or by seeking to enjoin Teva from selling its generic; or (2) it could violate antitrust law, and orchestrate a market allocation with Teva. Amgen chose the latter.

25. On or about January 2, 2019, [redacted] Amgen and Teva (then horizontal competitors) announced that they had entered into a settlement agreement (the "Amgen-Teva Delay Agreement") to delay additional sales of Teva's generic cinacalcet hydrochloride until [redacted] Teva then ceased selling its generic product. Teva is estimated to have realized approximately $213 million in net revenue as a result of its six-day generic product launch.

26. Also pursuant to the Amgen-Teva Delay Agreement, Amgen and Teva agreed to allocate the profits Teva had made during its one-week of sales. Teva agreed to pay Amgen up to $40 million of the profits that Teva made during the one-week when it was the sole generic in

the market. This represented only a fraction of the hundreds of millions of dollars Teva actually made launching at risk for just six days, and was merely intended to give the settlement agreement with Amgen a veneer of legitimacy. In fact, Amgen effectively paid Teva to stay off the market by allowing it, *inter alia*, to retain hundreds of millions in sales revenue from its generic product.

27. Teva and Amgen also agreed to seek a vacatur of Judge Goldberg's non-infringement judgment on the Watson ANDA. On January 8, 2019, Amgen and Teva jointly moved the court to issue an Indicative Ruling informing the Appeals Court that if it remands that portion of the Non-Infringement Judgments pertaining to the Watson ANDA, the district court will vacate it, and replace it with Teva and Amgen's consent decree declaring that the Watson ANDA infringes Amgen's '405 patent.

28. This was a remarkable step, given that Teva (and before its acquisition by Teva, Watson) had spent *millions* of dollars and litigated for *years* to obtain the exact *opposite* ruling. In March 2019, Judge Goldberg denied Defendants' request to vacate his prior judgment.[4]

29. Meanwhile, on January 10, 2019, a prior settling generic, Cipla, stated in a letter to the court that the Amgen-Teva Delay Agreement "is anticompetitive, has far-reaching consequences, and raises important legal questions that are not rightly swept under the rug."[5] Within days, Cipla filed a lawsuit alleging antitrust claims against Amgen. Prior settling generic manufacturers, Mylan and Sun Pharma, have also contested the Amgen-Teva Delay Agreement

[4] *See Amgen Inc. v. Amneal Pharms. LLC*, C.A. No. 16-853, D.I. 439 (D. Del. Mar. 26, 2019). Amgen and Teva have both appealed this ruling to the Federal Circuit (Appeal No. 19-1650).

[5] Letter from M. Farnan to The Honorable Mitchell S. Goldberg, dated January 10, 2019, *Amgen Inc. v. Amneal Pharm.*, No. 1:16-cv-00853 (D. Del.) (ECF No. 414).

through letters and filings to the district court from which Amgen and Teva requested the Indicative Ruling.

30. Cipla subsequently launched its own generic. Amgen responded by alleging counterclaims against Cipla and seeking a preliminary injunction precluding Cipla from selling its product. In the course of that proceeding, Amgen's executives and experts submitted declarations stating the effects that the launch of Cipla's generic would have on Amgen's Sensipar revenues and market share. [redacted]

And even if Amgen was ultimately successful in arresting generic Sensipar sales at some later date, [redacted]

31. But for Amgen and Teva's anticompetitive scheme and agreement, and Amgen's scheme involving the various generic settlements, one or more generic manufacturers could have entered the cinacalcet hydrochloride market with a generic version of Sensipar as early as March 8, 2018. As a result, less expensive generic cinacalcet would have been available as early as

March 8, 2018, and Plaintiffs and the members of the class would have substituted the less expensive generic products for their purchases of branded Sensipar.

32. Defendants' unlawful scheme and agreements were designed to and did in fact: (a) delay the entry of less expensive, AB-rated generic versions of cinacalcet hydrochloride; (b) fix, raise, maintain or stabilize the price of Sensipar; and (c) dis-incentivize generic manufacturers from commencing full generic competition.

33. By inducing Teva to quickly withdraw its generic Sensipar from the market, and thereby restrict the ability of other generics to enter the market and commence full generic competition, Amgen was able to secure at least $865 million of additional sales.

34. As alleged in more detail below, Defendants violated sections 1 and 2 of the Sherman Act through their conspiracy to improperly restrain trade by foreclosing competition from lower-priced, AB-rated generic versions of Sensipar.

III. PARTIES

35. Plaintiff CCI is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business located at Bo. Quebradas Arena, Rd. #1 Km. 26.0, Rio Piedras, Puerto Rico, 00926. During the Class Period (as defined below), CCI purchased branded Sensipar directly from Amgen at supracompetitive prices, and therefore suffered an antitrust injury as a result of the anticompetitive conduct alleged herein. Absent the unlawful conduct alleged herein, CCI would have purchased less expensive generic alternatives, rather than branded Sensipar.

36. Plaintiff KPH is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH is the assignee of McKesson Corporation, who directly purchased Sensipar from Amgen during the Class Period. As a result of Amgen's

alleged anticompetitive conduct, KPH paid supracompetitive prices for its Sensipar purchases and KPH was injured by the illegal conduct alleged herein.

37. Defendant Amgen is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1 Amgen Center Drive, Thousand Oaks, California 91320-1779. Amgen engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this judicial district.

38. Defendant Watson Laboratories, Inc. is a company organized and existing under the laws of Nevada, having its principal place of business at 311 Bonnie Circle, Corona, California 92880. Watson Laboratories is the owner of the ANDA 204377 which is the subject of the Amgen-Teva Delay Agreement and referenced herein as the "Watson ANDA."

39. Defendants Actavis Pharma, Inc. and Watson Laboratories, Inc., as noted above, are collectively referred to herein as "Watson." Watson was acquired by Teva in 2016 and is engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this District.

40. Defendant Teva Pharmaceuticals USA, Inc. is a company organized and existing under the laws of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.

41. All of the Defendants' wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization scheme and restraint of trade alleged herein. These actions were authorized, ordered, and/or undertaken by the Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their

duties and employment and/or with their actual, apparent, or ostensible authority of the Defendants.

IV. JURISDICTION AND VENUE

42. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by Plaintiffs and members of the class (defined below) resulting from the following: (i) the Defendants' unlawful monopolization of the United States market for cinacalcet hydrochloride; and (ii) the Defendants' conspiracy to restrain trade in the United States market for cinacalcet hydrochloride and its generic equivalents.

43. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1332(d), § 1337(a), 1407, and 15 U.S.C. § 15.

44. Venue is proper in this District under 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because the Defendants transact business within this District and/or have agents in and/or that can be found in this District.

45. This Court has personal jurisdiction over each Defendant. The Defendants have transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at, and has had the intended effect of causing injury to, individuals and companies residing in or doing business throughout the United States, including in this District.

46. During the Class Period, Amgen manufactured, sold and shipped Sensipar in a continuous and uninterrupted flow of interstate commerce. The conspiracy in which the Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

47. During the Class Period, Defendants, or one or more of their affiliates, used the instrumentalities of interstate commerce to join or effectuate its scheme.

V. INDUSTRY BACKGROUND

48. Drug companies obtain patents that cover their new prescription drug products.

49. Valid patents provide a limited protection from competition by other drug companies for a fixed period of time.

50. The health and welfare of millions of Americans depends on access to safe, effective, and affordable medications. Modern medicine treats chronic conditions and prevents serious illnesses with maintenance prescription drugs – drugs that are taken for many months or years. The high cost of drugs can mean no treatment, or inadequate treatment, for many. Affordable drugs lead to better treatment and prevention.

51. On the other hand, the American pharmaceutical industry is a business. Companies that sell brand name drugs seek to recoup their research and development investment, cover their marketing costs, and turn a profit for their shareholders.

52. To accommodate these economic concerns, brand name drugs have a statutory period of time to charge very high prices for medications that cost little to manufacture. Once the lawful exclusivity period expires, generic manufacturers may get FDA approval to manufacture and sell a generic drug that is as safe and effective as the brand name drug, but far less expensive than the brand.

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

53. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and

effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

54. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may list in the Orange Book, within thirty days of issuance, any patents issued after the FDA approved the NDA.[6]

55. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments.

56. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[7] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is

[6] 21 U.S.C. §§ 355(b)(1) & (c)(2).

[7] *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

57. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart.[8]

58. Congress enacted the Hatch-Waxman Amendments to expedite the entry of less expensive generic competitors to branded drugs, thereby reducing healthcare expenses nationwide.

59. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

60. 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 manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue had soared to $300 billion.

[8] 21 U.S.C. § 355(j)(8)(B).

2. ANDA Paragraph IV Certifications.

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

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

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

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

d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").[9]

62. If a generic manufacturer files a Paragraph IV certification as to a patent that is listed in the Orange Book at the time the ANDA is filed, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five 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, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA.[10] Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. 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.

[9] 21 U.S.C. § 355(j)(2)(A)(vii).

[10] 21 U.S.C. § 355(j)(5)(B)(iii).

63. Often, a brand company will try to extend its monopoly by obtaining additional patents. And sometimes, such new patents are obtained or listed in the Orange Book *after* an ANDA has already been filed. In such circumstances, the generic whose ANDA is pending must updated its ANDA and submit a patent certification to the new patent. If this certification contains a Paragraph IV certification the brand company is still entitled to file a lawsuit against the generic, but they are not entitled to a 30-month stay as to that filing. (This process was designed, at least in part, to prevent brand companies from stacking 30-month stays and indefinitely delaying generic competition.)

3. There are tremendous economic incentives to be the sole generic in the market.

64. To encourage manufacturers to seek approval of generic versions of branded drugs, the Hatch-Waxman Amendments grant the first paragraph IV generic manufacturer ANDA filer ("first filer") a 180 day exclusivity period to market the generic version of the drug.[11] So, when a first filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the branded product are either invalid or not infringed by the generic's product, the FDA cannot approve a later generic company's ANDA until that first generic has been on the market for 180 days, or until its first-filer exclusivity has been forfeited. First filers that wait until all Orange Book listed patents expire before marketing their product do not get the 180-day exclusivity. Congress created this 180-day window to incentivize generic manufacturers to challenge weak or invalid patents, or to invent around such patents by creating non-infringing generics.

65. This 180-day window is referred to as the first filer's six-month or 180-day "exclusivity period." The label is a bit of a misnomer because, while later ANDA filers must

[11] 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D).

wait six months after the first filer's market entry to get final FDA approval, a brand's "authorized" generic may enter at any time; this market dynamic is described below. Nevertheless, the Supreme Court has recognized that "this 180 day period of exclusivity can prove valuable, possibly worth several hundred million dollars"[12] to the first filer.

66. In some circumstances, even if a generic filer is not entitled to first-to-file regulatory exclusivity, it may enjoy a period of de facto "exclusivity" that protects it from competition with other ANDA filers. This may be due to a variety of factors, such as where the FDA has not yet approved any other ANDAs or where other generics have agreed with the brand company to delay their entry. In those circumstances, that period of de facto exclusivity is just as valuable as the Hatch-Waxman provided 180 day exclusivity, but it may last for more or less than 180 days.

67. That is what happened in this case. No generic was entitled to 180 days of marketing exclusivity for generic Sensipar. Nor was Amgen entitled to a 30-month stay of the FDA's approval of any generic Sensipar ANDA. Consequently, upon receiving FDA final approval for its ANDA, any generic manufacturer could launch its generic version of Sensipar.

B. The Competitive Effects of AB-Rated Generic Competition.

68. 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 branded 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 counterparts when there is a

[12] *FTC v. Actavis*, 133 S. Ct. 2223, 2229 (2013) (citation omitted).

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 for all drug purchasers.

69. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise). 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 branded drug, often capturing 80% or more of the market within the first six months. 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 Amgen, as a grave threat to their bottom lines.

70. 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.

71. 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 Amgen, are well aware of generics' rapid erosion of their brand sales.

Branded manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible – including illegal means.

1. The First AB-rated Generic is Priced Below the Brand.

72. Periods of actual or *de facto* generic exclusivity are extremely valuable to any generic entrant – likely far more than twice as valuable – if the brand does not launch an authorized generic during this time. Without an authorized generic, a sole generic selling in the market is left with 100% of generic sales until a second ANDA filer generic manufacturer launches.

73. Experience and economic research show that the first generic manufacturer to launch prices its product below the prices of its branded counterpart.[13] Every state either requires or permits that a prescription written for the branded drug 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. At the same time, there is a reduction in average price paid for a prescription for the molecule.

74. During the regulatory or *de facto* exclusivity period, there is only one ANDA-approved generic manufacturer on the market. As recognized by the Supreme Court, it is often the case that most of a generics profits are earned during such exclusivity period.[14]

75. If there is no authorized generic on the market, then the sole generic prices its product below the brand product, but not as low as if it were facing generic competition. Since in these circumstances the sole generic's product competes only with the brand, and because the

[13] Saha, A., Grabowski, H., Birnbaum, H., Greenberg, P., Bizan, O. (February 2006). "Generic Competition in the US Pharmaceutical Industry," *Int. J. Econ. Bus.* 13:15-38 n.1 ("Saha, et al. (2006)") (For 40 drugs that experienced generic entry between July 1992 and January 1998, the average price of generics was 76% of the brand price one month after generic entry).

[14] *See Actavis*, 133 S. Ct. at 2229.

branded company rarely drops the brand price to match the first generic entrant, the first entrant does not face the kind of price competition it will when additional generic products, including an authorized generic, are available. A first filer earns substantially greater sales and profits without an authorized generic being marketed alongside it, compared with when an authorized generic is marketed.

2. Later Generics Drive Prices Down Further.

76. When multiple generic competitors enter the market, one sees the competitive process accelerate 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.[15]

77. 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 around 10%, but that with two generic entrants near term retail price reduction is about 50%.

78. Soon after generic competition begins, the vast majority of the sales formerly enjoyed by the brand shift to generic sellers. A 2009 FTC Study found that generics captured between approximately 72% and 85% of sales in the first six months.[16] In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid

[15] *See*, *e.g.*, Patricia M. Danzon & Li-Wei Chao. "Does Regulation Drive Out Competition in Pharmaceutical Markets? *43 J.L. & Econ.* 311 (2000); Tracy Regan. "Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market." *26 Int'l J. Indus. Org.* 930 (2008); Richard G. Frank. "The Ongoing Regulation of Generic Drugs." *357 New Eng. J. Med.* 1993-1996, n.20 (2007).

[16] FTC Study, Federal Trade Commission, "Authorized Generics: An Interim Report," 2009 WL 1785171 (June 2009).

prior to generic entry. "Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[17]

C. Pharmaceutical Manufacturers Game the Regulatory Structure In Order to Impair Competition.

79. When they do not face generic competition, manufacturers of brand drugs can usually sell them far above the marginal cost of production, generating profit margins in excess of 70% while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins is what economists call market power. When generics enter the market, however, they quickly take 90% or more of the unit sales. When multiple generics are in the market, the competition between the generics drives their prices to near only 10% above the marginal cost of production. This competition puts an end to the brand manufacturer's market power and delivers enormous savings to drug purchasers.

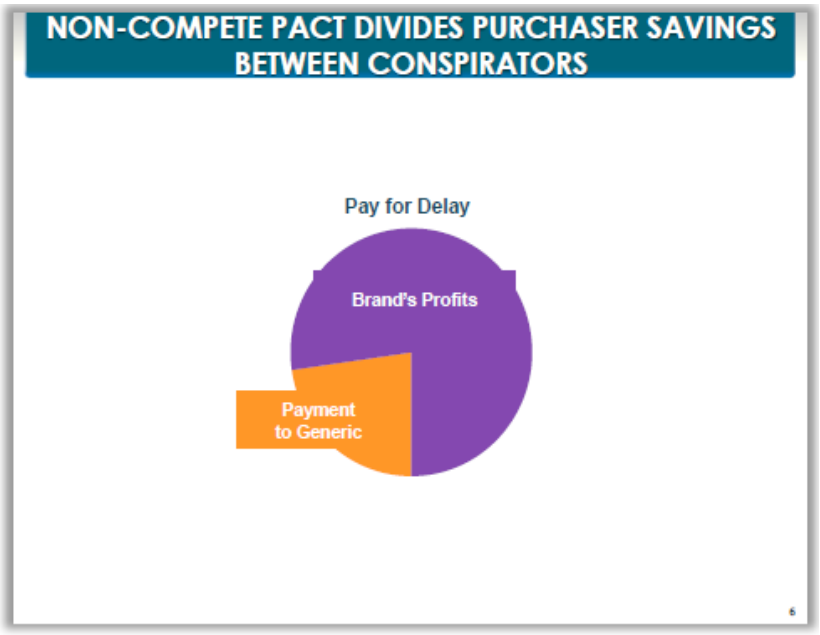
80. The brand and generic manufacturers have a collective interest in preventing this competition from erupting. If they work together to prevent or delay competition, they can keep the profit margins on all of the unit sales at 70% rather than 10% and split the resulting excess profits among themselves. They can keep the enormous savings that competition would have delivered to drug purchasers. The following pie charts demonstrate the manufacturers' collective interest in delaying competition.

81. A brand manufacturer in the marketplace without competition from generics gets all of the profits on all of the unit sales:

[17] *See* FDA Website, Generic Drugs: Questions and Answers, *available at* http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm.

82. When generic entry occurs, the brand manufacturer loses most of the unit sales, the generic manufacturers sell most of the units, but at drastically reduced prices; and competition delivers enormous savings to consumers. Competition converts what formerly were excess profits into purchaser savings:

83. To avoid this reduction in profits, the brand and generic manufacturer can agree not to compete and instead split the potential purchaser savings between themselves:



84. In order for such an anticompetitive pact to work, the brand and generic manufacturers need a means by which to divide the purchaser savings between themselves. The generic manufacturer will not refrain from competing if it does not share in the ill-gotten gains. Pay-offs from the brand manufacturer is the means by which the brand and generic manufacturers divide between themselves the ill-gotten gains that the delayed competition makes possible. These unlawful pay-off deals are often referred to as "pay-for-delay" agreements or "exclusion payment" agreements.

85. It is often necessary for the brand manufacturer to pay off only the first generic manufacturer that included a Paragraph IV Certification in its ANDA, the so-called first-filer. The first-filer's agreement to delay marketing its drug may also prevent other generic manufacturers from marketing their drugs. Later ANDA filers have more modest financial expectations because they have no expectation of any form of market exclusivity. By the time they enter the market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been commoditized.

86. When an anticompetitive agreement with the first filer is already in place, however, litigation becomes less attractive to later filers. The later generic manufacturers know that the first filer is not leading the charge against the brand's patent(s) (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive, reverse payment settlement). The later generics have to bear the brunt of the litigation costs themselves, and, upon prevailing in the patent litigation, expect to face competition from at least the first filer generic, and typically an authorized generic as well, despite having expended time and resources litigating the infringement case. The first settlement between a brand and first-filer generic (such as the Exclusion Payment Agreement at issue here) will often provide that, if a later generic filer launches its generic before the delayed date agreed to by the brand and the first filer, the first filer is permitted to launch then as well – greatly reducing the incentive the later filer would otherwise have to continue fighting to enter as soon as possible.

87. Thus, some later generics decide to simply give in to the conspiracy between the brand manufacturer and the first-filer generic and agree to drop their challenges to the brand's patent(s) and stay off the market until after entry by the first filer.

88. Exclusionary payment agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman Amendments. In particular, they extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy the expensive brands instead.

D. Manufacturers Also Use Anticompetitive "Acceleration" Clauses To Delay Competition.

89. Where there is no generic filer who holds first-to-file exclusivity, it is not as easy for brand manufacturers to implement a strategy for delaying generic competition. But that is not to say they do not do so. Quite the contrary, they simply find other means, such as entering a

series of agreements designed to dis-incentivize generic filers from entering the market by eliminating the possibility of obtaining *de facto* exclusivity.

90. Brand manufacturers can induce generics to enter settlements by including "acceleration" clauses in their agreements. In practice, such "acceleration" clauses do not accelerate generic entry – they delay it.

91. The purpose and effect of an "acceleration" clause is to dramatically *reduce* any other generic manufacturer's incentive to try to enter the market as quickly as they can. Absent the "acceleration" clause, other generic manufacturers would have an incentive to enter the market as soon as they were able, thereby enjoying a substantial period as the only ANDA-based generic product on the market. By eliminating this possibility, an "acceleration" clause results in delayed generic entry by, *inter alia*, disincentivizing generics that would otherwise be willing and able to come to market from doing so because of the knowledge that other generics would immediately flood the market.

92. The Chairman and CEO of Apotex, Inc. – one of the largest generic manufacturers in the world – twice testified to Congress that "acceleration" clauses, or what he referred to as "poison pill" provisions, represent "the primary anticompetitive aspects of settlements" because they "eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry."[18] The clauses both induce prospective generic competitors to accept later entry dates and deter others from challenging weak patents:

> [N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. Consumers are the biggest losers under

[18] *Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the Subcomm. On Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce*, 110th Cong., at 65, 67 (2007) (statement of Bernard Sherman, CEO, Apotex, Inc.), *available at* http://www.gpo.gov/fdsys/pkg/CHRG- 110hhrg38992/pdf/CHRG-110hhrg38992.pdf.

> this system. If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase.[19]

93. Most settlement agreements between brand and generic manufacturers provide that the agreement's terms are confidential. However, where the brand company advises other generic manufacturers of the existence of "acceleration" clauses in earlier settlements, that can dissuade other generic manufacturers from trying to enter the market before the delayed entry date to which the prior settling parties agreed.

94. Here, Amgen and Teva's overarching scheme results in years of unlawfully prolonged monopolization in the lucrative market for Sensipar and its AB-rated generic equivalents. Amgen's scheme has delayed generic entry since March 8, 2018.

VI. THE DEFENDANTS' ANTICOMPETITIVE CONDUCT

A. The Cinacalcet Hydrochloride Patents and FDA Approval.

95. Amgen listed seven patents in the Orange Book as covering Sensipar – U.S. Patent Nos. 6,211,244 (expiry October 23, 2015); 6,001,884 (expiry December 14, 2016); 6,031,003 (expiry December 14, 2016); 6,313,146 (expiry December 14, 2016); 6,011,068

[19] *Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. On Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce*, 111th Cong., at 218 (2009) (statement of Bernard Sherman, CEO, Apotex, Inc.) (hereinafter "Apotex 2009 Statement"), available at http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf. Apotex addressed acceleration clauses in the context in which the first-filing generic retained the 180-day exclusivity. Regardless, here as well, the acceleration clause all but eliminates a generic manufacturer's incentive to try to enter before *t*he scheduled date.

(expiry March 8, 2018); 7,829,595, (expiry September 22, 2026) and 9,375,405 (expiry September 22, 2026).

1. Amgen Obtains an Exclusive License for Patents Covering Cinacalcet Hydrochloride, Including the '068 Substance Patent.

96. Development of cinacalcet began with a collaboration between Brigham and Women's Hospital, Inc. (the "Hospital") and NPS Pharmaceuticals, Inc. ("NPS") and led to the application for, and subsequent allowance of the '068 patent, '003 patent, '244 patent,'146 patent, and '884 patent (collectively, the "NPS Patents"). The NPS patents relate to the production and/or medicinal use of cinacalcet hydrochloride. The '068 patent – stating claims related to calcimimetic compounds – was the primary substance patent.

97. The NPS patents were originally assigned by the inventors to either NPS or NPS and the Hospital.

98. On March 18, 1996, NPS entered into a licensing agreement with Amgen. Under the agreement, Amgen is the exclusive licensee of the NPS Patents in the United States. Amgen also is responsible for all development and commercial activities involving Sensipar – Amgen's brand cinacalcet hydrochloride product – as well as enforcing applicable patent rights in the licensed territories. Under the Amgen-NPS licensing agreement, NPS is entitled to receive from Amgen royalty payments on sales of Sensipar, as well as certain milestones payments.[20]

99. Each of the NPS Patents has now expired.

[20]https://www.sec.gov/Archives/edgar/data/890465/000110465908040231/a08-16813_1ex99d1.htm.

2. Amgen's Cinacalcet Hydrochloride NDA is Approved.

100. On March 8, 2004, the FDA approved Amgen's NDA No. 021688 for using cinacalcet in a method of treating patients with parathyroid carcinoma and secondary hyperparathyroidism.

101. Beginning in April 2004, Amgen marketed, distributed, and sold Sensipar tablets throughout the United States.

102. Early ANDA filers, including Barr and Teva, launched unsuccessful challenges to the '068 patent and were judicially prohibited from entering the market until the expiration of that patent on March 8, 2018.

3. Amgen Obtains Two Additional Patents, Including the '405 Substance Patent.

103. Amgen also became the assignee of the '595 patent (issued November 9, 2010) and the '405 patent (issued June 28, 2016) from those patents' inventors. The '405 patent is a formulation patent stating claims related to a binder composition that requires one of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, or a mixture thereof as a binder present in a pharmaceutical composition.

4. Amgen's '405 Patent is Weak.

104. Amgen knew it would have to rely on its '405 patent to retain its exclusivity and block generics from the market after March 8, 2018.

105. Amgen also knew, however, that the '405 patent provided minimal patent protection in that a non-infringing product could easily be developed.

106. Claim 1 of the '405 patent requires, among other things,"(d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovidine, sodium starch glycolate, croscarmellose sodium, and mixtures thereof."

107. Thus, if a generic ANDA product formulation does not contain at least one of crospovidine, sodium starch glycolate, croscarmellose sodium, and mixtures thereof, there can be no literal infringement of claim 1 or any of its dependent claims.

108. Indeed, as discussed below, a federal district court ruled that Teva (vis-a-vis the Watson ANDA) did not infringe any of the asserted claims of the '405 patent because the binder and disintegrant elements are "closed to unrecited binders and disintegrants" and "there could be no literal infringement if the [Watson] ANDA product contained an unrecited (or unlisted) binder or disintegrant."[21]

109. Amgen thus knew that its product was vulnerable to a rapid and near-complete loss of sales once its '068 patent expired on March 8, 2018, and non-infringing, less expensive, generic versions entered the market on that date.

B. Sensipar Hits the Billion Dollar Mark in 2015 and Manufacturers Seek FDA Approval to Market Generic Versions.

110. By 2015, Amgen's U.S. sales of Sensipar topped $1 billion in revenues and the brand drug was one of Amgen's top revenue products:

Year	Annual Revenue in U.S.
2015	$1.069 Billion
2016	$1.24 Billion
2017	$1.374 Billion
2018	$1.4 Billion

[21] *Amgen Inc. v. Amneal Pharm. LLC,* 328 F. Supp. 3d 373, 381 (D. Del. 2018).

111. Beginning as early as March 2008, more than 20 generic manufacturers had filed ANDAs and,[22] upon final approval, planned to market their generic cinacalcet hydrochloride products on or about March 8, 2018, when the ’068 patent expired.

112. Almost as soon as the ’405 patent was listed in the Orange Book, generic manufacturers began to challenge it through Paragraph IV certifications in connection with ANDAs seeking to obtain approval to market generic versions of this blockbuster drug.

113. Each of these generic manufacturers represented to the FDA, via a Paragraph IV certification, that Amgen’s ’405 patent was invalid, unenforceable, or not infringed by its particular proposed generic drug for which it was seeking approval via an ANDA filing. Amgen was duly notified of each Paragraph IV certification attacking its patent.

C. Amgen Begins a Wave of Generic Delay Tactics: Suing the FDA and Suing Generic Manufacturers.

114. In order to delay the onset of generic competition and continue reaping more than a billion-dollar annually from its Sensipar sales, Amgen embarked on a scheme to block generics from entering the market.

115. Between September 22, 2016 and October 11, 2016, Amgen filed fourteen lawsuits (later consolidated) alleging infringement of the ’405 patent in the U.S. District of Delaware. The generic manufacturer defendants included: Aurobindo, Micro Labs, Teva (for the Watson ANDA), Cipla, Strides, Sun Pharma, Dr. Reddy’s, Ajanta, Amneal, Apotex, Hetero, Breckenridge, Mylan, Zydus.

116. On May 25, 2017, Amgen also sued the FDA for denying its application for pediatric exclusivity for Sensipar. Obtaining pediatric exclusivity would have given Amgen six months of additional protection against generic manufacturers’ market entry.

[22] *See supra* note 3.

117. Amgen alleged that the FDA had improperly denied an additional six months of pediatric exclusivity for Sensipar. Amgen needed the FDA to grant approval by June 8, 2017 in order to satisfy the statutory requirement that pediatric exclusivity for a pharmaceutical product be granted no later than nine months before the expiration of the relevant patent.[23]

118. On June 5, 2017, the FDA agreed to reconsider Amgen's request, and Amgen and the FDA agreed to stay the litigation pending that review. The FDA also agreed that if Amgen achieved a favorable outcome in the future, it would apply retroactively in order to satisfy the deadline.[24] On August 2, 2017 the FDA again denied Amgen's request.[25]

119. Also in June 2017, Amgen sued four more generic cinacalcet hydrochloride ANDA-filers: Piramal, Alkem, Lupin and Macleods.

120. Specifically, Amgen claimed in each of these lawsuits, *inter alia*, that the generic cinacalcet hydrochloride product would infringe claims 1-6 and 8-20 of the '405 patent.

121. The generic manufacturer defendants responded with defenses including non-infringement, invalidity and prosecution history estoppel. Macleods also included a counterclaim alleging sham litigation in violation of the Sherman Act, which Amgen denied.

D. Amgen Begins a Wave of Generic Settlements, Inserts "Acceleration" Clauses to Delay Generic Entry and Suffers Patent Setbacks.

1. Amgen Enters Into Generic Settlements Using "Acceleration" Clauses.

122. With the March 8, 2018 expiration of its '068 patent just months away, by the fall of 2017, Amgen began to systematically enter into [redacted]

[23] *Amgen Inc. v. Price*, No. 1:17-cv-1006-RDM, ECF No. 1 (D.D.C. May 25, 2017).

[24] *Amgen Inc. v. Price*, No. 1:17-cv-1006-RDM, ECF No. 15 (D.D.C. June 5, 2017).

[25] *Amgen Inc. v. Price*, No. 1:17-cv-1006-RDM, ECF No. 24 (D.D.C. Aug. 10, 2017).

[redacted]

123. These settlement agreements provided [redacted]

[redacted]

124. But these settlement agreements [redacted]

[redacted]

125. These clauses provided, that if a [redacted]

[redacted]

[redacted]

126. If Amgen [redacted]

127. Moreover, several of Amgen's settlements provide that [redacted][26]

128. The settlement agreements that Amgen struck with generic manufacturers to settle the'405 patent litigation included [redacted]

[26] [redacted]

129. [redacted]

130. Amgen proclaimed its intentions as to those clauses in the course of its pending litigation against Cipla: [redacted] Amgen likewise disclosed its intentions in the course of its negotiations with Teva: [redacted]

131. Generic manufacturer Alkem alleged that Amgen had orchestrated even broader similarities in its settlement agreements. In seeking to observe a hearing addressing another generic manufacturer's Sensipar settlement with Amgen, Alkem counsel claimed that, in all such cases: "the brand controls the drafting of the settlement agreement"; "the brand offers the template up in the negotiations and carries it through . . . with each [generic] defendant"; and that, as a result, "they're all going to contain substantially the same language."[27] [redacted]

132. The purpose and effect of the [redacted]

[27] July 9, 2019 Hr'g Tr. at 10-11, *Amgen, Inc. v. Amneal Pharms.,* C.A. 16-853 (D. Del.).

[redacted]

133. On September 11, 2017, Amgen entered into a stipulation of dismissal of its case against Apotex without prejudice.[28]

134. On September 20, 2017, entered into a stipulation of dismissal of its case against Micro Labs without prejudice.[29]

135. On September 21, 2017, Amgen entered into a consent decree with Breckenridge, stipulating "to entry of judgment of infringement and validity of the '405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of, or distribution into the United States of the respective defendant's cinacalcet product during the term of the '405 Patent unless specifically authorized under the confidential settlement agreement."[30]

136. On November 2, 2017, Amgen entered into consent decrees with Sun Pharma and Hetero, respectively, stipulating "to entry of judgment of infringement and validity of the '405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of, or distribution into the United States of the respective defendant's cinacalcet product during the term of the '405 Patent unless specifically authorized under the confidential settlement agreement."[31]

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[28] 1:16-cv-00926 (ECF Nos. 30 and 34).

[29] 1:16-cv-00854 (ECF Nos. 32 and 34).

[30] Amgen 2017 Form 10-K, *available at* https://www.sec.gov/Archives/edgar/data/318154/000031815418000004/amgn-12312017x10k.htm.

[31] Amgen 2017 Form 10-K, *available at* https://www.sec.gov/Archives/edgar/data/318154/000031815418000004/amgn-12312017x10k.htm.

137. On November 9, 2017, Amgen entered into a consent decree with Ajanta, stipulating "to entry of judgment of infringement and validity of the '405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of, or distribution into the United States of the respective defendant's cinacalcet product during the term of the '405 Patent unless specifically authorized under the confidential settlement agreement."[32]

138. All told, between March 2017 and January 2019, Amgen settled with 14 would-be generic Sensipar manufacturers (the date of each settlement is included in parentheses):

a. Breckenridge Pharmaceutical (Sept. 15, 2017)

b. Sun Pharmaceutical (Oct. 24, 2017)

c. Hetero Labs (Oct. 24, 2017)

d. Ajanta Pharma (Nov. 1, 2017)

e. Cipla Ltd. (Feb. 26, 2018)

f. Mylan Pharmaceuticals (Feb. 27, 2018)

g. Strides Pharma (Mar. 2, 2018)

h. Dr. Reddy's Laboratories (Mar. 2, 2018)

i. Aurobindo Pharma (Mar. 19, 2018)

j. Macleods Pharma (Mar. 27, 2018)

k. Lupin Pharmaceuticals (Apr. 18, 2018)

l. Alkem Laboratories (Apr. 30, 2018)

m. Torrent Pharma (May 23, 2018)

n. Heritage/Emcure (Dec. 4, 2018)

[32] Amgen 2017 Form 10-K, *available at* https://www.sec.gov/Archives/edgar/data/318154/000031815418000004/amgn-12312017x10k.htm.

2. Amgen is Denied Pediatric Exclusivity for Sensipar.

139. In January 2018, Amgen suffered another blow to its bid to obtain pediatric exclusivity. A federal district court granted the FDA summary judgment on all but one of Amgen's claims against the FDA, and remanded the matter to the FDA for the limited purpose of the FDA addressing whether the FDA's denial of pediatric exclusivity in the case was inconsistent with a prior FDA pediatric-exclusivity decision on Johnson & Johnson's Ortho Tri-Cyclen.

140. The FDA responded that its denial of pediatric exclusivity was appropriate and not inconsistent with its prior decision. Amgen appealed the decision.[33]

141. On February 17, 2018, the federal district court ruled in the FDA's favor. This ended Amgen's bid for six additional months' exclusivity to stay on the market without any generic competition.

142. In its February 2018 earnings call, "Amgen executives cited uncertainty around Sensipar's loss of exclusivity as a big reason for the billion-dollar gap between the low end and high end of the company's 2018 guidance."[34]

3. Amgen Enters Into More Generic Settlements Using "Acceleration" Clauses.

143. On February 6, 2018, nine of the remaining consolidated cases were reassigned to Judge Mitchell S. Goldberg from the Eastern District of Pennsylvania, who was acting as a visiting District of Delaware judge. Judge Goldberg bifurcated the remaining claims of infringement and invalidity.

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[33] *Amgen Inc. v. Azar II*, No. 1:17-cv-1006-RDM, ECF No. 88 (D.D.C. Feb. 17, 2018).

[34] Eric Sagonowsky, "Amgen sued FDA for a 6-month reprieve from Sensipar generics—and lost," *FiercePharma* (Feb. 21, 2018), https://www.fiercepharma.com/legal/amgen-comes-up-short-lawsuit-against-fda-sensipar-pediatric-exclusivity-as-generics-inch.

144. On February 26, 2018, just ahead of the March 5 bench trial, Amgen struck a delay agreement with Cipla to settle its patent litigation.

145. In or around late February and early March, Amgen also entered into delay agreements with Mylan, Strides, Aurobindo and Macleods.

146. The Cipla, [redacted] agreements included "acceleration" clauses or "authorizations" providing that, [redacted]

147. [redacted]

148. The purpose and effect of the [redacted] to enter the market before its licensed entry.

149. On March 8, 2018 – the same day that the '068 patent expired – Cipla and Aurobindo received Final Approval to market their generic cinacalcet hydrochloride products under their respective ANDAs, 208915 and 206125 and, but for Amgen's unlawful conduct, would have launched their generic products.

150. Amgen's scheme to delay full generic competition and secure for itself monopoly profits to which it was not lawfully entitled depended on its ability to convince at least some (but as many as possible) of the generic ANDA filers to accept a delayed entry date. And as an enticement, Amgen dangled [redacted]

[redacted]

151. Of course, it was not in the independent, self-interest of any of the generics to delay its generic entry without being assured that others would do the same. Applied microeconomic theory, industry experience, and the facts as they played out shows that the coordinated Amgen agreements had a significant deleterious impact on competition.

152. Under applied microeconomic theory, and as it is for the economic inferences used by the Supreme Court in *Actavis*, the telling behavior is from the brand company, and what a rational brand company would do. An acceleration clause is in the interest of a rational brand company only if the clause actually reduces the likelihood of competition in the first place. Of course, the likelihood that a spoiler might be able to circumvent the scheme and gain early entry depends on the facts of each case. And the extent to which [redacted] might inhibit the interest of the would-be spoiler in continuing its efforts to achieve early entry is also case dependent. But under microeconomic theory, [redacted] means that in all cases the clause must reduce to some extent the likelihood of the spoiler continuing the chase.

153. Since [redacted] often work to cause the later-filed generics drop patent challenges and simply accept the later-agreed entry dates.

154. In this case, the fact is that [redacted]

155. The [redacted] were intended to have, and did have, significant, anticompetitive consequences. Reducing the incentive for non-settling generics to enter the market in a manner that resulted in full competition was of enormous benefit to the brand, but came at great cost to purchasers because the clauses were a substantial cause for other generics to avoid full generic competition.

156. Under the various agreements, Amgen purportedly [redacted] Since the agreements actually contained commitments by each generic *to not market* generics for an extended period of time, then for that period of time the provisions cannot be characterized as "licenses" and are instead better characterized as anti-licenses – agreements that prohibit, rather than grant, market entry. And while, ostensibly, the agreements provided [redacted] a "license" (in the sense of a consensually derived business arrangement) was neither needed nor appropriate to settle the patent challenge. Instead, in substance, these defendants [redacted] The [redacted] as a pretext to hide the reality that the substance of the arrangements was delay of entry (not permission of entry), with a barren covenant not to sue thereafter.

157. [redacted]

[redacted]

158. The [redacted] and related scheme served as a mask for collusive conduct. If Amgen's scheme had not unlawfully enticed its would-be generic competitors to work together, consumers would have been able to purchase generic options earlier, and those purchases all would have been made at lower prices than they did once those generics came to market.

159. All of these benefits had substantial value to the generics, and are compensation that they could not have obtained if they had litigated and won the various patent cases. The arrangements led multiple generics to stay out of the market far longer than they otherwise would have.

160. In the absence of Amgen's scheme, reasonable generic companies in the position of those here would each have demanded, and received, an entry date dependent upon an individual assessment of the strength or weakness of their particular product, position, and circumstances. Instead, they all agreed to delay entry in exchange for Amgen's promise that [redacted]

4. The District Court Finds No Infringement of the '405 Patent by Three Generic Manufacturers.

161. Among the lawsuits Amgen filed against generics was a September 22, 2016, complaint for patent infringement against Watson, Amneal, Piramal, and Zydus, and five other defendants.

162. Amgen asserted that these defendants infringed claims of the ’405 patent. The defendants filed counterclaims asserting that the patent was invalid and/or not infringed.

163. Before trial, Amgen claimed that the elements used by the defendants were functionally equivalent to those listed in claim 1 of the ’405 patent, and that these Markush groups were thus open.

164. In a February 27, 2018 pre-trial ruling, Judge Goldberg ruled that Amgen had “not overcome the very strong presumption that the Markush groups for the binder and disintegrant elements are closed to unrecited binders and disintegrants.”[35] Judge Goldberg construed the Markush groups for the binder and disintegrant elements as “closed to unrecited binders and disintegrants” and, thus, as articulated in an April 2018 Order denying Amgen’s motion for reargument, “there could be no literal infringement if the Defendants’ ANDA product contained an unrecited (or unlisted) binder or disintegrant.”[36]

165. This ruling confirmed the ’405 patent’s weakness of limited claim scope.

166. Amgen also argued that if the Markush groups were closed, it could still rely on the doctrine of equivalents to prove infringement. Judge Goldberg agreed that Amgen was not precluded from doing so, though this left Amgen in a significantly weaker position than if the Markush groups were open.[37]

167. A four-day bench trial on the infringement issue as to the four remaining non-settling defendants — Amneal, Piramal, Watson and Zydus — began on March 5, 2018.

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[35] *Amgen Inc. v. Aurobindo Pharma Ltd. et al*., No. 16-cv-853-GMS, 2018 WL 1061369, at *3 (D. Del. Feb. 27, 2018).

[36] *Amgen Inc. v. Amneal Pharm. LLC*, No. 16-cv-853-MSG, 2018 WL 1885664, at *3 (D. Del. Apr. 19, 2018).

[37] 2018 WL 1061369, at *3.

168. On July 27, 2018, Judge Goldberg ruled that Watson, Amneal and Piramal did not infringe any of the asserted claims of the '405 patent.[38]

169. Judge Goldberg also found that the product described in Zydus' ANDA would not infringe some of the asserted claims, but would infringe others.[39]

170. On August 24, 2018, Judge Goldberg entered final judgment stating, *inter alia*, that "[a] judgment of NON-INFRINGEMENT of claims 1-6 and 8-20 of the '405 patent is hereby entered in favor of Watson and against Amgen."

171. This judgment further underscored the '405 patent's weakness.

172. The court dismissed without prejudice, as moot, the generic manufacturer defendants' invalidity counterclaims.

173. On September 25, 2018, Amgen appealed to the United States Court of Appeals for the Federal Circuit. (D.I. 397). At this time, the appeal remains pending.[40]

174. On November 30, 2018, Amgen filed its opening brief with the Court of Appeals for the Federal Circuit. The brief largely focuses on issues of claim construction and infringement that have no bearing on the case against Watson. Amgen's brief did not address the district court's opinion on the doctrine of equivalents analysis as to Watson until page fifty-five of its sixty-four page brief.

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[38] *Amgen Inc. v. Amneal Pharm*. LLC, 328 F. Supp. 3d 373, 386, 396 (D. Del. 2018).

[39] *Id.* at 399.

[40] *See Amgen Inc. v. Amneal Pharm., LLC*, Nos. 2018-2414, 2019-1086 (Fed. Cir. Sept. 25, 2018).

E. On March 8, 2018, the very day that the '068 patent expired, the FDA begins approving generic ANDAs.

175. To date, the FDA has approved at least eight generic Sensipar ANDAs:

Company	ANDA	Approval Date
Cipla Ltd	208915	March 8, 2018
Aurobindo Pharma. Ltd	206125	March 8, 2018
Strides Pharma Global PTE Ltd	209226	April 30, 2018
Piramal Healthcare UK Ltd	210207	August 1, 2018
Sun Pharma Global	207008	October 11, 2018
Mylan Pharmaceuticals Inc.	203422	October 16, 2018
Teva	Watson ANDA 204377	December 27, 2018
Lupin	210548	June 28, 2019

F. The FDA Approves the Watson ANDA

176. On December 27, 2018, the FDA approved the Watson ANDA.

177. On that same day, Teva immediately launched the Watson ANDA generic cinacalcet hydrochloride product at-risk. Teva knew that its generic launch was a substantial threat to Amgen because the launch would trigger the numerous acceleration clauses and open the marketplace to full generic competition.

178. Teva also knew it could leverage its launch so as to both (a) maximize its own profits and (b) allow Amgen to unlawfully maintain its monopoly.

179. Over the course of approximately seven days, Teva sold [redacted]

180. During the period that Teva's generic cinacalcet hydrochloride product was on the market, Amgen lost [redacted]

G. Amgen and Teva Enter a Delay Agreement and Teva Ceases Sales of Its Generic Cinacalcet Until 2021.

181. On January 2, 2019, after Amgen filed its opening appellate brief, but before Teva filed its responsive brief, Amgen and Teva executed a settlement resolving their respective infringement claims and invalidity counterclaims as to the '405 patent on which Teva had received a non-infringement ruling from the district court.

182. Under the terms of the Amgen-Teva Delay Agreement, the parties agreed to request that the district court approve a consent judgment stating the *opposite* of the ruling Teva previously sought and obtained:

183. Despite Defendants' purported agreement that Teva's sales infringed the '405 patent—which if that were true and adjudicated as such would entitle Amgen to hundreds of millions of dollars in infringement damages—Amgen required Teva to return only a small

fraction of the revenues it realized from "infringing" sales and allowed for Teva's customers to resell their Teva product, such that it would continue to compete with Amgen's Sensipar. [redacted]

184. To effect this reversal, Amgen and Teva jointly moved the district court to issue an Indicative Ruling (under Federal Rule of Civil Procedure 62.1) that it would grant the parties' motion under Federal Rule of Civil Procedure 60(b) to vacate its non-infringement ruling as to the Watson ANDA's generic product and enter the parties' proposed consent judgment, including Teva's admission of infringement. The court denied that motion, holding that "the request was "solely based on [Defendants'] settlement agreement, and [Defendants] have provided no other basis whatsoever which would amount to exceptional circumstances permitting my grant of vacatur under Federal Rule of Civil Procedure 60(b)."[41]

185. Also in connection with the Amgen-Teva Delay Agreement, Teva:

a. immediately ceased sales of its generic, eliminating future competition from Teva, which was costing Amgen tens of millions of dollars;

b. [redacted]

c. agreed to pay Amgen no more than $40 million, a small fraction of the hundreds of millions the company made launching at risk for just six days, giving its settlement agreement with Amgen a false air of legitimacy; and

d. was not required to pull any of its product distributed over its six-day at-risk launch off the market.

[41] *Amgen Inc. v. Amneal Pharms. LLC*, C.A. No. 16-853, D.I. 439 (D. Del. Mar. 26, 2019).

186. Former Aurobindo CEO and VP of sales at Teva, retained as an expert in the Cipla/Amgen litigation, summarized the effects of the agreement in each of two declarations as follows:

[redacted]

* * * *

[redacted]

187. The nature and purpose of Teva's payment to Amgen is reflected in [redacted] which included the following:

a. [redacted]

b. [redacted]

[redacted]

c. [redacted]

d. [redacted]

188. In the Memorandum Opinion explaining its denial of Amgen's motion for a preliminary injunction in the *Cipla* Action, the court likewise recognized the nature of Teva's payment: "Teva . . . agreed to pay Amgen up to $40 million dollars, depending (in part) on how long the cinacalcet market remains free of non-Amgen and non-Teva generic products, and appears to have agreed to stop selling the Teva Product. (*See id*. §§ 3.1, 7.1, 7.3)."[42]

189. Importantly, [redacted]

190. Teva was incentivized to enter into the agreement with Amgen during that grace period because doing so ensured that no other generics would come to market and eat into the de facto, months-long generic Sensipar exclusivity that Teva had secured by dumping its product into the market and settling with Amgen. Teva's agreements with its wholesale customers

[42] *Cipla Ltd. v. Amgen Inc.,* No. 19-cv-44-LPS, 2019 WL 1970780, at *3 (D. Del. May 2, 2019)*, aff'd sub nom. Cipla Ltd. v. Amgen Inc.,* No. 19-cv-2017, 2019 WL 3202824 (3d Cir. July 16, 2019).

emphasized this incentive. Those wholesale customers could have, among other things, made full-credit returns or received "shelf-stock adjustments" in the event that Teva's contract price was higher than the prices offered by other competing generics.

191. After Amgen staved off the most immediate threat to its monopoly, it addressed other threats. On January 4, 2019, counsel for Amgen wrote a letter to counsel for Cipla that included the following: "Please confirm immediately that Cipla has not and will not engage in an at risk launch based on [Teva]'s Launch. Otherwise Amgen will seek all remedies available under the Cipla Agreement and under applicable law, including injunctive relief, breach of contract, treble damages, and sanctions."

192. Cipla's counsel sent a letter to Judge Goldberg on January 10, 2019, stating that the settlement between Amgen and Teva is "anticompetitive, has far-reaching consequences, and raises important legal questions that are not rightly swept under the rug as [Amgen's and Teva's Joint] Motion would have the Court do without comment."[43]

193. Through the Amgen-Teva Delay Agreement, the Defendants removed a significantly cheaper generic Teva product from the market, forestalled the launch of other approved generic cinacalcet products by prior settling generic manufacturers, and Teva secured, *inter alia*, hundreds of millions from its abbreviated launch. As a result, class members were deprived unlawfully of less expensive generic cinacalcet hydrochloride.

[43] Letter from M. Farnan to The Honorable Mitchell S. Goldberg, dated January 10, 2019, *Amgen Inc. v. Amneal Pharm.*, No. 1:16-cv-00853 (D. Del.) (ECF No. 414).

194. As one analyst summed up the ill-effects of this scheme: '"[the Hatch Waxman Amendments] were not written to allow the generics to greenmail innovators, but to reduce prices for the public."'[44]

195. Cipla launched on March 6, 2019.

196. Aurobindo launched on July 15, 2019.

VII. CLASS ALLEGATIONS

197. Plaintiffs bring this action as a class action under Rules 23(a) and (b)(3) of the Federal Rule of Civil Procedure on behalf of themselves and as representatives of a class defined as follows:

> All persons or entities in the United States and its territories who purchased Sensipar, and it generic equivalents, directly from any of the defendants or any other manufacturer at any time during the period from March 8, 2018 through and until the anticompetitive effects of the Defendants' conduct cease (the "Class Period").

Excluded from the class are the Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

198. Members of the class are so numerous that joinder is impracticable. Plaintiffs believe that there are dozens of class members. Further, the class is readily identifiable from information and records that the Defendants are required by law to maintain.

199. Plaintiffs' claims are typical of the claims of the members of the class. Plaintiffs and all members of the class were damaged by the Defendants' same wrongful conduct. Specifically, they paid artificially inflated prices for cinacalcet hydrochloride and were deprived

[44] Eric Sagonowsky, "Locked in a Sensipar patent fight, Teva rolled its generic anyway—and then Amgen settled," *FiercePharma* (Jan. 3, 2019), https://www.fiercepharma.com/pharma/amgen-teva-strike-sensipar-patent-deal-after-brief-generic-launch (quoting Bernstein analyst Ronny Gal).

– and are still deprived – of the benefits of competition from cheaper generic versions of Sensipar as a result of the Defendants' wrongful conduct.

200. Plaintiffs will fairly and adequately protect and represent the interests of the class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the class.

201. Plaintiffs and the class are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation involving pharmaceutical products.

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

203. Questions of law and fact common to the class include:

a. whether the Defendants conspired to restrain generic competition to Sensipar;

b. whether Defendants' agreement was a *per se* violation of federal antitrust laws;

c. whether Teva unlawfully agreed to delay its entry into the market for oral tablets comprised of cinacalcet hydrochloride, *i.e.*, Sensipar and its AB-rated generic bioequivalents;

d. whether Amgen made payment(s) to Teva in exchange for a delay in generic competition for Sensipar;

e. whether Amgen's compensation to Teva was necessary to yield some procompetitive benefit that is legally cognizable and non-pretextual;

f. whether Amgen entered agreements with other generic ANDA filers, to protect Amgen's and Teva's anticompetitive scheme;

g. whether the Defendants' challenged conduct suppressed generic competition to Sensipar;

h. whether the Defendants' challenged conduct harmed competition in the market for oral tablets comprised of cinacalcet hydrochloride;

i. whether Amgen possessed market power in the market for oral tablets comprised of cinacalcet hydrochloride, *i.e.*, Sensipar and its AB-rated generic bioequivalents;

j. whether the relevant antitrust market (if a relevant market must be defined) is the market for oral tablets comprised of cinacalcet hydrochloride, *i.e.*, Sensipar and its AB-rated generic bioequivalents;

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

l. whether, and to what extent, the Defendants' conduct caused antitrust injury to the business or property of Plaintiffs and members of the class in the nature of overcharges; and

m. the quantum of overcharges paid by Plaintiffs and the class in the aggregate.

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

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

VIII. MARKET POWER AND RELEVANT MARKET

206. Pharmaceutical products comprising cinacalcet hydrochloride have pharmacological properties which differentiate them from other drugs for treating secondary hyperparathyroidism and enable sellers of such products to earn supra-competitive profits on their sale.

207. At all relevant times, Amgen has had market power over oral tablets (in 30 mg, 60 mg, and 90 mg strengths) comprised of cinacalcet hydrochloride, *i.e.*, Sensipar and its AB-rated generic bioequivalents, because Amgen has had the power to maintain the price of these products at supracompetitive levels without losing substantial sales to other secondary hyperparathyroidism products. This market power may be shown directly, and therefore no relevant market needs to be defined.

208. A small but significant, non-transitory price increase for Sensipar by Amgen would not have caused a significant loss of sales to other secondary hyperparathyroidism products sufficient to make such a price increase unprofitable.

209. Sensipar does not exhibit significant, positive cross-elasticity of demand with respect to price, with any other secondary hyperparathyroidism product other than AB-rated generic versions of Sensipar. Medi-Span Price Rx data for Sensipar shows, for example, that from 2012 through 2017, Amgen repeatedly raised Sensipar's wholesale average cost (WAC) price across Sensipar's 30 mg, 60 mg, and 90 mg strengths.

210. Sensipar is not reasonably interchangeable with any products other than AB- rated generic versions of Sensipar. [redacted]

[redacted]

211. Functional similarities between Sensipar and non-Sensipar secondary hyperparathyroidism products are insufficient to permit inclusion of those other secondary hyperparathyroidism products in the relevant market with Sensipar. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would be maintained in a competitive market. No other secondary hyperparathyroidism product (except for AB-rated generic versions of Sensipar) will take away sufficient sales from Sensipar to prevent Amgen from raising or maintaining the price of Sensipar above levels that would prevail in a competitive market.

212. Amgen needed to control only Sensipar and its AB-rated generic equivalents, and no other products, in order to maintain the price of Sensipar profitably at supracompetitive

prices. Only the market entry of a competing, AB-rated generic version of Sensipar would render Amgen unable to profitably maintain its current prices of Sensipar without losing substantial sales. This is particularly true for Medicare-based programs. As Mr. Georghiou noted, Medicare reimbursements under the "Transitional Drug Add-on Payment Adjustment" policy ("TDAPA") are "based on a four-quarter running average selling price and any generic drug sharing the same Healthcare Common Procedure Coding System ("HCPCS") code as Sensipar." Providers, he conceded, "will be strongly incentivized to switch to the generic after a full-scale launch by Cipla [of generic Sensipar] and strongly disincentivized from administering Sensipar because the reimbursement they receive for their acquisition cost of these products will be based on the combined retrospective running average selling price for these products [*i.e.*, both branded and generic versions of Sensipar]."

213. At all relevant times, Amgen has sold Sensipar at prices well in excess of the competitive price.

214. Amgen had, and exercised, the power to exclude and restrict competition to Sensipar and AB-rated generic bioequivalents.

215. Amgen, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

216. Plaintiffs allege that the relevant product market is oral tablets comprised of cinacalcet hydrochloride (*i.e.*, Sensipar and its AB-rated generic equivalents). During the relevant time, Amgen has been able to profitably maintain the price of oral tablets comprised of cinacalcet hydrochloride well above competitive levels.

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

218. Amgen's market share in the relevant market was 100% at relevant times.

IX. MARKET EFFECTS AND DAMAGES TO THE CLASS

219. But for the anticompetitive conduct alleged above, generic cinacalcet hydrochloride manufacturers, including Cipla and Aurobindo, would have entered the market with their generic Sensipar products on March 8, 2018 when the '068 patent expired.

220. The Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Sensipar from generic competition.

221. The Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of Sensipar, has caused Plaintiffs and the class to pay more than they would have paid for oral tablets comprised of cinacalcet hydrochloride absent the Defendants' illegal conduct.

222. Typically, generic versions of brand drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, virtually all brand drug purchases are rapidly substituted for generic equivalents of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand drug loses even more of its market share to the generic versions of the drug.

223. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices; (b) purchases generic equivalents of the drug at a lower price, sooner; and/or (c) 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.

224. But for the Defendants' anticompetitive conduct, Plaintiffs and members of the class would have paid less for oral tablets comprised of cinacalcet hydrochloride by: (a) substituting purchases of less-expensive AB-rated generic Sensipar for their purchases of more-expensive branded Sensipar; (b) receiving discounts on their remaining branded Sensipar purchases; and (c) purchasing generic cinacalcet hydrochloride at lower prices sooner.

225. Moreover, due to the Defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in (a) launching generic cinacalcet hydrochloride, and/or (b) challenging the validity or infringement of the '405 patent in court.

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

X. ANTITRUST IMPACT

227. During the relevant period, Plaintiffs and members of the class purchased substantial amounts of Sensipar directly from Amgen. As a result of Defendants' illegal conduct, Plaintiffs and members of the class were compelled to pay, and did pay, artificially inflated prices for their oral tablets comprised of cinacalcet hydrochloride requirements. Those prices were substantially greater than the prices that Plaintiffs and members of the class would have paid absent the illegal conduct alleged herein, because: (1) the price of cinacalcet hydrochloride was artificially inflated by Defendants' illegal conduct, and (2) Plaintiffs and class members were deprived of the opportunity to purchase lower-priced generic cinacalcet hydrochloride.

228. 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.

XI. EFFECT ON INTERSTATE COMMERCE

229. At all material times, substantial amounts of Sensipar, manufactured and sold by Amgen, were shipped across state lines and sold to customers located outside its state of manufacture.

230. During the relevant time period, in connection with the purchase and sale of Sensipar, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

231. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The Defendants' activities were within the flow of, and have substantially affected, interstate commerce.

XII. CLAIMS FOR RELIEF

COUNT ONE
VIOLATION OF 15 U.S.C. § 1 – AGREEMENT RESTRAINING TRADE
(Against All Defendants)

232. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

233. Defendants Amgen and Teva have engaged, and continue to engage, in an unlawful contract, combination or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. Amgen and Teva entered into an unlawful market division agreement that restrained competition in the market for branded and generic versions of Sensipar. Their agreement is and was a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to:

a. eliminate existing competition between Amgen and Teva and to prevent Teva from competing with Amgen by selling its generic version of Sensipar until [redacted];

b. delay entry of generic versions of Sensipar by companies other than Teva in order to maintain the period in which Amgen brand Sensipar monopolizes the relevant market; and

c. raise and maintain the prices that Plaintiffs and the class would pay for Sensipar to and at supra-competitive levels.

234. The unlawful Amgen-Teva market division agreement is a per se violation of the Sherman Act, 15 U.S.C. § 1. And even if the conduct alleged in this Complaint is subject to a "quick look" analysis, it would satisfy that analysis: "an observer with even a rudimentary understanding of economics could conclude that the [Amgen-Teva agreement] in question would have an anticompetitive effect on customers and markets."[45]

235. Further, even if the conduct alleged in this Complaint is held subject to the Rule of Reason, there is no legitimate, non-pretextual, procompetitive business justification for the value Teva received that outweighs the agreements harmful effects. Specifically, under *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013), a patent settlement agreement between a brand and generic manufacturer may be unlawful when the brand provides the generic manufacturer a "large and unjustified" payment in exchange for the generic manufacturer dropping its challenge to the brand manufacturer's patents. This is particularly the case when the size of the payment exceeds any saved or avoided litigation costs.

236. The unlawful combination or conspiracy consisted of Amgen and Teva entering into the unlawful Amgen-Teva Delay Agreement in which Amgen provided, upon information and belief, a large and unjustified payment to Teva in the form of Teva's retained revenue from

[45] *California Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999).

its generic product launch, an agreed entry date that provides Teva with exclusive market entry before other generic entrants, [redacted] among other things – to delay generic entry into the cinacalcet hydrochloride market.

237. The unlawful contract, combination or conspiracy consisted of Amgen and Teva entering into the Amgen-Teva Delay Agreements to remove Teva from the competitive marketplace and further delay bringing generic versions of Sensipar to the market. The purpose and effect of this agreement and conduct were, and are, to: (a) allocate 100% of the market for cinacalcet hydrochloride products in the United States to Amgen; (b) delay the sale of generic versions of cinacalcet hydrochloride in the United States, thereby protecting Sensipar from generic competition for approximately two years ; and (c) fix, raise, maintain or stabilize the price at which direct purchasers would pay for brand cinacalcet hydrochloride or its AB-rated generic equivalent at supracompetitive levels.

238. The Amgen-Teva Delay Agreement harmed the Plaintiffs and the class as set forth above.

239. The Amgen-Teva Delay Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

240. The Amgen-Teva Delay Agreement between and among Amgen and Teva and their conduct under the agreement is an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, non-pretextual, procompetitive business justification for the exclusion payment that outweighs its harmful effect. Even if there were some conceivable justification, payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

241. As a direct and proximate result of Amgen's and Teva's anticompetitive conduct, as alleged herein, Plaintiffs and the class have been harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

COUNT TWO
VIOLATION OF 15 U.S.C. § 2 – MONOPOLIZATION
(Against Amgen)

242. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

243. Amgen possessed and possesses monopoly power in the relevant market and possessed the power to raise and maintain supracompetitive prices and/or exclude competitors from the relevant market.

244. Amgen engaged in an exclusionary conduct scheme that involved (i) paying Teva to remove its generic product from the market and delay its entry; and (ii) deterring all generic manufacturers from marketing generic cinacalcet hydrochloride before the expiration of the '405 patent or another agreed to delayed date[redacted]

245. The goal, purpose, and/or effect of Amgen's scheme were to maintain and extend its monopoly power with respect to cinacalcet hydrochloride. Amgen's illegal scheme to delay the introduction of generic cinacalcet hydrochloride allowed it to continue charging supra-competitive prices for cinacalcet hydrochloride without a substantial loss of sales.

246. As a result of Amgen's illegal scheme, Plaintiffs and the class paid more than they would have paid for cinacalcet hydrochloride, absent the illegal conduct. But for the illegal conduct, competitors would have begun marketing generic versions of cinacalcet hydrochloride by March 8, 2018, resulting in cost savings to Plaintiffs and other direct purchasers.

247. During the relevant period, Plaintiffs and the class purchased substantial amounts of cinacalcet hydrochloride directly from Amgen. As a result of Amgen's illegal conduct, Plaintiffs and the members of the class were compelled to pay, and did pay, artificially inflated prices for cinacalcet hydrochloride that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein.

248. The anticompetitive consequences of Amgen's actions far outweigh any arguable procompetitive benefits. Amgen acquired and extended a monopoly through unlawful means. Amgen's scheme was, in the aggregate, an act of monopolization undertaken with the specific intent to monopolize the market for cinacalcet hydrochloride and generic cinacalcet hydrochloride in the United States.

XIII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed 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) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the class, and declare Plaintiffs as the representative of the class;

b. Enter joint and several judgments against the Defendants and in favor of Plaintiffs and the class on all counts;

c. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

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

e. Award such other and further relief as the Court deems just and proper.

XIV. JURY DEMAND

Plaintiffs, on behalf of themselves and the proposed class, under Rule 38 of the Federal Rules of Civil Procedure, demand a trial by jury on all issues so triable.

Dated: September 13, 2019

Respectfully submitted,

/s/ Tiffany J. Cramer

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