UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UFCW LOCAL 1500 WELFARE FUND, on behalf of itself and all others similarly situated,

Plaintiff,

v.

AMGEN INC., TEVA PHARMACEUTICALS USA., INC., WATSON LABORATORIES, INC., ACTAVIS INC., and ACTAVIS PHARMA INC.,

Defendants.

Civil Action No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff UFCW Local 1500 Welfare Fund, on behalf of itself and all others similarly situated, files this Complaint against Defendants Amgen Inc. ("Amgen"), Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Actavis, Inc., and Actavis Pharma, Inc. (collectively, "Teva"). Plaintiff's claims arise from Defendants' anticompetitive scheme to restrain competition in the market for Sensipar® and its AB-rated generic equivalents sold in the United States. Plaintiff's allegations are made on personal knowledge as to Plaintiff and Plaintiff's own acts and upon information and belief as to all other matters.

I. NATURE OF THE ACTION

1. Plaintiff seeks damages and equitable relief arising from Defendants' anticompetitive agreement, which eliminated generic competition in the United States for branded and generic versions of Sensipar (cinacalcet hydrochloride tablets). Sensipar is a drug used to treat certain conditions associated with chronic kidney disease and thyroid cancer.

2. Amgen received FDA approval for Sensipar in March 2004. After launch, Sensipar's sales grew rapidly. As of 2017, Amgen's U.S. sales of Sensipar exceeded $1.3 billion annually.

3. Because Sensipar was a blockbuster drug, numerous generic manufacturers filed Abbreviated New Drug Applications ("ANDAs") with the FDA seeking the approval of generic versions of Sensipar. Teva was one such generic. Other generic manufacturers filing ANDAs included Aurobindo Pharma, Hetero Labs, Apotex, Sun Pharmaceutical Industries, Cipla Ltd., Mylan Pharmaceuticals, Amneal Pharmaceuticals, Dr. Reddy's Laboratories, Breckenridge Pharmaceutical, Micro Labs, Piramal Healthcare, Strides Pharma, Ajanta Pharma, and Zydus Pharmaceuticals.

4. As part of their applications, these generic manufacturers were required to make certain certifications against the patents covering Sensipar. Among these patents was U.S. Patent

No. 9,375,405 ("the '405 patent"), "Rapid dissolution formulation of a calcium receptor-active compound." Generic manufacturers filed "Paragraph IV" certifications against the '405 patent, stating that the patent was invalid, unenforceable, or not infringed by the proposed ANDA applicants' generics.

5. Amgen sued each generic manufacturer that filed an ANDA for allegedly infringing the '405 patent. While many of the generics thereafter settled with Amgen, a few—including Teva, Amneal, Piramal, and Zydus—continued litigating. A bench trial in the Court (Goldberg, D.J.) was held in March 2018. After the submission of post-trial briefs, in July 2018 the Court issued an opinion, finding that Teva, Amneal, and Piramal's generic versions of Sensipar did not infringe the '405 patent. In September 2018, Amgen appealed the Court's non-infringement ruling to the Federal Circuit.[1]

6. With Amgen's appeal pending, on December 27, 2018, the FDA approved Teva's ANDA for a generic version of Sensipar. The recipient of a non-infringement judgment, Teva immediately launched its generic product. During the one week that followed, Teva flooded the market with roughly six weeks of product sales. Teva itself reportedly realized approximately ***$59 million*** in profits (assuming at 25% discount off Sensipar's price), while Amgen lost an estimated ***$79 million*** in profits.[2] With Teva competing in the market, Amgen had limited options: either apply to the trial or appellate court for a stay of the non-infringement order and an injunction against Teva—or engage in self-help.

[1] *Amgen Inc. v. Amneal Pharms. LLC, et al.*, No. 1:16-cv-00853 (D. Del.), Dkt. #397. The Court also found that Zydus's proposed generic product would infringe the '405 patent. Zydus has appealed that part of the decision to the Federal Circuit. *See Amgen Inc. v. Amneal Pharmaceuticals LLC, et al.*, No. 1:16-cv-00853 (D. Del.), Dkt. #406.

[2] Sue Sutter, *Launch Abbreviated: Teva Halts US Generic Sensipar Sales After Patent Deal With Amgen*, Pink Sheet (Jan. 3, 2019).

7. Instead of applying for relief in court, Amgen chose self-help—and broke the law. On January 2, 2019, Teva and Amgen entered a confidential agreement in which Teva agreed to stop selling its generic version of Sensipar. Public reports also stated that the agreement: (1) ended Amgen's appeal against Teva; (2) required Teva to delay any further sales for nearly two and a half years, until mid-year 2021; (3) called on Teva to pay Amgen an undisclosed sum; and (4) called on Amgen to pay Teva for licenses to other Teva products.

8. Amgen's quickly-reached deal with Teva re-established and maintained Amgen's brand monopoly. Moreover, the deal eliminated not only Teva as a competitor but other generics as well. Amgen's '405 patent action settlements, include acceleration clauses, which permit the generics to enter the market after a short delay if another generic, like Teva, launched. The hasty deal between Amgen and Teva avoided triggering the acceleration clauses, thereby preventing other settling generics from launching their products. Amgen and Teva thus stopped other generics from entering and driving the price of Sensipar well below Teva's discount.

9. Absent Defendants' unlawful agreement, Plaintiff and the members of the Classes would have been able to purchase generic Sensipar tablets during the period after January 2, 2019 at significantly lower prices than Amgen has charged since then. Indeed, the injury to Plaintiff and the Classes is ongoing, as there still is no generic alternative to Amgen's branded Sensipar available to purchase.

10. An agreement by competing companies to cease competing is "anticompetitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other."[3] Accordingly, to redress the economic injury Defendants have already caused—and continue to cause—Plaintiff, on behalf of

[3] *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990).

itself and all others similarly situated, seeks injunctive and other equitable relief under the federal antitrust laws, as well as damages and other monetary relief under state antitrust, consumer protection, and common laws.

II. JURISDICTION AND VENUE

11. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1337 because this action seeks injunctive and equitable relief under the Clayton Act, 15 U.S.C. § 26. This Court also has jurisdiction under Clayton Act § 12, 15 U.S.C. § 22.

12. This Court also has jurisdiction under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed Damages Class exceeds $5,000,000, and at least one member of the Damages Class is a citizen of a state different from that of one of Defendants. This Court also has supplemental jurisdiction over state law claims under 28 U.S.C. § 1367(a).

13. Venue is appropriate in this District under 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §1391(b). Defendants reside, transact business, are found, or have agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District. Moreover, the effects of Defendants' conduct on interstate trade or commerce are ongoing.

14. This Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of causing injury

to, persons residing in, located in, or doing business throughout the United States, including in this District.

III. THE PARTIES

15. Plaintiff UFCW Local 1500 Welfare Fund ("**Local 1500**") is an employee welfare benefits fund with its principal place of business at 425 Merrick Avenue, Westbury, New York 11590. Local 1500 provides nearly 23,000 plan participants with health and welfare benefits and, with 15,000 members, is the largest grocery union in New York. During the Class Period, Local 1500 purchased and paid for some or all of the purchase price of Sensipar, thereby suffering injury to its business and property. Local 1500 paid and reimbursed more for these products than it would have absent Defendants' anticompetitive conduct.

16. Defendant Amgen Inc. ("**Amgen**") is a Delaware corporation with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen is the holder of NDA #021688 and sells Sensipar throughout the United States.

17. Defendant Teva Pharmaceuticals USA, Inc. ("**Teva Pharmaceuticals**") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva Pharmaceuticals launched generic Sensipar at the end of 2018 and entered the agreement with Amgen, from which this action arises. The relation between Teva Pharmaceuticals and the non-Amgen defendants is described below.

18. Defendant Watson Laboratories, Inc. ("**Watson**") is a Nevada corporation with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Watson is a direct or indirect subsidiary of Teva Pharmaceuticals. Watson is a defendant in Amgen's Sensipar patent infringement suit and is a beneficiary, directly or indirectly, of the Amgen-Teva agreement from which this action arises. Watson is the holder of ANDA #204377 for generic Sensipar tablets.

19. Defendant Actavis, Inc. ("**Actavis**") is a Nevada corporation with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Actavis is a direct or indirect subsidiary of Teva Pharmaceuticals. Actavis is a defendant in Amgen's Sensipar patent infringement suit and is a beneficiary, directly or indirectly, of the Amgen-Teva agreement from which this action arises.

20. Defendant Actavis Pharma, Inc. ("**Actavis Pharma**") is a Delaware corporation with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Actavis Pharma is a direct or indirect subsidiary of Teva Pharmaceuticals. Actavis Pharma is a defendant in Amgen's Sensipar patent infringement suit and is a beneficiary, directly or indirectly, of the Amgen-Teva agreement from which this action arises. Actavis Pharma is the packager of Teva's generic Sensipar.

21. Defendants Teva Pharmaceuticals, Watson, Actavis, and Actavis Pharma are collectively referred to as "**Teva**." Between December 27, 2018 and January 2, 2019, Teva sold throughout the United States generic Sensipar under Watson's ANDA.

22. Defendants Amgen and Teva are collectively referred to as "**Defendants**."

23. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged in this Complaint. These actions were authorized, ordered, or undertaken by Defendants' various officers, agents, employees, or other representatives while engaged in the management of Defendants' affairs (or those of their predecessors-in-interest) within the course and scope of their duties and employment or with the actual, apparent, and/or ostensible authority of Defendants.

IV. FACTUAL ALLEGATIONS

A. Amgen Launches Sensipar and Earns Billions of Dollars

24. In March 2004, Amgen received FDA approval for New Drug Application #021688 for Sensipar tablets. Sensipar is indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis, and the treatment of hypercalcemia in patients with parathyroid carcinoma. Amgen currently markets Sensipar in three strengths: 30 mg, 60 mg, and 90 mg.

25. Beginning in April 2004, Amgen marketed, distributed, and sold Sensipar tablets throughout the United States. Sales of Sensipar in the U.S. grew rapidly, ultimately reaching over $1.3 billion annually in 2017.

B. Amgen Acquires the '405 Patent

26. The U.S. Patent and Trademark Office ("PTO") issued the '405 patent in 2016. The '405 patent purportedly describes "a pharmaceutical composition compromising a therapeutically effective amount of calcium receptor-active compound and at least one pharmaceutically acceptable excipient, wherein the composition has a controlled dissolution profile."[4] The '405 patent was assigned to Amgen, and Amgen is the owner of the '405 patent. Amgen listed the patent in the Orange Book.

C. Generic Manufacturers Seek FDA Approval for Generic Versions of Sensipar

27. Pharmaceutical companies can seek FDA approval of generic versions of a brand drug by filing an ANDA. To have an ANDA approved, a company must demonstrate, among other things, that its proposed generic is therapeutically equivalent to the brand drug. Beginning at least as early as March 2008, over a dozen generic drug manufacturers filed ANDAs seeking

[4] Abstract, United States Patent No. 9,375,405.

approval of generic versions of Sensipar. These manufacturers included (among others) Teva, Aurobindo Pharma, Alkem Laboratories, Hetero Labs, Apotex Corp., Sun Pharmaceutical Industries, Lupin Pharmaceuticals, Cipla Ltd., Macleods Pharma, Mylan Pharmaceuticals, Amneal Pharmaceuticals, Dr. Reddy's Laboratories, Breckenridge Pharmaceutical, Micro Labs, Piramal Healthcare, Strides Pharma, Ajanta Pharma, Torrent Pharma, Heritage-Emcure, and Zydus Pharmaceuticals.

28. As part of their ANDAs, each manufacturer submitted a Paragraph IV certification against Amgen's '405 patent. In these Paragraph IV certifications, each ANDA applicant represented that the '405 patent was invalid, unenforceable, or not infringed by the generic's proposed ANDA product.

D. Amgen Sues the Generic ANDA Applicants for Infringement of the '405 Patent

29. Each ANDA applicant provided notice of its respective Paragraph IV certifications to Amgen. Because filing a Paragraph IV certification constitutes an act of infringement, *see* 35 U.S.C. § 271(e), upon receipt of these notices, Amgen sued each generic ANDA applicant for patent infringement.

30. As the patent litigations continued, certain generic manufacturers settled with Amgen. The table below lists the generic companies that settled with Amgen, as well as the dates that Amgen's infringement actions were dismissed:

Generic Company	Date of Dismissal
Aurobindo Pharma	March 23, 2018
Cipla Ltd.	March 5, 2018
Apotex Corp.	September 11, 2017

Generic Company	Date of Dismissal
Sun Pharmaceutical	November 2, 2017
Mylan Pharmaceuticals	March 5, 2018
Breckenridge Pharmaceutical	September 21, 2017
Dr. Reddy's Laboratories	March 5, 2018
Strides Pharma	March 5, 2018
Hetero Labs	November 2, 2017
Ajanta Pharma	November 9, 2017
Micro Labs	September 20, 2017
Alkem Laboratories	May 9, 2018
Lupin Pharmaceuticals	April 23, 2018
Macleods Pharma	April 10, 2018
Torrent Pharma	June 12, 2018
Heritage-Emcure	December 7, 2018

31. Certain generic manufacturers, as part of their settlements with Amgen, received acceleration clauses that permit them to market their generic versions of Sensipar before their settlement-prescribed market entry dates. One condition that permits earlier entry is the launch of a competing generic version of Sensipar. As is typical, these acceleration clauses build in a short delay period, during which the settling generics must refrain from sales in order to permit the brand the opportunity to seek judicial relief, if warranted, to stop the generic that launched.

32. In a 2018 SEC quarterly filing, Amgen disclosed that in the consent judgments with certain generic manufacturers (including Cipla, Strides, and Aurobindo):

> [T]he parties stipulated to an 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 applicable defendants' cinacalcet product during the term of the '405 Patent ***unless specifically authorized pursuant to the confidential settlement agreement***.[5]

The bold, italicized language reflects, among other things, the parties' agreements to acceleration clauses. Indeed, an Alliance Bernstein analyst has stated that Amgen's Sensipar settlements "all sensibly contain acceleration clauses, where the settling generic can launch if another generic enters the market."[6]

33. Although many generic manufacturers settled with Amgen, others—Teva, Aurobindo, Amneal, Piramal, and Zydus—continued litigating through a four-day bench trial, held in March 2018. In July 2018, the Court found that Teva, Amneal, and Piramal did not infringe the '405 patent.[7] A copy of the ruling is attached as **Exhibit 1**. In September 2018, Amgen appealed the Court's ruling of non-infringement in favor of Teva, Amneal, and Piramal to the Federal Circuit. That appeal is pending.

E. Teva Receives FDA Final Approval and Launches Its Generic Version of Sensipar

34. Because Teva, Amneal, and Piramal had received non-infringement rulings, these manufacturers needed only to obtain FDA final approval of their ANDAs to launch their generic versions of Sensipar, regardless of the pendency of Amgen's appeal. On December 27, 2018, the

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[5] Amgen SEC Form 10-Q at 25-26 (filed Apr. 25, 2018), http://investors.amgen.com/phoenix.zhtml?c=61656&p=irol-SECText&TEXT=aHR0cDovL2FwaS50ZW5rd2l6YXJkLmNvbS9maWxpbmcueG1sP2lwYWdlPTEyMjAxMjc1JkRTRVE9MCZTRVE9MCZTUURFU0M9U0VDVElPTl9FTlRJUkUmc3Vic2lkPTU3 (emphasis added).

[6] Sutter, *supra* note 2.

[7] The Court also found that Zydus had infringed the '405 Patent, but Zydus is currently appealing that ruling.

FDA granted final approval to Teva's ANDA for generic Sensipar. Upon receiving approval, Teva launched its generic version the drug.

35. Over an approximately one-week period, Teva sold roughly ***six weeks'*** worth of generic Sensipar, realizing an estimated ***$59 million*** in profits, assuming a 25% discount off Sensipar's price. Teva's launch also caused Amgen to lose an estimated ***$79 million*** in profits.[8] For drug purchasers and insurers, the benefits of Teva's launch were immediate, saving millions of dollars by purchasing—or reimbursing purchases of—Teva's generic product.

36. Moreover, had Teva continued selling generic Sensipar, Teva's entry would have triggered the acceleration clauses in settlements Amgen had with other generic manufacturers. If the other settling generics entered, the price for generic versions of Sensipar would have dropped significantly below that offered by Teva, as is typical when multiple generics compete.[9] In addition, as more generics entered the market to compete, Amgen's share of branded and generic Sensipar tablet sales would have eroded by 90%.[10] Therefore, Amgen had to move quickly once Teva launched—both to stop sales by Teva and to avoid triggering the acceleration clauses in its patent settlements with other generics.

F. Amgen and Teva Enter an Unlawful Market Division Agreement to Eliminate and Delay Generic Competition

37. Having lost against Teva at trial, to stop Teva's sales of its competing generic product, Amgen had to either persuade the district court or the Federal Circuit to stay the non-infringement ruling and to enjoin Teva's sales—or engage in self-help. Amgen chose the latter

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[8] Sutter, *supra* note 2.

[9] FTC Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions (Jan. 2010), at 8, https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff ("Publicly available information about recent generic launches suggests that a generic market typically matures about one year after the first entrant comes on the market. The generic penetration rate at that point is about 90% on average . . .").

[10] *Id.*

and negotiated an agreement to end Teva's competitive threat and keep Teva off the market for an extended period of time.

38. On January 2, 2019, Amgen and Teva executed an agreement that ended competition from Teva's generic product. Under the agreement, Amgen also agreed to drop its appeal of the Court's non-infringement decision as it related to Teva and pay Teva for licenses to other Teva products. In exchange, Teva agreed to (1) cease all sales of generic Sensipar; (2) delay all future sales until mid-year 2021—*i.e.*, two and one-half years; and (3) pay Amgen an undisclosed sum of money, which apparently represented a portion of Teva's generic Sensipar sales, to Amgen.[11]

39. Thus, as a result of the agreement:

(a) Amgen eliminated existing generic competition from Teva, which was costing it tens of millions of dollars in lost profits;

(b) Amgen also eliminated imminent competition by other generics, whose acceleration clauses otherwise would have triggered and allowed them to compete as well;

(c) Teva retained tens of millions of dollars in profits from selling six weeks' worth of product in a week;

(d) Teva eliminated the risk that the Federal Circuit might overturn the favorable non-infringement ruling on the '405 patent;

(e) Teva secured both a certain entry date comparable to the dates that the other generics who had settled received and, in all likelihood, an acceleration clause that assured Teva's earlier entry if another generic launched first; and

[11] Sue Sutter, *Launch Abbreviated: Teva Halts US Generic Sensipar Sales After Patent Deal With Amgen*, Pink Sheet (Jan. 3, 2019).

(f) Teva received additional value from Amgen's agreement to pay Teva for licenses to other Teva products.

40. Simply put, two competitors—Amgen and Teva—agreed to divide the market for Sensipar and Teva's generic version of the product. Amgen received Teva's promise not to enter for another two and one-half years, until mid-2021, unless another generic broke Amgen's monopoly by launching first. By its agreement with Teva, Amgen maintained its monopoly of branded and generic Sensipar sales.

41. A week after entering their illegal agreement, Amgen and Teva applied jointly to the Court to vacate its non-infringement judgment in favor of Teva and, instead, to enter a judgment stating that Teva's "manufacture, use, sale, offer to sell, and distribution of [its generic Sensipar] in the United States and importation of [its generic Sensipar] into the United States, ***would infringe*** the ['405] Patent."[12] Defendants' attempt to rewrite the Court's trial ruling confirms the anticompetitive intent underlying their market division agreement.

42. The Amgen-Teva agreement did not go unnoticed by the other generics that were blocked from entering the market. In January 2019, Cipla Ltd. filed a complaint against Amgen, alleging, among other claims, that the Amgen-Teva agreement violated the antitrust laws.[13] Cipla Ltd. also opposed Defendants' motion to vacate the district court's non-infringement ruling, as did Sun Pharmaceutical, another generic that had settled with Amgen.

43. The Amgen-Teva market division agreement injured Plaintiff and the members of the Classes. They lost the ability to buy Teva's less expensive generic version of Sensipar. Moreover, but for the unlawful agreement, Teva's sales would have allowed market entry by

[12] *Amgen Inc. v. Amneal Pharmaceuticals LLC*, No. 16-853, ECF No. 412 (D. Del., filed Jan. 9, 2019) (emphasis added).

[13] *See Cipla Ltd. v. Amgen Inc.*, No. 19-cv-00044 (D. Del.).

other generic manufactures, further driving the price down. At least Aurobindo Pharma, Cipla Ltd., Mylan Pharmaceutical, Strides Pharma, and Sun Pharmaceutical each had FDA final approval at the time of Teva's launch, and Teva's continued sales would have triggered the acceleration clauses in their settlements with Amgen. The resulting increased generic competition would have driven down the prices of generic versions of Sensipar below Teva's discount. Today, however, there is no such competition. Defendants saw to that on January 2, 2019.

V. THE ANTICOMPETITIVE EFFECTS ON INTERSTATE AND INTRASTATE COMMERCE

44. Defendants' anticompetitive scheme had the purpose and effect of unreasonably restraining trade by eliminating competition between Amgen and generic competitors. But for the market division agreement, Teva would have continued selling its generic Sensipar after January 2, 2019, and other FDA-approved generics would have soon launched their own generic versions of Sensipar.

45. But for Defendants' illegal conduct, Plaintiff and members of the Classes would have paid less for branded and generic versions of Sensipar. Defendants' conduct proximately caused Plaintiff's and the Classes' injuries because it forced them to pay tens of millions of dollars in overcharges on purchases of Amgen's branded Sensipar.

46. If Defendants had not blocked generic competition for branded Sensipar, Plaintiff and members of the Classes would have paid less for cinacalcet hydrochloride tablets by: (a) purchasing less-expensive generic versions of Sensipar instead of branded Sensipar and (b) purchasing generic Sensipar at lower prices sooner.

47. As a result of the delay in generic competition caused by Defendants' anticompetitive scheme, Plaintiff and members of the Classes paid, and continue to pay, more for branded and generic Sensipar than they would have paid absent Defendants' illegal conduct.[14]

48. Defendants' restraints of competition in the market for branded and generic versions of Sensipar have substantially affected both interstate and intrastate commerce.

49. At all material times, Amgen manufactured, promoted, distributed, and sold substantial amounts of branded Sensipar in a continuous and uninterrupted flow of commerce across state lines and throughout the United States. Defendants' anticompetitive conduct also had substantial intrastate effects in every state of purchase in that, among other things, retailers within each state were foreclosed from offering less-expensive generic versions of Sensipar to purchasers within each state, which directly impacted and disrupted commerce for consumers and third-party payors within each state.

50. At all material times, Defendants transmitted funds and contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state lines in connection with the sale of branded and generic versions of Sensipar.

51. Economics recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. Professor Herbert Hovenkamp explains that "[e]very person at every stage in the chain will be poorer" as a result of the anticompetitive price at the top. [15] Professor Hovenkamp also states that "[t]heoretically, one can calculate the

[14] Teva's generic version of Sensipar remained in the distribution "pipeline" even after Teva entered its agreement with Amgen. The price for this pipeline product was and is higher than it would have been if other generics had entered. Thus, members of the Classes who purchase or reimburse for the pipeline product also sustain injury.

[15] *See* Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice*, at 564 (1994).

percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."[16] Here, wholesalers and retailers passed on the inflated prices of branded and generic versions of Sensipar to Plaintiff and members of the Classes.

52. Defendants' unlawful agreement enabled Amgen to charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent the Defendants' agreement. These prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

VI. MONOPOLY POWER AND MARKET DEFINITION

53. To the extent the conduct here may be held subject to the Rule of Reason—and thus requires pleading a relevant product and geographical market—the relevant product market is cinacalcet hydrochloride tablets in 30 mg, 60 mg, and 90 mg strengths, including branded Sensipar and its bioequivalent (*i.e.*, AB-rated) generic versions of Sensipar. The relevant geographic market is the United States, including its territories, possessions, and the Commonwealth of Puerto Rico.

54. At all relevant times, Amgen has had monopoly power over the market for cinacalcet hydrochloride tablets. Direct evidence of Amgen's monopoly power includes, among other things, the abnormally-high price-cost margins enjoyed by Amgen prior to entry of generic versions of Sensipar and Amgen's ability to profitably maintain the price of Sensipar above competitive levels.

55. A small but significant non-transitory price increase above the competitive level for Sensipar by Amgen would not cause a loss of sales sufficient to make the price increase unprofitable.

[16] *Id.*

56. Other drugs that are not AB-rated to Sensipar cannot be substituted automatically for Sensipar by pharmacists and do not exhibit substantial cross-price elasticity of demand with respect to Sensipar. Thus, they are not economic substitutes for, nor reasonably interchangeable with, Sensipar.

57. Pharmaceutical products with cinacalcet hydrochloride as the active ingredient have pharmacological properties that differentiate them from other drugs for treating secondary hyperparathyroidism and hypercalcemia. The existence of other products indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease and hypercalcemia in patients with parathyroid carcinoma or other illnesses has not significantly constrained Amgen's pricing of Sensipar.

58. 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 prices of Sensipar without losing substantial sales.

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

60. Amgen has maintained and exercised the power to exclude and restrict competition to Sensipar and AB-rated generics.

61. At all relevant times, other than the roughly one-week period of Teva's sales, Amgen's market share in the relevant market was at or near 100%.

VII. CLASS ACTION ALLEGATIONS

62. Plaintiff brings this action on behalf of itself and all others similarly situated as a class action under Rules 23(a), (b)(2), and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of the following classes (the "Classes"):

> **The Injunction Class**
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> All persons and entities that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of Sensipar or its AB-rated generic equivalents from Defendants, beginning at least as early as January 2, 2019 until the effects of Defendants' conduct cease ("Class Period"), anywhere in the United States.
>
> **The Damages Class**
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> All persons and entities that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of Sensipar or its AB-rated generic equivalents from Defendants, beginning at least as early as January 2, 2019 until the effects of Defendants' conduct cease ("Class Period"), in the District of Columbia, Puerto Rico, or any of the following states and commonwealths: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, or Wyoming.

63. The following persons and entities are excluded from each of the above-described proposed Classes:

(a) Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;

(b) All governmental entities, except for government-funded employee benefit plans;

(c) All persons or entities who purchased Sensipar for purposes of resale or directly from Defendants or their affiliates;

(d) Fully-insured health plans (plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members);

(e) Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs);

(f) Pharmacy Benefit Managers;

(g) All Counsel of Record; and

(h) The Court, Court personnel, and any member of their immediate families.

64. Members of the Classes are so numerous and geographically dispersed that joinder of all members of the Classes is impracticable. Plaintiff believes that there are thousands of members of the Classes widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together.

65. Plaintiff's claims are typical of the claims of members of the Classes. Plaintiff and members of the Classes were harmed by the same wrongful conduct by Defendants in that they paid artificially inflated prices for branded and generic Sensipar and were deprived of the benefits of earlier and more robust competition from less-expensive generic equivalents of Sensipar as a result of Defendants' wrongful conduct.

66. Plaintiff will fairly and adequately protect and represent the interests of the members of the Classes. Plaintiff's interests are coincident with, and not antagonistic to, those of the members of the Classes.

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

68. Questions of law and fact common to the members of the Classes predominate over questions that may affect only individual members of the Classes because Defendants have acted on grounds generally applicable to both Classes. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

69. Questions of law and fact common to the Classes include:

(a) Whether Defendants' conspired to delay generic competition in the market for cinacalcet hydrochloride tablets;

(b) Whether Defendants' agreement was a *per se* violation of federal and state antitrust laws;

(c) Whether Defendants' agreement violated federal and state antitrust laws under a "quick look" analysis;

(d) Whether Defendants' agreement violated federal and state antitrust laws under a Rule of Reason analysis;

(e) To the extent the Rule of Reason applies, whether the relevant product market is cinacalcet hydrochloride tablets;

(f) To the extent the Rule of Reason applies, whether the relevant geographic market is the United States, including its territories, possessions, and the Commonwealth of Puerto Rico.

(g) Whether Amgen unlawfully maintained monopoly power through the Defendants' Agreement;

(h) Whether Defendants' scheme, in whole or in Part, has substantially affected intrastate and interstate commerce;

(i) Whether Defendants' agreement harmed competition;

(j) For the Injunction Class, the nature and scope of injunctive relief;

(k) For the Damages Class, whether Defendants' unlawful agreement, in whole or in part, caused antitrust injury through overcharges to the business or property of Plaintiff and the members of the Class;

(l) For the Damages Class, the quantum of overcharges paid by the Class in the aggregate.

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

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

VIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Contract, Combination, and Conspiracy in Restraint of Trade under the Sherman Act § 1 (Against All Defendants)

72. Plaintiff incorporates the preceding paragraphs by reference.

73. An agreement by competing companies to cease competing is "anticompetitive regardless of whether the parties split a market within which both do business or whether they

merely reserve one market for one and another for the other."[17] Defendants here 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 mid-2021;

(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 Plaintiff and the Injunction Class Members would pay for Sensipar to and at supra-competitive levels.

74. The unlawful Amgen-Teva market division agreement is a *per se* violation of the Sherman Act, 15 U.S.C. § 1. Moreover, if the conduct alleged in this Complaint is held subject to a "quick look" analysis, it would satisfy the Supreme Court's test in *California Dental*.[18] That is, "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."[19]

75. 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,*

[17] *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990).

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

[19] *Id.*

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.

76. Here, in exchange for Teva's agreement to delay entering the market until mid-2021 notwithstanding its judgment of non-infringement, under the Amgen-Teva agreement, Teva received at least (a) tens of millions of dollars in profits from sales of generic Sensipar, which it retained and did not pay to Amgen and which reduced Amgen's own revenue from sales of branded Sensipar; (b) an acceleration provision, assuring Teva an ability to resume sales of its generic product if another generic launched before Teva's entry date; and (c) additional value from Amgen's agreement to pay Teva to license certain other Teva products.

77. Individually and collectively, the value that Amgen transferred and Teva received under their agreement exceeded the costs of continued litigation or any arguably procompetitive benefits—and thus was "large and unjustified." Indeed, given that Teva made the calculated decision to launch at risk, presumably based on its own assessment of the strength of its arguments on appeal, it would have been unlikely to change course by withdrawing from the market just one week later absent some significant inducement by Amgen. Accordingly, the Amgen-Teva agreement is unlawful.

78. As a direct and proximate result of Defendants' violation of Sherman Act § 1, Plaintiff and the Injunction Class have been injured in their business and property throughout the Class Period.

79. Plaintiff and the Injunction Class are entitled to injunctive and other equitable relief, pursuant to 15 U.S.C. § 26.

SECOND CLAIM FOR RELIEF
Monopolization under the Sherman Act § 2
(Against Amgen)

80. Plaintiff incorporates the preceding paragraphs by reference.

81. Amgen entered into an unlawful market division agreement that restrained competition in the market for Sensipar and its AB-rated generic equivalents. The agreement:

(a) eliminates existing competition between Amgen and Teva and prevents Teva from competing with Amgen by selling its generic version of Sensipar until mid-2021;

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

(c) raises and maintains the prices that Plaintiff and the Injunction Class Members have to pay for Amgen's Sensipar to and at supra-competitive levels.

82. Amgen's conduct violates Section 2 of the Sherman Act, 15 U.S.C. § 2. Amgen's agreement with Teva perpetuates Amgen's monopoly in the relevant market by excluding competition from Teva, as well as other generics that would have entered pursuant to acceleration clauses in their settlements with Amgen. As a result, Amgen's share of the cinacalcet hydrochloride tablet market is at or near 100%.

83. As a direct and proximate result of Defendants' violation of Sherman Act § 2, Plaintiff and the Injunction Class have been injured in their business and property throughout the Class Period.

84. Plaintiff and the Injunction Class are entitled to injunctive and other equitable relief, pursuant to 15 U.S.C. § 26.

THIRD CLAIM FOR RELIEF
Conspiracy and Combination in Restraint of Trade under State Law
(Against All Defendants)

85. Plaintiff incorporates the preceding paragraphs by reference.

86. Defendants 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 mid-2021;

(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 Plaintiff and the Damages Class Members would pay for Sensipar to and at supra-competitive levels.

87. The unlawful Amgen-Teva market division agreement is a *per se* violation of the below-listed state antitrust laws. Moreover, if the conduct alleged in this Complaint is held subject to a "quick look" analysis, it would satisfy the Supreme Court's test in *California Dental*.[20] That is, "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."[21]

88. 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

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

Teva received that outweighs the agreement's 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.

89. Here, in exchange for Teva's agreement to delay entering the market until mid-2021 notwithstanding its judgment of non-infringement, under the Amgen-Teva agreement, Teva received at least (a) tens of millions of dollars in profits from sales of generic Sensipar, which it retained and did not pay to Amgen and which reduced Amgen's own revenue from sales of branded Sensipar; (b) an acceleration provision, assuring Teva an ability to resume sales of its generic product if another generic launched before Teva's entry date; and (c) additional value from Amgen's agreement to pay Teva to license certain other Teva products.

90. Individually and collectively, the value that Amgen transferred and Teva received under their agreement exceeded the costs of continued litigation or any arguably procompetitive benefits—and thus was "large and unjustified." Indeed, given that Teva made the calculated decision to launch at risk, presumably based on its own assessment of the strength of its arguments on appeal, it would have been unlikely to change course by withdrawing from the market just one week later absent some significant inducement by Amgen. Accordingly, the Amgen-Teva agreement is unlawful.

91. Defendants' conduct violated the following state antitrust laws:

(a) Ariz. Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by the Damages Class Members;

(b) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in California by the Damages Class Members;

(c) D.C. Code Ann. §§ 28-4501, et seq., with respect to purchases in the District of Columbia by the Damages Class Members;

(d) Hawaii Code § 480, et seq., with respect to purchases in Hawaii by the Damages Class Members;

(e) 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by the Damages Class Members;

(f) Iowa Code §§ 553 et seq., with respect to purchases in Iowa by the Damages Class Members;

(g) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by Damages Class Members;

(h) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by the Damages Class Members;

(i) Mich. Comp. Laws Ann. §§ 445.772, et seq., with respect to purchases in Michigan by the Damages Class Members;

(j) Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by the Damages Class Members;

(k) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Damages Class Members;

(l) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by the Damages Class Members;

(m) Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by the Damages Class Members, in that thousands of sales of branded and generic versions of Sensipar took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct;

(n) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by the Damages Class Members;

(o) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by the Damages Class Members;

(p) N.Y. Gen. Bus. L. §§ 340, et seq., with respect to purchases in New York by the Damages Class Members;

(q) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by the Damages Class Members;

(r) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by the Damages Class Members;

(s) Or. Rev. Stat. §§ 6.46.705, et seq., with respect to purchases in Oregon by the Damages Class Members;

(t) S.D. Codified Laws Ann. §§ 37-1, et seq., with respect to purchases in South Dakota by the Damages Class Members;

(u) Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by the Damages Class Members, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of Sensipar at Tennessee pharmacies;

(v) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by Damages Class Members who are either citizens or residents of Utah;

(w) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by the Damages Class Members;

(x) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by the Damages Class Members; and

(y) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by the Damages Class Members, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of Sensipar at Wisconsin pharmacies.

92. Plaintiff and the Damages Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

93. Defendants are jointly and severally liable for all damages suffered by Plaintiff and the Damages Class Members.

FOURTH CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme under State Law
(Against Amgen)

94. Plaintiff incorporates the preceding paragraphs by reference.

95. Amgen entered into an unlawful market division agreement that restrained competition in the market for branded and generic versions of Sensipar. The agreement:

(a) eliminates existing competition between Amgen and Teva and prevents Teva from competing with Amgen by selling its generic version of Sensipar until mid-2021;

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

(c) raises and maintains the prices that Plaintiff and the Damages Class Members have to pay for Amgen's Sensipar to and at supra-competitive levels.

96. Amgen's agreement with Teva perpetuates Amgen's monopoly in the relevant market by excluding competition from Teva, as well as other generics that would have entered pursuant to acceleration clauses in their settlements with Amgen. As a result, Amgen's share of the cinacalcet hydrochloride tablet market is at or near 100%.

97. Amgen's conduct violated the following state antitrust laws:

(a) Ariz. Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by the Damages Class Members;

(b) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in California by the Damages Class Members;

(c) D.C. Code Ann. §§ 28-4501, et seq., with respect to purchases in the District of Columbia by the Damages Class Members;

(d) Hawaii Code § 480, et seq., with respect to purchases in Hawaii by the Damages Class Members;

(e) 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by the Damages Class Members;

(f) Iowa Code §§ 553 et seq., with respect to purchases in Iowa by the Damages Class Members;

(g) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by Damages Class Members;

(h) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by the Damages Class Members;

(i) Mich. Comp. Laws Ann. §§ 445.772, et seq., with respect to purchases in Michigan by the Damages Class Members;

(j) Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by the Damages Class Members;

(k) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Damages Class Members;

(l) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by the Damages Class Members;

(m) Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by the Damages Class Members, in that thousands of sales of branded and generic versions of Sensipar took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendant's conduct;

(n) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by the Damages Class Members;

(o) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by the Damages Class Members;

(p) N.Y. Gen. Bus. L. §§ 340, et seq., with respect to purchases in New York by the Damages Class Members;

(q) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by the Damages Class Members;

(r) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by the Damages Class Members;

(s) Or. Rev. Stat. §§ 6.46.705, et seq., with respect to purchases in Oregon by the Damages Class Members;

(t) S.D. Codified Laws Ann. §§ 37-1, et seq., with respect to purchases in South Dakota by the Damages Class Members;

(u) Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by the Damages Class Members, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of Sensipar at Tennessee pharmacies;

(v) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by Damages Class Members who are either citizens or residents of Utah;

(w) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by the Damages Class Members;

(x) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by the Damages Class Members; and

(y) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by the Damages Class Members, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of Sensipar at Wisconsin pharmacies.

98. Plaintiff and the Damages Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Amgen's anticompetitive conduct

FIFTH CLAIM FOR RELIEF
State Consumer Protection Violations
(Against All Defendants)

99. Plaintiff incorporates the preceding paragraphs by reference.

100. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and the Damages Class Members were deprived of the opportunity to purchase generic versions of Sensipar and were forced to pay higher prices for branded and generic versions of Sensipar.

101. There is gross disparity between the price that Plaintiff and the Damages Class Members paid for Sensipar compared to what they would have paid for less expensive generic versions of Sensipar, which should and would have been available but for Defendants' unlawful conduct.

102. By engaging in the foregoing conduct, Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the following state unfair and deceptive trade practices and consumer protection statutes:

Florida Deceptive & Unfair Trade Practices Act ("FDUTPA")
Florida Stat. §§ 501.201, et seq.

103. The primary policy of the FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Florida Stat. §§ 501.202(2).

104. A claim for damages under the FDUTPA has three elements: (1) a prohibited practice; (2) causation; and (3) actual damages.

105. Under Florida law, indirect purchasers have standing to maintain an action under the FDUTPA based on the facts alleged in this Complaint.

106. Defendants' conduct constitutes an unfair method of competition because Defendants' market division agreement restrained trade in the market for branded and generic versions of Sensipar by (1) eliminating existing competition between Amgen and Teva and preventing Teva from competing with Amgen by selling its generic version of Sensipar until mid-2021; (2) delaying entry of generic versions of Sensipar by companies other than Teva in order to maintain the period in which Amgen monopolizes the relevant market; and (3) raising and maintaining the prices that Plaintiff and the Damages Class Members have to pay for Amgen's Sensipar to and at supra-competitive levels.

107. Defendants sold branded and generic versions of Sensipar in Florida, and their conduct had a direct and substantial impact on trade and commerce in Florida. Accordingly, such conduct falls within the prohibitions in Florida Stat. §§ 501.202(2).

Massachusetts Consumer Protection Act ("MCPA")
Mass. Gen. L. Ch. 93A, et seq.

108. The MCPA regulates trade and commerce "directly or indirectly affecting the people of this commonwealth." Mass. Gen. L. Ch. 93A § 9(1).

109. Under the MCPA, "[a]ny person, who has been injured by another person's use or employment of any method, act or practice" that constitutes "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. L. Ch. 93A §§ 2, 9(1). MCPA § 2(b) provides that these terms are interpreted consistent with Section 5 of the FTC Act (15 U.S.C. § 45(a)), which also prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce." Mass. Gen. L. Ch. 93A § 2(b); 15 U.S. § 45(a)(1).

110. Defendants' conduct constitutes an unfair method of competition because Defendants' market division agreement restrained trade in the market for branded and generic versions of Sensipar by (1) eliminating existing competition between Amgen and Teva and preventing Teva from competing with Amgen by selling its generic version of Sensipar until mid-2021; (2) delaying entry of generic versions of Sensipar by companies other than Teva in order to maintain the period in which Amgen monopolizes the relevant market; and (3) raising and maintaining the prices that Plaintiff and the Damages Class Members have to pay for Amgen's Sensipar to and at supra-competitive levels.

111. Defendants sold branded and generic versions of Sensipar in Massachusetts, and their conduct had a direct and substantial impact on trade and commerce in Massachusetts. Accordingly, such conduct falls within the prohibitions in Ch. 93A § 2.

Missouri Merchandising Practices Act ("MMPA")
Mo. Rev. Stat. 407.020

112. Under Section 407.020, the MMPA prohibits "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce." Mo. Rev. Stat. 407.020.

113. The Missouri Attorney General has defined an "unfair practice" as:

> any practice which . . . [o]ffends any public policy as it has been established by the Constitution, statutes or common law of this state, or by the Federal Trade Commission, or its interpretive decisions; or . . . [i]s unethical, oppressive, or unscrupulous; and . . . [p]resents a risk of, or causes, substantial injury to consumers.

Mo. Att'y Gen. Reg., 15 CSR 60-8.02.

114. Defendants' conduct constitutes an unfair method of competition because Defendants' market division agreement restrained trade in the market for branded and generic

versions of Sensipar by (1) eliminating existing competition between Amgen and Teva and preventing Teva from competing with Amgen by selling its generic version of Sensipar until mid-2021; (2) delaying entry of generic versions of Sensipar by companies other than Teva in order to maintain the period in which Amgen monopolizes the relevant market; and (3) raising and maintaining the prices that Plaintiff and the Damages Class Members have to pay for Amgen's Sensipar to and at supra-competitive levels.

115. Defendants sold branded and generic versions of Sensipar in Missouri, and Defendants' conduct had a direct and substantial impact on trade and commerce in Missouri. Upon information and belief, Defendants also directed advertising and marketing efforts for branded and generic versions of Sensipar in Missouri. Accordingly, Defendants' conduct falls within the prohibitions in the MMPA.

SIXTH CLAIM FOR RELIEF
Unjust Enrichment
(Against All Defendants)

116. Plaintiff incorporates by reference the preceding allegations.

117. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

118. This claim is pled by Plaintiff and the Damages Class against all Defendants.

119. Defendants have financially benefited from overcharges on sales of branded and generic versions of Sensipar, which resulted from the unlawful and inequitable acts alleged in this Complaint. These overcharges were borne by Plaintiff and the Damages Class Members who purchased and/or reimbursed all or part of the purchase price of branded and generic Sensipar. The benefits conferred upon Defendants are substantial and measurable, in that the revenues Defendants have earned due to unlawful overcharges are ascertainable by review of both sales records and the unlawful agreement itself.

120. There is gross disparity between the price that Plaintiff and the Damages Class Members paid for Sensipar compared to what they would have paid for less expensive generic versions of Sensipar, which should and would have been available but for Defendants' unlawful and inequitable conduct.

121. Defendants repeatedly and continuously received financial benefits at the expense of Plaintiff and the Damages Class Members through each sale of branded and generic versions of Sensipar at an inflated price.

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

123. It would be futile for Plaintiff and the Damages Class Members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Sensipar, as those intermediaries cannot reasonably be expected to compensate Plaintiff and the Damages Class Members for Defendants' unlawful conduct.

124. The financial benefits that Defendants derived rightfully belong to Plaintiff and the Damages Class Members, which paid anticompetitive prices that inured to Defendants' benefit.

125. It would be inequitable under the unjust enrichment principles of the states listed below for Defendants to retain any of the overcharges that Plaintiff and the Damages Class Members paid for branded and generic versions of Sensipar, which were derived from Defendants' anticompetitive, unfair, and unconscionable methods, acts, and trade practices.

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

127. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received, which arise from overpayments for branded and generic versions of Sensipar by Plaintiff and the Damages Class Members.

128. Plaintiff and the Damages Class Members have no adequate remedy at law.

129. By engaging in the foregoing unlawful or inequitable conduct, which deprived Plaintiff and the Damages Class Members of the opportunity to purchase lower-priced generic versions of Sensipar and forced them to pay higher prices for branded and generic versions of Sensipar, Defendants have been unjustly enriched in violation of the common law of various states and commonwealths, as outlined below:

Alabama

130. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Alabama at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Damages Class as a direct result of the unlawful overcharges and have retained this money. Defendants have benefitted at the expense of the Damages Class from revenue resulting from unlawful overcharges for branded and generic versions of Sensipar. It is inequitable for Defendants to accept and retain the benefits received without compensating the Damages Class.

Alaska

131. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Alaska at prices

that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefits bestowed upon them by the Damages Class. Defendants accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Arizona

132. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Arizona at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Sensipar. The Damages Class has been impoverished by the overcharges for branded and generic versions of Sensipar resulting from Defendants' unlawful conduct. Defendants' enrichment and the Damages Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment and the Damages Class's impoverishment, because the Damages Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Damages Class has no remedy at law.

Arkansas

133. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Arkansas at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Damages Class as a direct result of the unlawful overcharges and have

retained this money. Defendants have paid no consideration to any other person in exchange for this money. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

California

134. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in California at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class as a direct result of the unlawful overcharges. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of the Damages Class.

Colorado

135. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Colorado at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants have benefitted at the expense of the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Connecticut

136. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Connecticut at prices that were more than they would have been but for Defendants' actions. Defendants were benefitted in the nature of revenue resulting from unlawful overcharges to the economic

detriment of the Damages Class. Defendants have paid no consideration to any other person in exchange for this benefit. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of the Damages Class.

Delaware

137. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Delaware at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Sensipar. The Damages Class has been impoverished by the overcharges for branded and generic versions of Sensipar resulting from Defendants' unlawful conduct. Defendants' enrichment and the Damages Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Damages Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Damages Class has no remedy at law.

District of Columbia

138. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in the District of Columbia at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Damages Class. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits.

Florida

139. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Florida at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefits bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Georgia

140. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Georgia at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Hawaii

141. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Hawaii at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Idaho

142. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Idaho at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit conferred upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Illinois

143. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Illinois at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Damages Class. It is against equity, justice, and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Iowa

144. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Iowa at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Sensipar, which revenue resulted from anticompetitive prices paid by the Damages Class, which inured to Defendants' benefit. Defendants' enrichment has occurred at the expense of the

Damages Class. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Damages Class.

Kansas

145. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Kansas at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Kentucky

146. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Kentucky at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit conferred upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Louisiana

147. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Louisiana at prices that were more than they would have been but for Defendants' actions. Defendants have

been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Sensipar. The Damages Class has been impoverished by the overcharges for branded and generic versions of Sensipar resulting from Defendants' unlawful conduct. Defendants' enrichment and the Damages Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Damages Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Damages Class has no other remedy at law.

Maine

148. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Maine at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Maryland

149. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Maryland at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Damages Class. Under the

circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Massachusetts

150. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Massachusetts at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of or appreciated the benefit conferred upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Michigan

151. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Michigan at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Minnesota

152. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Minnesota at prices that were more than they would have been but for Defendants' actions. The Damages

Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated and knowingly accepted the benefits bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Mississippi

153. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Mississippi at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Damages Class as a direct result of the unlawful overcharges. Defendants retain the benefit of overcharges received on the sales of branded and generic versions of Sensipar, which in equity and good conscience belong to the Damages Class on account of Defendants' anticompetitive conduct. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Missouri

154. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Missouri at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit bestowed upon them by the Damages Class. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Damages Class.

Montana

155. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Montana at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Nebraska

156. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Nebraska at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Damages Class as a direct result of the unlawful overcharges and have retained this money. Defendants have paid no consideration to any other person in exchange for this money. In justice and fairness, Defendants should disgorge such money and remit the overcharged payments back to the Damages Class.

Nevada

157. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Nevada at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges for branded and generic versions of Sensipar. Defendants appreciated the benefits bestowed upon them by the Damages Class, for which they have paid no consideration to any

other person. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

New Hampshire

158. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in New Hampshire at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Under the circumstances, it would be unconscionable for Defendants to retain such benefits.

New Jersey

159. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in New Jersey at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Damages Class. Defendants have paid no consideration to any other person for any of the unlawful benefits they received from the Damages Class with respect to Defendants' sales of branded and generic versions of Sensipar. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Damages Class.

New Mexico

160. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in New Mexico at prices that were more than they would have been but for Defendants' actions. Defendants have knowingly benefitted at the expense of the Damages Class from revenue resulting from unlawful overcharges for branded and generic versions of Sensipar. To allow Defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Defendants' benefit and because Defendants have paid no consideration to any other person for any of the benefits they received.

New York

161. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in New York at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Sensipar, which revenue resulted from anticompetitive prices paid by the Damages Class, which inured to Defendants' benefit. Defendants' enrichment has occurred at the expense of the Damages Class. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

North Carolina

162. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in North Carolina at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. The Damages Class did

not interfere with Defendants' affairs in any manner that conferred these benefits upon Defendants. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from unlawful overcharges to the Damages Class. The benefits conferred upon Defendants are measurable, in that the revenue Defendants have earned due to unlawful overcharges are ascertainable by review of sales records. Defendants consciously accepted the benefits conferred upon them.

North Dakota

163. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in North Dakota at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Sensipar. The Damages Class has been impoverished by the overcharges for branded and generic versions of Sensipar resulting from Defendants' unlawful conduct. Defendants' enrichment and the Damages Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Damages Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Damages Class has no remedy at law. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Damages Class.

Oklahoma

164. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Oklahoma at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Damages Class as a direct result of the unlawful overcharges and have

retained this money. Defendants have paid no consideration to any other person in exchange for this money. The Damages Class has no remedy at law. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Oregon

165. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Oregon at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Damages Class.

Pennsylvania

166. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Pennsylvania at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Puerto Rico

167. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Puerto Rico at prices that were more than they would have been but for Defendants' actions. Defendants have

been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Sensipar. The Damages Class has been impoverished by the overcharges for branded and generic versions of Sensipar resulting from Defendants' unlawful conduct. Defendants' enrichment and the Damages Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment and the Damages Class's impoverishment, because the Damages Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Damages Class has no remedy at law.

Rhode Island

168. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Rhode Island at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

South Carolina

169. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in South Carolina at prices that were more than they would have been but for Defendants' actions. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Damages Class. Defendants realized value from the benefit bestowed upon them by the Damages Class. Under

the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

South Dakota

170. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in South Dakota at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants were aware of the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without reimbursing the Damages Class.

Tennessee

171. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Tennessee at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class. It would be futile for the Damages Class to seek a remedy from any party with whom they have privity of contract. Defendants have paid no consideration to any other person for any of the unlawful benefits they received indirectly from the Damages Class with respect to Defendants' sales of branded and generic versions of Sensipar. It would be futile for The Damages Class to exhaust all remedies against the entities with which the Damages Class has

privity of contract because the Damages Class did not purchase branded and generic versions of Sensipar directly from any Defendant.

Texas

172. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Texas at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants were aware of or appreciated the benefit bestowed upon them by the Damages Class. The circumstances under which Defendants have retained the benefits bestowed upon them by the Damages Class are inequitable in that they result from Defendants' unlawful overcharges for branded and generic versions of Sensipar. The Damages Class has no remedy at law.

Utah

173. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Utah at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Vermont

174. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Vermont at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants accepted the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Virginia

175. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Virginia at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of the benefit bestowed upon them. Defendants should reasonably have expected to repay the Damages Class. The benefits conferred upon Defendants were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Defendants' illegal and unfair actions to inflate the prices of branded and generic versions of Sensipar. Defendants have paid no consideration to any other person for any of the benefits they have received from the Damages Class.

Washington

176. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Washington at

prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of or appreciated the benefit conferred upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

West Virginia

177. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in West Virginia at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Wisconsin

178. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Wisconsin at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Wyoming

179. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for branded and generic versions of Sensipar in Wyoming at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants accepted, used and enjoyed the benefits bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

IX. DEMAND FOR JUDGMENT

180. Accordingly, Plaintiff, on behalf of itself and the proposed Classes, respectfully demands that this Court:

(a) Determine that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Classes, and declare Plaintiff as the representative of the Classes;

(b) Enter joint and several judgments against the Defendants and in favor of Plaintiff and the Classes;

(c) Enjoin Defendants from continuing their unlawful market division agreement;

(d) Grant Plaintiff and the Classes equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

(e) Award the Damages Class damages, and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial;

(f) Award Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

(g) Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

X. JURY DEMAND

181. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Classes, demands a trial by jury on all issues so triable.

Date: February 21, 2019

LABATON SUCHAROW LLP

By: *<u>/s/ Ned Weinberger</u>*
Ned Weinberger (Bar No. Bar No. 5256)
300 Delaware Avenue
Suite 1340
Wilmington, Delaware 19801
Tel: (302) 573-2540
nweinberger@labaton.com

Ian Connor Bifferato (Bar No. 3273)
THE BIFFERATO FIRM, P.A.
1007 N. Orange Street, 4th Floor
Wilmington, DE 19801
Tel.: (302) 225-7600
cbifferato@tbf.legal

Counsel for UFCW Local 1500 Welfare Fund and the Proposed Classes

OF COUNSEL:

Gregory S. Asciolla
Jay L. Himes
Karin E. Garvey
Robin A. van der Meulen
Matthew J. Perez
Domenico Minerva
LABATON SUCHAROW LLP
140 Broadway
New York, New York 10005
Tel: (212) 907-0700
Fax: (212) 818-0477
gasciolla@labaton.com
jhimes@labaton.com
kgarvey@labaton.com
rvandermeulen@labaton.com
mperez@labaton.com
dminerva@labaton.com

Scott A. Martin
Irving Scher
HAUSFELD LLP
33 Whitehall Street, 14th Floor
New York, NY 10004
Tel: (646) 357-1100
Fax: (212) 202-4322
smartin@hausfeld.com
ischer@hausfeld.com

Brent Landau
HAUSFELD LLP
325 Chestnut Street, Suite 900
Philadelphia, PA 19106
Tel: (215) 985-3270
Fax: (215) 985-3271
blandau@hausfeld.com

Melinda R. Coolidge
HAUSFELD LLP
1700 K Street, NW
Suite 650
Washington, DC 20006
Tel: (202) 540-7200
Fax: (202) 540-7201
mcoolidge@hausfeld.com

Roberta D. Liebenberg
Jeffrey S. Istvan
Paul Costa
Adam J. Pessin
FINE, KAPLAN AND BLACK, R.P.C.
One South Broad Street, 23rd Floor
Philadelphia, PA 19107
Tel: (215) 567-6565
Fax: (215) 568-5872
rliebenberg@finekaplan.com
jistvan@finekaplan.com
pcosta@finekaplan.com
apessin@finekaplan.com

Counsel for UFCW Local 1500 Welfare Fund and the Proposed Classes

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AMGEN INC., Plaintiff, v. AMNEAL PHARMACEUTICALS LLC, et al., Defendants.	)	Civ. No. 16-853-MSG CONSOLIDATED

Jack B. Blumenfeld, Esquire and Maryellen Noreika, Esquire of Morris, Nichols, Arsht & Tunnell LLP, Wilmington, Delaware. *Counsel for Plaintiff Amgen Inc*. Of Counsel: Frederick C. Millett, Esquire and Rosanna W. Gan, Esquire of Fitzpatrick, Cella, Harper & Scinto, New York, New York, and Kathryn E. Easterling, Esquire of Fitzpatrick, Cella, Harper & Scinto, Washington, D.C.

David E. Moore, Esquire, Alan R. Silverstein, Esquire, Bindu A. Palapura, Esquire, and Stephanie O'Byrne of Potter, Anderson & Corroon, LLP, Wilmington, Delaware. *Counsel for Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York LLC*. Of Counsel: Jake M. Holdreith, Esquire and Kelsey J. Thorkelson, Esquire of Robins Kaplan LLP, Minneapolis, Minnesota, Oren D. Langer, Esquire of Robins Kaplan LLP, New York, New York.

John C. Phillips, Jr., Esquire and David A. Bilson, Esquire of Phillips, Goldman, McLaughlin & Hall, P.A., Wilmington, Delaware. *Counsel for Defendant Piramal Healthcare UK Ltd*. Of Counsel: Aaron F. Barkoff, Esquire, Alejandro Menchaca, Esquire, and Rajendra A. Chiplunkar, Esquire of McAndrews Held & Malloy Ltd., Chicago, Illinois.

John W. Shaw, Esquire, Karen E. Keller, Esquire, and David M. Fry, Esquire of Shaw Keller LLP, Wilmington, Delaware. *Counsel for Defendants Watson Laboratories, Inc., Actavis, Inc., and Actavis Pharma, Inc.* Of Counsel: Christopher B. Essig, Esquire, George C. Lombardi, Esquire, Elizabeth E. Grden, Esquire, and Zachary L. Sorman, Esquire of Winston & Strawn LLP, Chicago, Illinois.

John C. Phillips, Jr., Esquire and David A. Bilson, Esquire of Phillips, Goldman, McLaughlin & Hall, P.A., Wilmington, Delaware. *Counsel for Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (d.b.a. Zydus Cadila)*. Of Counsel: William D. Hare, Esquire and Renita S. Rathinam, Esquire of McNeely, Hare & War LLP, Washington, D.C., and Christopher S. Casieri, Esquire of McNeely, Hare & War LLP, Princeton, New Jersey.

GOLDBERG, M., District Judge **JULY 26, 2018**

OPINION

I. INTRODUCTION

This is a consolidated patent infringement action arising under the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355, also known as the Hatch-Waxman Act. United States Patent No. 9,375,405 (the "'405 patent") is assigned to Plaintiff Amgen Inc. ("Amgen") and listed in the Approved Drug Products with Therapeutic Equivalents (the "Orange Book") as covering Sensipar®. Amgen accuses multiple Defendants of infringing the '405 patent by filing Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to manufacture, use and/or sell generic versions of Sensipar®. These Defendants are Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York LLC (collectively, "Amneal"), Piramal Healthcare UK Ltd. ("Piramal"), Watson Laboratories, Inc., Actavis, Inc., and Actavis Pharma, Inc. (collectively, "Watson"), and Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively, "Zydus").

I bifurcated the infringement claims and invalidity counterclaims for trial, and held a four-day bench trial on infringement beginning on March 5, 2018. At the time of the pretrial conference, this case involved five additional defendants that have since entered into a consent judgment or stipulation of dismissal. (D.I. 316, D.I. 317, D.I. 320, D.I. 321, D.I. 348). Of those

five defendants, only one participated at trial: Aurobindo Pharma USA Inc. and Aurobindo Pharma USA, Inc., known collectively as "Aurobindo." Presently before me are the parties' post-trial proposed findings of fact and conclusions of law concerning infringement of the '405 patent. (D.I. 359, D.I. 360, D.I. 366, D.I. 367). I have subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this court under 28 U.S.C. §§ 1391 and 1400(b).[1]

II. BACKGROUND

A. The '405 Patent

The '405 patent, entitled "Rapid Dissolution Formulation of Calcium Receptor-Active Compound," was issued by the United States Patent and Trademark Office ("Patent Office") on June 28, 2016. (D.I. 293, Ex. 1 at ¶ 5). The patent issued from U.S. Patent Application No. 12/942,646 (the "'646 application"), filed on November 9, 2010, and claims priority to U.S. Provisional Patent Application No. 60/502,219, filed on September 12, 2003. (*Id*. at ¶¶ 7, 8). The '405 patent has two independent claims (claims 1 and 20) and twenty-one dependent claims. (JTX 2 at 13:18-15:3).

For most of the asserted claims, the parties' stipulated that a finding of infringement would depend on the findings for claim 1 of the '405 patent. (*See* D.I. 336). Claim 1 recites a pharmaceutical composition combining specific excipients in specific amounts with the active ingredient cinacalcet hydrochloride ("cinacalcet HCI"). Excipients are the inert ingredients used in drug formulations to perform specific functions, such as diluent, binder, or disintegrant. (JTX 11 at 2545). Diluents provide bulk to the formulation so that the tablets are of sufficient size for

[1] On May 18, 2017, Chief Judge D. Brooks Smith of the United States Court of Appeals for the Third Circuit designated me as a visiting judge for the District of Delaware, pursuant to 28 U.S.C. § 292(b), to handle this and other Delaware cases.

handling. (PTX 454 at 404; D.I. 356 at 946:13-19). Binders act as the adhesive that holds the drug and excipients together. (D.I. 353 at 186:8-20). Disintegrants ensure the breakup of the tablet upon ingestion thereby promoting absorption of the drug substance. (JTX 11 at 2545; PTX 447 at 105). With that background in mind, claim 1 of the '405 patent specifically states:

> A pharmaceutical composition comprising:
>
> (a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg;
>
> (b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrins, and mixtures thereof;
>
> (c) from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof; and
>
> (d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovidine (sic), sodium starch glycolate, croscarmellose sodium, and mixtures thereof;
>
> wherein the percentage by weight is relative to the total weight of the composition, and wherein the composition is for the treatment of at least one of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

(JTX 2 at 13:18-39).

For reasons unknown to me, the parties' stipulation did not cover three of the dependent claims Amgen has asserted against various defendants. Those are claims 5, 6, and 18. Claim 5 recites, "The composition according to claim 1, wherein the at least one binder is povidone." (JTX 2 at 13:53-54). Claim 6 recites, "The composition according to claim 1, wherein the at least one disintegrant is crospovidone." (*Id*. at 13:55-56). Claim 18 recites, "The composition according to claim 1, wherein the hyperparathyroidism is primary hyperparathyroidism or secondary hyperparathyroidism." (*Id*. at 14:23-24).

B. Person of Ordinary Skill in the Art ("POSA")

The parties' definitions of a POSA do not meaningfully differ. (*See, e.g.*, D.I. 356 at 907:1-8; D.I. 353 at 183:5-16). A POSA should have an advanced degree with a M.S. or Ph.D. in chemistry, pharmacy and/or pharmacology or a related field, as well as work experience in drug dosage and formulations. (D.I. 356 at 939:17-940:4; *accord* D.I. 353 at 182:10-183:4).

C. Prosecution of the '405 Patent

1. The Original Claim

The '646 application was a continuation of U.S. Patent Application No. 10/937,870 (the "'870 application"). As originally-filed by Amgen, the '646 application contained one broad claim. (JTX 5 at SENS-AMG 47; D.I. 355 at 621:23-622:14). Claim 1 covered a "pharmaceutical composition comprising an effective dosage amount of a calcium receptor active compound and at least one pharmaceutically acceptable excipient." The claim further stated that the composition had a particular dissolution profile. (JTX 5 at SENS-AMG 47). But the dissolution profile has not been relevant in this litigation, except to note that the inventive feature of the '405 patent was a "rapid" dissolution profile for a poorly soluble drug. (*Id*. at SENS-AMG 520).

2. The 2011 Preliminary Amendment

Before the Patent Office took formal action on the original claim, Amgen filed a preliminary amendment on November 15, 2011 (the "2011 Preliminary Amendment") cancelling claim 1 and adding new claims 2 through 24. (JTX 5 at SENS-AMG 257-62). Claim 2 narrowed the scope of the claims by requiring specific amounts of three specific types of excipient—diluents, binders, and disintegrants—and further requiring that the diluent be selected from a Markush group. (*Id.*; D.I. 354 at 393:16-20). A Markush group "lists alternative species

or elements that can be selected as part of the claimed invention." *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp*., 831 F.3d 1350, 1357 (Fed. Cir. 2016). It is typically expressed in the form: "a member selected from the group consisting of A, B and C." *Abbott Labs. v. Baxter Pharm. Prods., Inc*., 334 F.3d 1274, 1280 (Fed. Cir. 2003). New independent claim 2 read:

> A pharmaceutical composition comprising:
>
> (a) from about 10% to about 40% by weight of cinacalcet HCl;
>
> (b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrins, and mixtures thereof,
>
> (c) from about 1% to about 5% by weight of at least one binder; and
>
> (d) from about 1% to 10% by weight of at least one disintegrant, wherein the percentage by weight is relative to the total weight of the composition.

(JTX 5 at SENS-AMG 258). Claims 3 through 23 were dependent on claim 2; claim 24 was the same as claim 2 except without the Markush group. (*Id.*).

On September 16, 2014, the Patent Office issued a non-final Office Action rejecting claims 2 through 24 as obvious "over Van Wagenen (US 6,211,244 B1) as evidenced by Kajiyama et al. (US 6,656,492), in view of Creekmore (US 6,316,460 B1) and Hsu et al. (US 2005/0147670)." (JTX 5 at SENS-AMG 291-97). As the Examiner explained, Van Wagenen discloses compounds that "read on cinacalcet HCl" and "can be used to treat diseases such as primary hyperparathyroidism and secondary hyperparathyroidism." (*Id.* at SENS-AMG 293-94). Hsu discloses pharmaceutical formulations where eleven specific binders—including starch and all four binders in claim 1 of the '405 patent—may be present in an amount from about 1% to about 80% by weight. (*Id.*; PTX 11 at ¶¶ 17, 46). Hsu also discloses twelve specific disintegrants—including all three disintegrants in claim 1 of the '405 patent—that may be

present in an amount of about 0.1% to about 10% by weight. (JTX 5 at SENS-AMG 293-97; PTX 11 at ¶ 51). Creekmore discloses pharmaceutical formulations where nineteen binders—including starch, pregelatinized starch, and three of the four binders in claim 1 of the '405 patent—may be present in an amount of 2% to 90% by weight. (JTX 5 at SENS-AMG 295; PTX 7 at 2:32-43). Creekmore also discloses that eight disintegrants—including all three disintegrants in claim 1 of the '405 patent—may be present in an amount of about 2% to 10%. (JTX 5 at SENS-AMG 295; PTX 7 at col. 2-3).

3. The 2014 Amendment

On December 15, 2014, Amgen responded to the September 16, 2014 Office Action by filing an amendment (the "2014 Amendment") that narrowed the claims. (D.I. 354 at 394:20-395:1). Amgen amended independent claim 2 to add that the cinacalcet HCl must be present "in an amount of from about 20 mg to about 100 mg." (JTX 5 at SENS-AMG 308-318). Amgen argued to the Patent Office that the 2014 Amendment overcame the prior art references cited in the Office Action by adding a precise amount of cinacalcet HCI. (*Id.* at SENS-AMG 313-319).

4. The Examiner's Amendment

The Examiner did not allow the 2014 Amendment. (D.I. 354 at 398:2-7). Instead, on March 12, 2015, the Examiner had an interview with Amgen's counsel and proposed an Examiner's Amendment that further narrowed the claims. (JTX 5 at SENS-AMG 340). The Examiner's Amendment canceled dependent claims 6, 8, and 22 and imported those limitations into independent claim 2 (which later issued as claim 1). (*Id*. at SENS-AMG 333-338). Original claim 6 stated, "The composition according to claim 1, wherein the at least one binder is selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof." (*Id.* at SENS-AMG 310). Original

claim 8 stated, "The composition according to claim 1, wherein the at least one disintegrant is selected from the group consisting of crospovidine (sic), sodium starch glycolate, croscarmellose sodium, and mixtures thereof." (*Id.*). Original claim 22 was a treatment limitation. Thus, as proposed by the Examiner, amended claim 2 now read:

> A pharmaceutical composition comprising:
>
> (a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg;
>
> (b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrins, and mixtures thereof,
>
> (c) from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof; and
>
> (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,
>
> wherein the percentage by weight is relative to the total weight of the composition, and wherein the composition is for the treatment of at least one of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

(*Id.* at SENS-AMG 333-34 (underlining Examiner's amendments)).

After Amgen agreed to the Examiner's Amendment, the Examiner found that the pending claims overcame the obviousness rejection. (JTX 5 at SENS-AMG 338). Thus, on March 25, 2015, the Patent Office issued a Notice of Allowance with three attachments: the Examiner-Initiated Interview Summary, the Examiner's Amendment, and the Examiner's Statement of Reasons for Allowance. (*Id*. at SENS-AMG 332). The Examiner's reasons for allowance stated:

> The closet [sic] prior art was that which was cited in the previous office action filed on 09/16/2014, but fails to specifically disclose or render obvious the combination of components and in the amounts thereof set forth in claim 2.

> The claimed subject matter is not taught or suggested by the cited reference and thus, the claimed subject matter are [sic] considered to be novel and patentably distinct over the prior art of the record.

(*Id.* at 338). Although there was additional prosecution after this first notice of allowance, the claims ultimately issued in the same form. Independent claims 2, 24, and 26 from the patent application issued as independent claims 1, 20, and 21, respectively. (*Id.*).

5. Additional Prosecution and Issuance of the '405 Patent.

After the Examiner allowed Amgen's claims, Amgen filed a series of Requests for Continued Examination ("RCE"). (JTX 5 at SENS-AMG 345-46, SENS-AMG 1092-93, SENS-AMG 1613-14). With each RCE, Amgen submitted Information Disclosure Statements identifying additional prior art and documents Amgen claimed were relevant to the prosecution of the '405 patent. (JTX 5 at SENS-AMG 348-1063, SENS-AMG 1095-1576, SENS-AMG 1611-12). None of Amgen's RCEs amended the claims or made further arguments for patentability. (*Id.*).

On December 1, 2015, while Amgen's second RCE was pending, Amgen submitted a preliminary amendment (the "2015 Preliminary Amendment"). (*Id.* at SENS-AMG 1577-86). In this amendment, Amgen re-submitted the claims as they appeared in the Examiner's Amendment, except Amgen underlined the Examiner's verbatim additions. (Compare JTX 5 at SENS-AMG 1578 (Amgen's Amendment), with *id.* at SENS-AMG 333-34 (Examiner's Amendment); *see also* D.I. 354 at 360:1-14). In the Remarks section of the document, Amgen's counsel stated that the "amendments have not been made in response to a prior art rejection but rather to place the claims in proper format and to better define the claimed subject matter, including equivalents." (*Id.* at SENS-AMG 1583). After each RCE and the 2015 Preliminary Amendment, the Examiner allowed the same claims as originally set forth in the Examiner's Amendment. The Examiner's statement of reasons for allowance identified "the amount of

cinacalcet HCl," "the nature of the excipients," and "their respective combinations." (*See* JTX 5 at SENS-AMG 1064-71, SENS-AMG 1587-95, SENS-AMG 1643-50, and SENS-AMG 1693).

D. Claim Construction

The court has construed three terms in claim 1 of the '405 patent. On July 19, 2017, the Honorable Gregory Sleet, who was first assigned to this matter, construed the term "relative to the total weight of the compositions" in accordance with its plain and ordinary meaning. (D.I. 186). On February 27, 2018, this case having been reassigned to me as a visiting judge, I construed the Markush groups for the binder and disintegrant elements as "closed to unrecited binders and disintegrants." (D.I. 300 at 6). I concluded that "there could be no literal infringement if the Defendants' ANDA product contained an unrecited (or unlisted) binder or disintegrant." (*Id*.). Thus, in order to prove literal infringement, Amgen must prove that all of the binders and disintegrants in a defendant's ANDA product are members of the respective Markush group. (*Id*. at 9).

Amgen opposed the court's construction of the Markush groups by filing a motion for reargument, which was denied. (D.I. 323, D.I. 358). Amgen also elicited testimony from its expert, Dr. Davies, and made arguments in its post-trial brief that were inconsistent with the controlling claim construction. (*See, e.g*., D.I. 354 at 283:4-18; *Id*. at 297:9-14; *Id*. at 457:8-15; D.I. 355 at 539:8-540:21; D.I. 359 at 25). "Once a district court has construed the relevant claim terms, and unless altered by the district court, then that legal determination governs for purposes of trial." *Exergen Corp. v. Wal-Mart Stores, Inc*., 575 F.3d 1312, 1321 (Fed. Cir. 2009). Thus, Dr. Davies' expert testimony regarding infringement will be disregarded where it was inconsistent with or "based on an incorrect understanding of the claim construction." *Cordis*

Corp. v. Boston Sci. Corp., 658 F.3d 1347, 1357–58 (Fed. Cir. 2011). In addition, I will not address Amgen's arguments that are based on a claim construction I have already rejected.[2]

Finally, I must correct Amgen's assertion in its post-trial brief that my opinion denying the motion for reargument held, as a matter of law, that any pregelatinized starch in a defendant's accused product "count[s]" only as a diluent. (D.I. 359 at 13, 17, 22). That opinion's discussion of pregelatinized starch was limited to the Example in the '405 patent. (*See* D.I. 357 at 9-11). In that opinion, I rejected Amgen's argument that the only way to give meaning to the Example was to construe claim 1 as open to unlisted binders. (*Id*.). As I explained, claim 1 of the '405 patent covers pregelatinized starch that functions as a diluent. (*Id*.). In addition, the '405 patent teaches that the pregelatinized starch in the Example is functioning as a diluent. (*Id*.). So, the '405 patent already covered the Example without having to construe the claim as open to unlisted binders. (*Id*.). What the '405 patent teaches about the Example, however, does not dictate how pregelatinized starch functions in a defendant's formulation. As every expert witness at trial testified, the particular function of pregelatinized starch in any given formulation depends on the context. (JTX 11 at 2548; PTX 438 at 686; D.I. 354 at 268:21-269:3; *Id*. at 309:21-22; *Id*. at 468:1-9; D.I. 355 at 504:14-505:1; *Id*. at 506:15-507:17; *Id*. at 510:2-11; *Id*. at 511:4-512:5; *Id*. at 584:19-585:5; D.I. 356 at 955:14-956:10; *Id*. at 1082:20-1083:15). My memorandum opinion on the motion for reargument was consistent with these scientific principles. Contrary to Amgen's assertion, I did not previously hold that the pregelatinized starch in a defendant's formulation counts only as a diluent.

[2] For example, Amgen argues that Opadry infringes the binder limitation, because the open-ended term "comprising" in claim 1 allows for unlisted excipients such as polyethylene glycol, and Opadry is an excipient made in part with polyethylene glycol. (D.I. 359 at 25).

III. CONCLUSIONS OF LAW

A. Standard

A patent is infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States ... during the term of the patent." 35 U.S.C. § 271(a). To provide jurisdiction over an infringement dispute before an ANDA applicant has actually made or marketed the proposed product, 35 U.S.C. § 271(e)(2) states that submission of an ANDA is an act infringement "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent . . . before the expiration of such patent." The filing of an ANDA alone does not prove infringement. *Glaxo, Inc. v. Novopharm, Ltd*., 110 F.3d 1562, 1570 (Fed. Cir. 1997). Rather, the patentee must show, using "traditional patent infringement analysis," that "the alleged infringer will likely market an infringing product." *Id*. at 1569-70; *see also Warner-Lambert Co. v. Apotex Corp*., 316 F.3d 1348, 1365–66 (Fed. Cir. 2003)

A traditional infringement analysis entails two steps. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). First, the court must determine the meaning and scope of the asserted claims. *Id.* Second, the trier of fact must compare the properly construed claims with the product accused of infringement. *Id*. The patent owner must show, by a preponderance of the evidence, that each and every limitation of the asserted patent claim is found in the accused product, either literally or by equivalent. *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

B. Amneal

Amneal filed Abbreviated New Drug Application No. 204364 ("ANDA") with the FDA seeking approval to market a generic version of cinacalcet hydrochloride in 30, 60, and 90 mg

dosage strengths. (D.I. 293, Ex. 1 at ¶ 35). Amneal included a certification in its ANDA pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") stating that the '405 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Amneal's product. (*Id*. at ¶ 36). Amgen claims that Amneal's product will infringe claims 1-4, 6, 8-12, and 14-18 of the '405 patent. (D.I. 293, Ex. 2 at ¶¶ 25-26). Amneal has stipulated that if its ANDA product infringes claim 1, then its ANDA product will also infringe claims 2-4, 8-12, and 14-17, to the extent each claim is found valid and enforceable. (D.I. 336 at ¶ 1). The stipulation did not cover the asserted claims 6 and 18.

According to the ANDA, Amneal's product has the following composition:[3]

Ingredient	**Function**
Cinacalcet HCl	Active
Mannitol	Diluent
Microcrystalline Cellulose	Diluent
Opadry Clear YS-1-7006	Binder
Crospovidone	Disintegrant
Pregelatinized Starch	Secondary Disintegrant

(PTX 183 at 42).

1. Binder

According to the ANDA, the only binder in Amneal's product is Opadry YS-1-7006 ("Opadry"). But claim 1 of the '405 patent does not list Opadry in the Markush group for binders, which means under my claim construction order, there is not a clear case of literal

[3] As is true for all defendants in this case, Amneal's pharmaceutical composition includes additional excipients not relevant to this litigation and, therefore, not discussed here.

infringement. Amgen nonetheless attempts to prove literal infringement by arguing that Opadry is a pseudonym for hydroxypropyl methylcellulose ("HPMC"), which is a listed binder. (D.I. 359 at 24-25). Alternatively, Amgen argues that infringement is established through the doctrine of equivalents. (*Id*. at 26-27). I disagree with Amgen on both of these arguments.

To start, I find that a POSA would not regard Opadry as a synonym or trade name for HPMC. Authoritative pharmaceutical handbooks relied on in the industry identify synonyms for excipients. (*See* PTX 438 at 326). Opadry is not one of the synonyms given for HPMC. (*Id*.). It was also common practice for the inventors of the '405 patent and Amneal's ANDA to list an excipient followed by its tradename in parenthesis. (*See, e.g*., JTX 2 at 11:21-42 ("Microcrystalline cellulose (Avicel PH102)," "Povidone (Plasdone K29/32)," etc.); PTX 183 at 42 ("Mannitol, USP (Mannogem EZ)," "Microcrystalline Cellulose, NF (Vivapur Type 101)," etc.)). Whenever HPMC appears in the '405 patent, it is not followed by a reference to Opadry. (JTX 2 at 6:61, 7:30-31). The opposite is also true. Whenever the '405 patent or Amneal's ANDA mention Opadry, it is not linked to HPMC. (JTX 2 at 11:37, 11:39, 12:22, 12:23; PTX 183 at 42).

In addition, I conclude for numerous reasons that Opadry is not literally HPMC. The excipients have different chemical structures, physical characteristics, binding mechanisms, and commercial sources. HPMC is a single molecule, whereas Opadry is a molecular dispersion of three distinct chemical ingredients: HPMC, polyethylene glycol 400, and polyethylene glycol 8000. (D.I. 355 at 796:8-22; DTX-AMN 7 at 8). HPMC is "an off-white poorly flowing powder," whereas the three ingredients in Opadry make a "slurry." (D.I. 355 at 791:4-24). HPMC binds principally through adhesion, while Opadry binds principally through cohesion. (*Id*. at 796:23-797:9). Specifically, HPMC acts as a wet granulation binder by sticking different

types of particles together, forming a granule from the inside, out. (*Id.* at 797:2-5). But Opadry acts as a wet granulation binder by spreading and surrounding the drug and excipient particles, forming a granule from the outside, in. (*Id.* at 797:5-9). Opadry is a product manufactured by a single company, Colorcon, using a proprietary method, whereas HPMC is not. (*Id*. at 788:18-21). Given the above evidence, Amgen has failed to prove by a preponderance of the evidence that Opadry is actually HPMC. Because Opadry is an unlisted binder, Amneal does not literally infringe the binder limitation of claim 1.

Amgen also does not infringe the binder limitation under the doctrine of equivalents. A finding of infringement under the doctrine of equivalents requires a showing that: (1) "the difference between the claimed invention and the accused product or method was insubstantial," or (2) "the accused product or method performs the substantially same function in substantially the same way with substantially the same result as each claim limitation of the patented product or method." *AquaTex Indus., Inc. v. Techniche Solutions*, 479 F.3d 1320, 1326 (Fed. Cir. 2007). Regardless of which test is used, a patentee must "provide particularized testimony and linking argument on a limitation-by-limitation basis." *Id*. at 1328-29. "[W]hile many different forms of evidence may be pertinent, when the patent holder relies on the doctrine of equivalents, as opposed to literal infringement, the difficulties and complexities of the doctrine require that evidence be presented to the jury or other fact-finder through the particularized testimony of a person of ordinary skill in the art, typically a qualified expert." *Id*. at 1329.

Here, Amgen's expert, Dr. Davies, never once used the word "function," "way," "result," or "substantial/insubstantial differences." (*See* D.I. 354 at 263:14-268:11). Nor did he provide

particularized testimony on each point of comparison.[4] (*Id.*). Instead, Dr. Davies opined in conclusory fashion that only the HPMC fraction of Opadry functioned as the binder, and "the polyethylene glycol … in the Opadry doesn't act as a binder." (*Id*. at 267:11-18). The court is not obligated to accept the conclusory assertions of an expert. *Optical Disc Corp. v. Del Mar Avionics*, 208 F.3d 1324, 1336 n. 5 (Fed. Cir. 2000). Thus, Dr. Davies' opinion, given without explanation or corroborating evidence, is not persuasive.

In addition, Amneal presented persuasive evidence refuting Dr. Davies' opinion that polyethylene glycol does not contribute to the binding properties of Opadry. Amneal's expert, Dr. McConville, credibly testified that Opadry is a "co-process excipient," which means that "those excipients work together and can never be separated." (D.I. 355 at 794:2-5). In addition, the presence of the polyethylene glycol in Opadry changes the mechanism by which HPMC binds, because polyethylene glycol, which is a liquid substance, allows the HPMC in Opadry to move freely, spread, and coat the other particles. (*Id*. at 802:13-24). Scientific literature states that, in tablet formulations, polyethylene glycols "can enhance the effectiveness of tablet binders." (PTX 438 at 518). Testing by Amneal demonstrated results consistent with this scientific statement. A series of tests compared formulations using HPMC and Opadry as binders and found a "significant difference" in the rate of release. (PTX 183 at 61-65). From these tests, Amneal concluded that Opadry was "the best choice of binder to achieve enhanced drug release profile."[5] (*Id*. at 65). Dr. Davies admitted that his opinion did not consider or respond to these tests. (D.I. 354 at 484:23-491:5). For all of the reasons stated above, I conclude

[4] It was not until post-trial briefs that Amgen defined the function, way, or result of the purported equivalents. (*See* D.I. 359 at 26-27).

[5] Amneal tested one formulation that compared HPMC to Klucel and found "no significant difference" between the two binders. (PTX 183 at 62-64). Amgen then tested a second formulation that compared Klucel to Opadry and found "faster in drug release" with Opadry as a binder. (PTX 183 at 64-65).

that Amgen has not proven by a preponderance of the evidence that Opadry is equivalent to HPMC.

2. Disintegrant

Amneal's ANDA discloses the use of the listed disintegrant crospovidone and the unlisted disintegrant pregelatinized starch. (PTX 183 at 42). Under my claim construction order, there is no literal infringement if the ANDA formulation contains any unlisted disintegrant. (D.I. 300 at 6). The '405 patent lists "starch" in the Markush groups for diluents, and the parties remaining in this litigation do not dispute that the term "starch" in the '405 patent covers pregelatinized starch. (JTX 2 at 13:21-25). Accordingly, Amgen argues that the pregelatinized starch in Amneal's product is not functioning as a disintegrant, but as a diluent. (D.I. 359 at 28). Amgen's sole support for its argument is Dr. Davies' opinion that crospovidone is a super-disintegrant which destroys the structure of a tablet so quickly that the pregelatinized starch does not have the opportunity to act as a disintegrant. (D.I. 359 at 28; D.I. 354 at 269:4-10). For several reasons, I do not find Dr. Davies' opinion, as applied to Amneal's ANDA product, convincing.

First, as Dr. McConville testified, Amneal's ANDA product does not appear to need another diluent. A diluent is used to increase a tablet's size and weight. (D.I. 353 at 185:20-186:7). Amneal's ANDA product already includes two diluents—microcrystalline cellulose and mannitol—in a large amount; specifically, 67.89% by weight of the accused product. (PTX 183 at 42). Given the presence of two diluents in such a large amount, it does not make sense that Amneal would add a small amount (5.24%) of a third diluent. (D.I. 355 at 821:7-822:2).

Second, Dr. McConville persuasively testified that, with Amneal's manufacturing process, the crospovidone cannot usurp the disintegration function of the pregelatinized starch.

(*Id*. at 809:3-6). In tablet manufacturing, ingredients can be either inside the granule with the active drug (intragranular) or outside the granule (extragranular). (*Id*. at 810:1-5). A disintegrant "can be more effective if used both 'intragranularly' and 'extragranularly,'" because the extragranular disintegrant will rupture the tablet to expose the granules, and the intragranular disintegrant will rupture the granules into fine particles to expose the drug. (DTX 216 at 8; D.I. 355 at 815:13-19, 818:15-819:3). Fine particles dissolve more quickly which helps achieve a rapid rate of dissolution—a required feature of the '405 patent. (D.I. 355 at 819:3-6; D.I. 359 at 6). Here, Amneal uses pregelatinized starch as an intragranular disintegrant and crospovidone as an extragranular disintegrant. (PTX 183 at 74 & 80). Because the crospovidone is only present outside the granules, it cannot accomplish that second disintegration of granules into fine particles. (D.I. 355 at 820:5-10). And because the pregelatinized starch is the only disintegrant inside the granules, it alone acts as a secondary disintegrant.

Third, Amneal's ANDA contains the results of testing which confirm that the pregelatinized starch in its product functions as a secondary disintegrant. (*See* PTX 183 at 70-73). To select a secondary disintegrant, Amneal tested the intragranular use of corn starch, pregelatinized starch, and crospovidone. (*Id*.). Amneal found that tablets with intragranular pregelatinized starch were "comparable" to Sensipar® in drug release, whereas corn starch was "slower in drug release." (*Id*. at 71). Amneal further found that the combination of pregelatinized starch and crospovidone was "better than [a] high amount of Crospovidone alone." (*Id*. at 73). Thus, Amneal concluded that pregelatinized starch was "the best choice for secondary disintegrant to design a robust, immediate release tablet dosage form of Cinacalcet Hydrochloride." (*Id*. at 71). Dr. Davies admits that his opinion does not account for these tests. (D.I. 354 at 466:18-467:24). He also acknowledged that he is not aware of any experiments or

scientific literature showing that, in the presence of crospovidone, pregelatinized starch does not contribute to tablet disintegration. (*Id*. at 527:7-530:24).

For all of these reasons, I find Dr. Davies' opinion regarding the function of pregelatinized starch in Amneal's ANDA product is not well supported. Instead, I conclude, consistent with Dr. McConville's opinion, that the pregelatinized starch in Amneal's product functions as a disintegrant. Because pregelatinized starch is an unlisted disintegrant, Amneal does not infringe the disintegrant limitation of claim 1.

3. Conclusion

To prove infringement, Amgen had the burden to show by a preponderance of the evidence that Amneal's binder Opadry was either a listed member of the binder Markush group or equivalent to a listed member. Amgen has done neither. In addition, Amneal's accused product includes an unlisted disintegrant (pregelatinized starch) that functions as a disintegrant. Thus, Amgen has failed to show by a preponderance of the evidence that Amneal's accused product infringes the binder and disintegrant limitations of the '405 patent. For the foregoing reasons, Amneal does not infringe claim 1 of the '405 patent. This means, pursuant to the parties' stipulation, Amneal does not infringe claims 2-4, 8-12, and 14-17. (D.I. 336 at ¶ 1). This also means that Amgen has not proven by a preponderance of the evidence that Amneal infringed dependent claims 6 and 18. "One who does not infringe an independent claim cannot infringe a claim dependent (and thus containing all the limitations of) that claim." *Wahpeton Canvas Co. v. Frontier, Inc*., 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989).

C. Watson

Watson filed Abbreviated New Drug Application No. 204377 ("ANDA") with the FDA, seeking approval to market a generic version of cinacalcet hydrochloride in 30, 60, and 90 mg

dosage strengths. (D.I. 293, Ex. 1 at ¶ 100). Watson included a Paragraph IV Certification in its ANDA stating that the '405 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Watson's product. (*Id*. at ¶ 101). Amgen claims that Watson's product will infringe claims 1-6 and 8-20 of the '405 patent. (D.I. 293, Ex. 2 at ¶¶ 39-40). Watson has stipulated that if its ANDA product infringes claim 1, then its ANDA product will also infringe claims 2-4, 8-17, and 19-20, to the extent each claim is found valid and enforceable. (D.I. 336 at ¶ 4). The stipulation did not cover the asserted claims 5, 6, and 18.

According to the ANDA, Watson's product has the following composition:

Ingredient	**Function**
Cinacalcet HCl	Active
Microcrystalline Cellulose	Diluent
Povidone	Binder
Pregelatinized Starch	Binder / Disintegrant
Low Substituted Hydroxypropyl Cellulose (L-HPC)	Disintegrant

(PTX 368 at 27).

The parties dispute whether Watson's ANDA product infringes the binder and disintegrant limitations of claim 1. I need not address the binder limitation, however, because a finding of non-infringement can be based on the disintegrant limitation alone. Watson uses an unlisted disintegrant, low substituted hydroxypropyl cellulose ("L-HPC"), which under my claim construction order means there is no literal infringement. As a result, Amgen argues that L-HPC infringes claim 1 under the doctrine of equivalence. As noted previously, there are two tests for proving equivalence: the function-way-result test or the insubstantial differences test. *Mylan*

Institutional LLC v. Aurobindo Pharma Ltd., 857 F.3d 858, 866 (Fed. Cir. 2017). Amgen's infringement theories under the doctrine of equivalence have shifted since trial.

At trial, Amgen took the position that L-HPC is equivalent only to crospovidone and only under the function-way-result test. (*See* D.I. 353 at 81:2-5 (Amgen's counsel stating in opening arguments that the evidence will show that L-HPC "is the equivalent to crospovidone."); D.I. 356 at 1089:5-7 (Amgen's counsel stating in closing arguments that the evidence has shown that "L-HPC is an equivalent to crospovidone."); D.I. 355 at 552:3-10 (Dr. Davies admitting that his opinions in this case rely only on the function-way-result test.). However, in its post-trial briefs, Amgen takes two new positions: (1) L-HPC is equivalent to all three listed disintegrants of claim 1 under the function-way-result test, and (2) L-HPC is equivalent to crospovidone under the insubstantial differences test.[6] (D.I. 359 at 32-36). Watson correctly points out that Amgen did not fairly present these positions in expert discovery or at trial. (D.I. 360 at 55). For that reason alone, Amgen's new infringement theories should be disregarded as an unfair surprise. Nevertheless, I will address Amgen's new infringement theories as presented in its post-trial briefs. Crospovidone is one of the three listed disintegrants in claim 1. Thus, in explaining why Amgen's new theories under the function-way-result test are not persuasive, I will necessarily explain why Amgen's original theory also would have failed.

1. Function-Way-Result Test

Amgen claims that L-HPC, a disintegrant listed in Watson's ANDA, is equivalent under the function-way-result test to all three listed disintegrants of claim 1. (D.I. 359 at 32-35). The three disintegrants listed in the Markush group of claim 1 are sodium starch glycolate,

[6] Amgen also makes the new argument in its post-trial briefs that L-HPC is "insubstantially different from [all of] the claimed disintegrants." (D.I. 359 at 32). Because Amgen provided no argument on this point besides this one sentence, I will not address it. It was not fairly presented to the court.

croscarmellose sodium, and crospovidone. (JTX 2 at 13:31-34). Under the function-way-result test, the patentee must show that the alleged equivalent "performs substantially the same function, in substantially the same way, to achieve substantially the same result, as disclosed in the claim." *Abbott Labs. v. Sandoz, Inc*., 566 F.3d 1282, 1296 (Fed. Cir. 2009).

The patentee should present its evidence on the doctrine of equivalence through the particularized testimony of an expert or person skilled in the art. *AquaTex*, 479 F.3d at 1329. Thus, Amgen should have presented through its expert, Dr. Davies, particularized testimony regarding the function, way, and result for each disintegrant to be compared. Dr. Davies, however, did not identify at trial what he considered to be the function, way, or result of the disintegrants being compared. (*See* D.I. 354 at 289:20-322:6). Instead, Amgen relies on a brief assertion by Dr. Davies that the disintegrants listed in claim 1 are "superdisintegrants," and L-HPC is "another superdisintegrant" with "similar disintegrant capability to other superdisintegrants." (*Id*. at 295:4-15). This testimony does not satisfy Amgen's burden to present the particularized testimony of an expert regarding the function, way, and result of the disintegrants being compared. Accordingly, Amgen failed to prove at trial that L-HPC is equivalent under the function-way-result test to all three disintegrants listed in claim 1.

Amgen's arguments in its post-trial brief fare no better. Amgen must show that L-HPC, sodium starch glycolate, croscarmellose sodium, and crospovidone perform substantially the same function, in substantially the same way, to achieve substantially the same result. According to Amgen, the function of L-HPC and the three listed disintegrants is to act as "superdisintegrants." (*See* PTX 359 at 9 (stating the disintegrants in claim 1 "function as superdisintegrants"); *Id*. at 32 (stating that "L-HPC functions as a superdisintegrant")). Scientific literature supports Dr. Davies' opinion that the three listed disintegrants are

superdisintegrants, but that same literature disproves Dr. Davies' assertion that L-HPC would be known by a POSA as a "superdisintegrant." According to scientific literature, L-HPC was one of the earliest known disintegrants upon which the new generation of disintegrants, known as superdisintegrants, improved. (JTX 11 at 2546; JTX 12 at 2155; DTX 334 at 235). Thus, the term "superdisintegrants" by its nature is used to distinguish the three disintegrants listed in claim 1 from the L-HPC used in Watson's product. (D.I. 355 at 669:14-670:6). Because L-HPC is not a superdisintegrant, it does not perform substantially the same function as the disintegrants listed in claim 1.

Amgen claims that L-HPC and the three listed disintegrants perform in substantially the same way, because they all use the same mechanism of disintegration: swelling.[7] (D.I. 359 at 32; D.I. 354 at 305:9-12). There is no dispute that the primary mechanism of action for L-HPC is swelling. (D.I. 355 at 671:7-9; DTX 324 at 2). But Amgen has not proven that the primary mechanism of action for each of the three listed disintegrants is swelling. For two of the three disintegrants—sodium starch glycolate and croscarmellose sodium—Amgen presented no evidence to corroborate Dr. Davies' testimony that the primary mechanism of action is swelling. (D.I. 359 at 32-33). In addition, Dr. Davies' testimony on this point was unclear: He also testified that "there are a number of different mechanisms by which [superdisintegrants] work." (D.I. 355 at 517:20-518:1). For the third listed disintegrant—crospovidone—Watson's expert, Dr. Appel, gave persuasive testimony, corroborated by scientific literature, that the primary mechanism of action is not swelling, but the recovery of elastic energy of deformation, also

[7] "Swelling is associated with dimensional amplification where particles enlarge omni-directionally to push apart the adjoining components, thereby initiating the break-up of the tablet matrix." (JTX 11 at 2546).

known as "strain recovery."[8] (*Id*. at 658:8-659:4, 668:3-20). Dr. Appel further testified that if swelling contributed to the disintegration mechanism of crospovidone it would play only a "minor role." (*Id*. at 725:20-726:12).

Scientific literature explains that initially there was no consensus regarding the primary mechanism of action for crospovidone, and researchers initially proposed swelling and wicking.[9] (JTX 11 at 2550). Since then, however, strain recovery has been "proposed and validated" as the "dominating disintegrant mechanism" of crospovidone. (*Id*.). Swelling makes only a "minor contribution." (DTX 334 at 239; *see also* JTX 12 at 2162 ("recovery of strain-energy … is the major mechanism of disintegrant action of crospovidone and not capillarity wicking or swelling")). I accept and credit this updated literature. Accordingly, Amgen has not proven that L-HPC and the three listed disintegrants perform in substantially the same way.

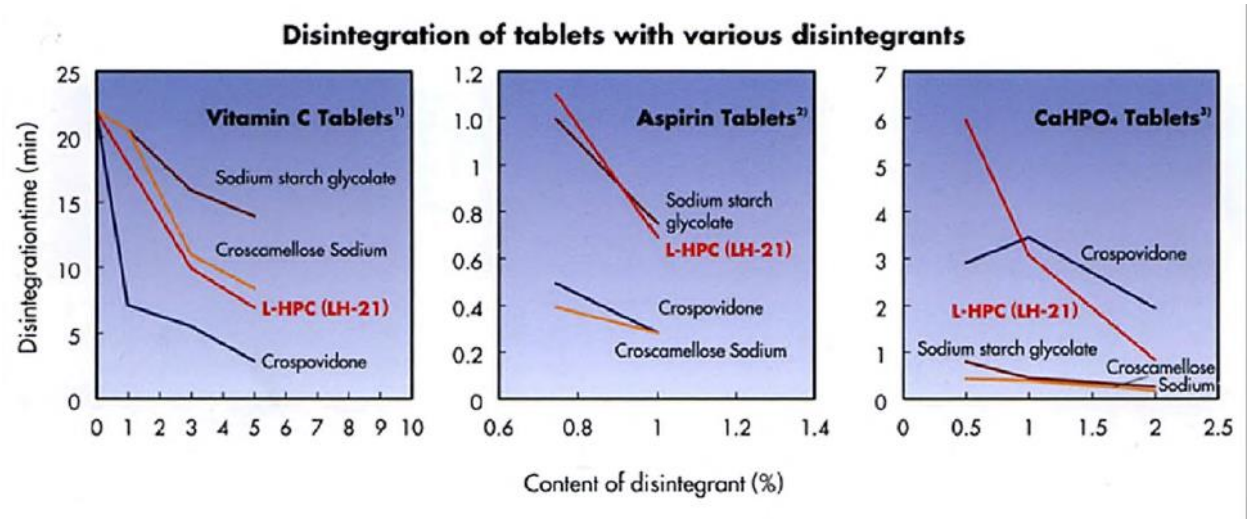
Finally, Amgen asserts that L-HPC and the three listed disintegrants achieve substantially the same result: "rapid tablet disintegration." (D.I. 359 at 32). Amgen's assertion, however, rests on a single sentence in a marketing brochure from the chemical company Shin Etsu stating: "L-HPC has similar disintegration capability to the other 'superdisintegrants.'" (*Id*. at 33; D.I. 354 at 295:4-19; PTX 463 at 12). A marketing brochure is not a peer reviewed scientific article and its goal is to sell a product, in this case L-HPC. (D.I. 355 at 673:24-675:20).

In addition, the marketing brochure itself calls into doubt Amgen's assertion. The brochure includes the caveat that the actual disintegration capability of various disintegrants "is

[8] To describe strain recovery, Dr. Appel used the analogy of a compressed spring returning to its original form. (D.I. 355 at 659:2-13; *see also* JTX 11 at 2548 and JTX 12 at 2155-56 (providing further detail on how the strain recovery mechanism operates in crospovidone)).

[9] Wicking may be defined as a process of liquid entry by capillarity into the microstructured crevices within the compact to displace the air. (JTX 11 at 2547).

dependent on [the] active ingredient and formulation." (PTX 463 at 12). The brochure illustrates its point with several graphs, reproduced below.



(*Id.*). Each graph represents a tablet with a different active ingredient. (D.I. 355 at 685:14-688:10). For each tablet, the graph compares the disintegration rates of L-HPC to the three superdisintegrants. (*Id.*).

Notably, the lines representing the rate of disintegration do not follow the same path and, at least for the CaHPO Tablets, do not even follow the same general direction. (*Id.* at 688:11-693:23). In addition, for Vitamin C tablets, crospovidone disintegrated at the fastest rate and sodium starch glycolate disintegrated at the slowest rate. (*Id.*). But for CaHPO4 tablets, the rankings flipped; sodium starch glycolate disintegrated at a faster rate than crospovidone. (*Id.*). Thus, two conclusions can be drawn from these graphs. One, L-HPC does not necessarily disintegrate at substantially the same rate as the superdisintegrants. (*Id.*). Two, it cannot be shown that L-HPC provides disintegration rates substantially similar to the superdisintegrants without testing involving the active ingredient at issue here, which is cinacalcet HCI. (D.I. 354 at 433:10-19). Amgen, however, did not present any tests or scientific literature that have made

this comparison.[10] Thus, Amgen has not proven that L-HPC achieves substantially the same result as all three listed disintegrants. Given the foregoing, Amgen has not proven by a preponderance of the evidence that L-HPC is equivalent to all three listed disintegrants under the function-way-result test.

2. Insubstantial Differences Test

Amgen argues that L-HPC is equivalent to crospovidone under the insubstantial differences test. (D.I. 359 at 36). The Federal Circuit has recognized that the function-way-result test can obscure important chemical differences and, therefore, advised that "the substantial differences test may be more suitable than [the function-way-result test] for determining equivalence in the chemical arts." *Mylan*, 857 F.3d at 867-69. Under the insubstantial differences test, "[a]n element in the accused product is equivalent to a claimed element if the differences between the two elements are 'insubstantial' to one of ordinary skill in the art." *Wi-Lan, Inc. v. Apple, Inc.*, 811 F.3d 455, 463 (Fed. Cir. 2016). Amgen's expert, Dr. Davies, did not provide an opinion regarding the insubstantial differences between L-HPC and crospovidone. (*See* D.I. 355 at 552:3-10 (Dr. Davies admitting that "[his] opinions in this case are entirely using the function way result test.")). Thus, the only particularized testimony in the trial record regarding the differences between L-HPC and crospovidone was presented by Watson's expert, Dr. Appel. She identified several differences between L-HPC and crospovidone, which were corroborated by scientific literature.

[10] Amgen's comparison of a disintegration test in Watson's Lab Notebook to a disintegration test in Watson's ANDA is not adequate for these purposes, because the formulations used different amounts of each excipient. (D.I. 359 at 33-34; PTX 368 at 27 & 50; PTX 391 at WTS-CNCLT-00173157 & 173159). Most noticeably, the intragranular disintegrant was almost doubled (6.66 mg compared to 10.20 mg) and the extragranular disintegrant was almost halved (16.20 mg compared to 9.75 mg). (PTX 368 at 27; PTX 391 at WTS-CNCLT-00173157). As Dr. Appel testified, a POSA would see these as two different formulations. (D.I. 355 at 740:3-741:14).

First, as Dr. Appel explained, L-HPC and crospovidone have different physical shapes. (D.I. 355 at 655:20-656:11). The physical shape of the particles affects how particles flow. (*Id*.). Particle flow "plays a crucial role" in pharmaceutical manufacturing, because "good flowability" ensures that the tablets' contents are uniform and consistent. (DTX 324 at 4; D.I. 355 at 655:20-656:11). Crospovidone particles are spherical "like marbles," whereas L-HPC particles are long and narrow "like spaghetti noodles." (D.I. 355 at 655:13-656:5; PTX 438 at 209 & 323). "Marbles flow really well," whereas spaghetti noodles "don't really flow well." (D.I. 355 at 655:13-656:5; *see also* DTX 324 at 1 (stating that L-HPC "showed poor flow properties" due to its high aspect ratios)).

Second, crospovidone and L-HPC have different chemical structures. Crospovidone is a five-member ring with four carbons and one nitrogen. (D.I. 355 at 653:1-7; PTX 438 at 208). L-HPC is a six-member ring with five carbons and one oxygen. (D.I. 355 at 653:1-15; PTX 438 at 322). Crospovidone is cross-linked, whereas L-HPC is not. (D.I. 355 at 661:22-662:18, 664:4-5). According to Dr. Appel, these differences mean a POSA would not consider L-HPC and crospovidone "as equivalent chemically." (*Id*. at 652:22-653:15).

Third, L-HPC is multi-functional, whereas crospovidone is not. (*Id*. at 656:15-22, 671:14-16). L-HPC can act as a binder or disintegrant, whereas crospovidone functions only as a disintegrant. (PTX 438 at 208 & 322). A POSA must take into account the multifunctional nature of an excipient, because the specific function such excipient will perform in any given formulation depends on the manufacturing process and the other excipients present. (D.I. 355 at 656:22-658:7; D.I. 354 at 268:21-269:3).

Fourth, when acting as a disintegrant, L-HPC is less potent than crospovidone. (*Id*. at 666:7-23; DTX 334 at 240 (stating that L-HPC "is not as effective as" crospovidone); JTX 12 at

2155 (explaining that crospovidone is "more efficient" than L-HPC)). Crospovidone levels are usually in the 2-5% range, and higher levels may cause problems, whereas L-HPC levels are typically in the 2-10% range, but can be higher. (DTX 334 at 239-40; D.I. 355 at 665:14-666:19). Given all of the foregoing evidence, Dr. Appel has credibly opined that L-HPC and crospovidone have differences that a POSA would find substantial. (D.I. 355 at 647:18-648:6, 653:19-654:7). Therefore, Amgen has not carried its burden of showing that L-HPC is equivalent to crospovidone under the insubstantial differences test.

3. Conclusion

Amgen has failed to prove by a preponderance of the evidence that L-HPC is equivalent to all of the disintegrants listed in claim 1 under the function-way-result test or that L-HPC is equivalent to crospovidone alone under the insubstantial differences test. Therefore, Watson does not infringe claim 1 of the '405 patent. This means, per the parties' stipulation, Watson does not infringe claims 2-4, 8-17, and 19-20. (D.I. 336 at ¶ 4). This also means, per *Wahpeton Canvas*, Watson does not infringe claims 5, 6, and 18. *Wahpeton Canvas*, 870 F.2d at 1552 n. 9 ("One who does not infringe an independent claim cannot infringe a claim dependent (and thus containing all the limitations of) that claim.").

D. Piramal

Piramal filed Abbreviated New Drug Application No. 210207 ("ANDA") with the FDA, seeking approval to market a generic version of cinacalcet hydrochloride in 30, 60, and 90 mg dosage strengths. (D.I. 293, Ex. 1 at ¶ 80). Piramal included a Paragraph IV Certification in its ANDA stating that the '405 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Piramal's product. (*Id.* at ¶ 81). Amgen claims that Piramal's product will infringe claims 1-6 and 8-20 of the '405 patent. (D.I. 293, Ex. 2 at ¶¶ 35-

36). Piramal has stipulated that if its ANDA product infringes claim 1, then its ANDA product will also infringe claims 2-4, 8-17, and 19-20, to the extent each claim is found valid and enforceable. (D.I. 336 at ¶ 3). The stipulation did not cover the asserted claims 5, 6, and 18.

According to the ANDA, Piramal's product has the following composition:

Ingredient	**Function**
Cinacalcet HCl	Active
Corn / Maize Starch	Diluent
Microcrystalline Cellulose	Diluent
Pregelatinized Starch	Binder
Crospovidone	Disintegrant

(PTX 494 at PIR 229).

The parties dispute whether Piramal's ANDA product infringes the binder and disintegrant limitations of claim 1. A finding of non-infringement, however, can be resolved on the binder limitation alone. Amgen argues that the unlisted binder in Piramal's ANDA product—pregelatinized starch—has two components; a native starch fraction that actually functions as a diluent; and a cold water soluble fraction that functions as a binder. (D.I. 359 at 18-21). Neither pregelatinized starch nor its cold water soluble fraction are listed in the Markush group for binders, which under my claim construction order means there is no literal infringement. Accordingly, Amgen argues that cold water soluble fraction is equivalent to povidone. (*Id*.). For the reasons explained below, however, I find that Amgen is foreclosed by prosecution history estoppel from asserting the doctrine of equivalents against Piramal's use of pregelatinized starch as a binder.

1. Prosecution History Estoppel Applies

Prosecution history estoppel prevents a patent owner from using the doctrine of equivalents to recapture subject matter surrendered to acquire the patent. *Honeywell Int'l v. Hamilton Sunstrand Corp*., 523 F.3d 1304, 1312 (Fed. Cir. 2008). A presumption arises that the patent owner surrendered all equivalents in "the territory between the original claim and the amended claim" where: (1) an amendment narrows the scope of the claims, and (2) the amendment is adopted for a substantial reason related to patentability. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 U.S. 722, 740 (2002). Amgen does not dispute that the Examiner's Amendment was a narrowing amendment. (*See* D.I. 359 at 49; D.I. 354 at 400:8-13, 402:19-22). Thus, the only issue here is whether the Examiner's Amendment was adopted for substantial reasons related to patentability. I find that it was.

Amgen tried—and failed—to overcome an obviousness rejection by making only one change to the claims: in the 2014 Amendment, Amgen narrowed the amount of cinacalcet HCl to "about 20 mg to about 100 mg." (JTX 5 at SENS-AMG 309, 316-17). The Examiner did not allow the claims in the 2014 Amendment. Instead, the Examiner proposed the Examiner's Amendment, which added the Markush groups to the binder and disintegrant limitations. (*Id*. at SENS-AMG 328-340). It was only after Amgen agreed to the entry of the Examiner's Amendment that the Examiner allowed the claims over the prior art. (*Id*.). There would have been no need for the Examiner to propose an amendment if Amgen's 2014 Amendment was sufficient. In addition, the Examiner expressly stated that he was allowing the claims as set forth in the Examiner's Amendment because, inter alia, the closest prior art "fails to specifically disclose or render obvious the *combination of components* and in the amounts thereof." (*Id*. at SENS-AMG 338). The Examiner's reliance on the "combination of components" underscores

the fact that the precise amount of cinacalcet HCI proposed in the 2014 Amendment was not enough by itself to overcome the obviousness rejection.

In addition, the Examiner's Amendment employed recognized methods for overcoming an obviousness rejection.[11] Original dependent claims 6 and 8 were canceled and the limitations in those claims—which were the Markush groups for binders and disintegrants respectively—were imported into now independent claim 1. *See, e.g.*, *Ranbaxy Pharm. Inc. v. Apotex, Inc.*, 350 F.3d 1235, 1240 (Fed. Cir. 2003) (where patentee rewrote dependent claims into independent form, amendment was made for a substantial reason related to patentability); *Mycogen Plant Science, Inc. & Agrigenetics, Inc. v. Monsanto Co.*, 261 F.3d 1345, 1350 (Fed. Cir. 2001) (finding that prosecution history estoppel applies where limitations were imported into independent claims from original dependent claims). At the same time, the Markush groups in claim 1 of the '405 patent resulted in fewer combinations of excipients than disclosed in the prior art. Creekmore disclosed 19 binders and 8 disintegrants, resulting in 152 combinations. (PTX 7 at 2:32-43; D.I. 355 at 633:10-21). Hsu disclosed 10 binders and 12 disintegrants, resulting in 120 combinations. (PTX 11 at ¶¶ 17, 46, 51; D.I. 355 at 633:22-634:11). The Examiner's Amendment disclosed a closed group of 4 binders and 3 disintegrants that resulted in 12 combinations. (D.I. 355 at 634:12-635:22). An obviousness rejection can be overcome by narrowing a claim to a smaller set of members within a group. *See, e.g.*, *Ranbaxy*, 350 F.3d at 1240-41 (limiting "highly polar solvent" to a "defined group of solvents" overcame obviousness rejection); *Merck & Co. v. Mylan Pharm. Inc.*, 190 F.3d 1335, 1340-41 (Fed. Cir. 1999) (broad claims to polymers narrowed to specific polymers). For all of these reasons, I find that the

[11] Amgen argues that the Examiner's Amendment did not overcome the obviousness rejection. (D.I. 359 at 60-65). However, a patentee "may not both make the amendment and then challenge its necessity in a subsequent infringement action on the allowed claim." *Bai v. L&L Wings, Inc.*, 160 F.3d 1350, 1356 (Fed. Cir. 1998).

Examiner's Amendment was adopted for substantial reasons related to patentability. Amgen's arguments to the contrary are unpersuasive.

First, Amgen relies heavily on its counsel's remark in the 2015 Preliminary Amendment that the "amendments have not been made in response to a prior art rejection but rather to place the claims in proper format and to better define the claimed subject matter." (D.I. 359 at 58-59; JTX 5 at SENS-AMG 1583). There is no reason to read this statement as describing anything more than the reason behind the 2015 Preliminary Amendment. Amgen itself states that "proper format" means the underlining added to show the changes made to the 2014 Amendment by the Examiner's Amendment, which is exactly what the 2015 Preliminary Amendment did. (D.I. 359 at 46 & 54). Thus, I find that a self-serving remark by Amgen's counsel in the 2015 Preliminary Amendment does not explain the reasons why Amgen agreed to the Examiner's Amendment over eight months earlier.

Second, Amgen relies heavily on the Examiner's statement in the second, third, and fourth notices of allowance that he was allowing the claims due to, inter alia, "the nature of the excipients." (D.I. 359 at 59). It is not clear from the record whether the phrase "nature of the excipients" means the genus of excipients (e.g., binder, diluent, etc.) or the species of excipients (e.g., sucrose, povidone, etc.). Nevertheless, when the Examiner described in the rejection the prior art that the claims failed to overcome, he explicitly pointed to the disclosure of specific excipients in specific functions. (*See*, *e.g.*, JTX 5 at SENS-AMG 295 (stating that Creekmore discloses "one or more fillers like microcrystalline cellulose," "one or more binders like starch," and "one or more disintegrants like polyvinylpyrrolidone (povidone)"); *Id*. (stating that Hsu discloses "binders like starch," "diluents like microcrystalline cellulose," and "disintegrants such as crospovidone")). When the Examiner first allowed the claims in the '405 patent, he explained

that the "combination of components … was not taught or suggested by" the prior art and is, therefore, "patentably distinct over the prior art." (JTX 5 at SENS-AMG 338). Thus, the Examiner very much had in mind the species of excipients when he decided that adding the Markush groups to claim 1 overcame the prior art. No further amendments or arguments were made after the first notice of allowance. So the later notices of allowance provide no additional insight into the reasons for the Examiner's Amendment.

Third, Amgen argues that if the Examiner's Amendment had been necessary for patentability, the Examiner would have checked one of the boxes in the Interview Summary form under the "Issues Discussed" section. (D.I. 354 at 348:4-349:20; D.I. 359 at 42). Several of the boxes are for common statutory bases used to reject claims: 35 U.S.C. § 101 (patent eligibility), § 112 (enablement), § 102 (novelty), and § 103 (obviousness). (JTX 5 at SENS-AMG 340). One box is for "Others" which, if checked, may have affirmatively indicated that some issue unrelated to patentability was discussed during the interview. (*Id*.). Here, none of the boxes were checked. (*Id*.). Accordingly, the boxes themselves provide no evidence either way regarding whether the amendment was made for reasons of patentability. It is also of no moment that none of the boxes are checked. The Manual of Patent Examining Procedure (the "MPEP") permits the Examiner to state his reasons for allowance in the Examiner's Amendment and not the Interview Summary Form. (*See* MPEP § 713 ("For an examiner-initiated interview, it is the responsibility of the examiner to make the substance of the interview of record either on an Interview Summary form *or*, when the interview results in allowance of the application, by incorporating a complete record of the interview *in an examiner's amendment*." (emphasis added)). Accordingly, I rely on the contents of the Examiner's Amendment to ascertain what was discussed in the interview.

Finally, I am not persuaded by Amgen's argument that the Examiner's Amendment was a clarifying amendment, because the cases on which Amgen relies to illustrate its position are inapposite. (D.I. 359 at 55-58). In those cases, the "clarifying" amendments did not lead to prosecution history estoppel, because the first prong of the *Festo* test was not satisfied: the amendment did not narrow the claims. *See, e.g.*, *Intendis GMBH v. Glenmark Pharma. Inc., USA*, 822 F.3d 1355, 1365 (Fed. Cir. 2016) ("Amendment-based estoppel does not apply because the amendment was not a narrowing amendment made to obtain the patent. Rather, this record demonstrates that the amendment to the dependent claims was a clarifying amendment."); *Interactive Pictures Corp. v. Infinite Pictures, Inc*., 274 F.3d 1371, 1377 (Fed. Cir. 2001) ("As to the amendment-based estoppel issue, we conclude that the addition of the words 'transform calculation' was not a narrowing amendment because that addition did nothing more than make express what had been implicit in the claim as originally worded."); *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co*., 264 F.3d 1111, 1126 (Fed. Cir. 2001) ("Here, the newly added claim only redefined the small clearance position limitation without narrowing the claim. Therefore *Festo* is not applicable."). If anything, these cases suggest that a clarifying amendment is one that by its nature adds additional language without narrowing a claim. Here, the Examiner's Amendment admittedly narrowed the claims, so it is not a clarifying amendment.

2. Scope of Equivalents Surrendered

Because the Examiner's Amendment narrowed the claims and the amendment was made for substantial reasons related to patentability, a presumption arises that Amgen surrendered all equivalents in "the territory between the original claim and the amended claim." *Festo Corp*., 535 U.S. at 740. Amgen may rebut that presumption by showing that the alleged equivalent (1) "could not reasonably have been described at the time the amendment was made," (2) "was

tangential to the purpose of the amendment," or (3) "was not foreseeable (and thus not claimable) at the time of the amendment." *Research Plastics, Inc. v. Fed. Packaging Corp.*, 421 F.3d 1290, 1298 (Fed. Cir. 2005). Amgen argues that "the tangentiality exception to prosecution history estoppel applies." (D.I. 359 at 66-67).

Amgen has failed to show that the Examiner's Amendment bore no more than a tangential relation to the equivalent in question. "Although there is no hard-and-fast test for what is and what is not a tangential relation, it is clear that an amendment made to avoid prior art that contains the equivalent in question is not tangential." *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010). Here, the Examiner's Amendment was able to overcome the prior art by claiming a smaller set of the binders disclosed in the prior art. By agreeing to the Examiner's Amendment, Amgen abandoned the other binders disclosed in the prior art. As the Examiner noted in making his rejection, one of the binders disclosed in both Creekmore and Hsu was "starch." (JTX 5 at SENS-AMG at 295). In fact, Hsu states, "[p]referrably the binder is starch." (PTX 11 at ¶ 46). In this litigation, Amgen has treated the term "starch" as encompassing "pregelatinized starch." Even if Amgen had not done so, Creekmore discloses as a binder the use of "modified starch," which includes pregelatinized starch. (PTX 7 at 2:32-43). The '405 patent does not claim starch or pregelatinized starch as a binder. As a result, prosecution history estoppel bars Amgen from asserting the doctrine of equivalents against Piramal to reclaim pregelatinized starch, or any portion thereof, as a binder. Because Amgen cannot assert the doctrine of equivalents against the binder in Piramal's ANDA product, Amgen cannot prove that Piramal's product infringes claim 1 of the '405 patent.

Finally, all other defendants against whom the doctrine of equivalents was asserted have, like Piramal, raised the defense of prosecution history estoppel. Nevertheless, I have decided for

the sake of expediency to only address the issue as it relates to Piramal.[12] I do not decide, however, that the estoppel defense was not available to these other defendants. Rather, I conclude that even if it was not available, Amgen still could not prove infringement for the reasons stated. In other words, I have not decided the full scope of what Amgen surrendered through prosecution history estoppel, only that it surrendered as an equivalent the use of pregelatinized starch, in whole or in part, as a binder.

3. Conclusion

For the foregoing reasons, Amgen cannot prove that Piramal's product infringes claim 1 of the '405 patent. Per the parties' stipulation, Piramal also does not infringe claims 2-4, 8-17, and 19-20. Finally, under *Wahpeton Canvas*, one who does not infringe an independent claim cannot infringe the dependent claims. 870 F.2d at 1552 n. 9. Therefore, Piramal does not infringe the dependent claims not covered by the stipulation, which are claims 5, 6, and 18.

E. Zydus

Zydus filed Abbreviated New Drug Application No. 20-8971 ("ANDA") with the FDA, seeking approval to market a generic version of cinacalcet hydrochloride in 30, 60, and 90 mg dosage strengths. (D.I. 293, Ex. 1 at ¶ 110). Zydus included a Paragraph IV Certification in its ANDA stating that the '405 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Zydus' product. (*Id*. at ¶ 111). Amgen, however, claims that Zydus' product will infringe claims 1-4, 6, 8-9, and 15-20 of the '405 patent. (D.I. 293, Ex. 2 at ¶¶ 41-42). Zydus has stipulated that if its ANDA product infringes claim 1, then its ANDA product will also infringe claims 2-4, 8-9, 15-17, and 19 to the extent each claim is found

[12] Amgen has repeatedly indicated that expediency in rendering a decision is important in order to avoid preliminary injunction proceedings. (*See, e.g.*, D.I. 322 at 21:12-16). Only one of the defendants is currently subject to the 30-month stay and Amgen's patent on the active drug cinacalcet HCI expired in March. (*Id*. at 17:22-18:24; 20:8-20).

valid and enforceable. (D.I. 336 at ¶ 5). The stipulation did not cover the asserted claims 6, 18, and 20.

According to the ANDA, Zydus' product has the following composition:

Ingredient	**Function**
Cinacalcet HCl	Active Ingredient
Microcrystalline Cellulose, NF	Diluent
Pregelatinized Starch, NF	Diluent
Hydroxy Propyl Cellulose, NF	Binder
Crospovidone, NF	Disintegrant

(PTX 395 at 27).

Amgen's dispute with Zydus comes down to the function of pregelatinized starch. Amgen takes the position that it functions as a diluent, as stated in Zydus' ANDA. (D.I. 367 at 11). Zydus takes the position that it functions as a binder. (D.I. 360 at 63). Zydus' position adopts an opinion Amgen's expert has asserted against other defendants. (*Id*. at 63-64). Thus, we are in a counterintuitive world where Amgen wins against Zydus only if the opinion of Amgen's expert—which Amgen relies on to prove infringement against the other defendants—is unpersuasive.

1. The Function of Pregelatinized Starch

In tablet formulations, pregelatinized starch can, depending on the context, function as a diluent, binder, or disintegrant. (PTX 438 at 691; PTX 439 at 62). The '405 patent, however,

limited itself by claiming pregelatinized starch only as a diluent.[13] (JTX 2 at 13:21-24). Where a defendant used pregelatinized starch as a binder (like Piramal), or had no binder but used pregelatinized starch as a diluent (like Aurobindo), Amgen's expert, Dr. Davies, opined that pregelatinized starch had two components: a cold water soluble fraction that functioned as a binder and a native starch fraction that functioned as a diluent. (PTX 494 at PIR 229; D.I. 353 at 220:4-221:5; PTX 199 at 30; D.I. 354 at 250:13-251:10). Neither pregelatinized starch nor its cold water soluble fraction are listed in the Markush group for binders. Under my claim construction order, there is no literal infringement if an accused product uses an unlisted binder. (D.I. 300 at 6).

On the face of the ANDA, Zydus' product appears to literally infringe each and every limitation of claim 1. To avoid a finding of literal infringement, Zydus simply adopted Dr. Davies' opinion that the cold water soluble fraction of pregelatinized starch functions as an unlisted binder.[14] (*See* D.I. 354 at 279:7-12). Normally, where literal infringement is unavailable, a patentee can still prove infringement by resorting to the doctrine of equivalents.[15] Here, however, I granted a motion *in limine*, which bars Amgen from asserting the doctrine of equivalents against Zydus. (D.I. 357, D.I. 358). So, if I find Dr. Davies' opinion persuasive, then Amgen cannot prove infringement against Zydus.

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[13] Actually, the '405 patent claims "starch" not "pregelatinized starch" as a diluent. (JTX 2 at 13:21-24). Nevertheless, the parties have litigated the case as if the term "starch" covers pregelatinized starch. (*See* D.I. 294, Ex. 7.1 at 97-99). Thus, for the purposes of this litigation, I read the term "starch" in the '405 patent as covering pregelatinized starch.

[14] Zydus presented its own expert, Dr. Roth, who gave the same opinion as Dr. Davies. (D.I. 356 at 909:18- 912:12). But the only evidence Zydus relied on to corroborate or explain its expert's opinion was Dr. Davies' opinion. (D.I. 360 at 63 (citing Dr. Davies' testimony as evidence for the opinion)). Accordingly, I do not focus on Dr. Roth's duplicative opinion.

[15] With respect to other defendants, Dr. Davies opined that the cold water soluble fraction was equivalent to povidone. (D.I. 353 at 220:20-221:1; D.I. 354 at 257:3-259:1).

Amgen makes no effort to attack the scientific basis for Zydus' argument as doing so would undermine the very infringement theory Amgen asserts against other defendants. (D.I. 359 at 17-18). Nevertheless, for the following reasons, I am not persuaded that Dr. Davies' opinion regarding pregelatinized starch is scientifically sound. To start, Amgen was not consistent in asserting where Dr. Davies' fractions opinion operates, a practice that does not comport with sound scientific principles. Amgen claims that three defendants literally infringe claim 1, because the fractions opinion applies to Aurobindo and Piramal but not to Zydus. But Dr. Davies could not provide a credible explanation for this variation in treatment. (D.I. 354 at 320:1-321:24). First, he said that the pregelatinized starch in Zydus' product functioned only as a diluent, because that was how Zydus identified the pregelatinized starch in its ANDA. (*Id*.). When it was pointed out that Dr. Davies did not accept how pregelatinized starch was identified in other defendants' ANDAs, he agreed and said that was why he was also asserting his fractions opinion against Zydus. (*Id*.).

This shift in infringement theories does not place Amgen in a better position. The '405 patent limits the weight of binders to "from about 1% to about 5%." (JTX 2 at 13:26-27). As Amgen acknowledges, Zydus already uses 4.98% of hydroxy propyl cellulose as a binder. (PTX 395 at 27). If the cold water soluble fraction in Zydus' product also acts a binder, then that is another 3.97% acting as a binder.[16] Adding 4.98% of hydroxy propyl cellulose to 3.97% of a cold water soluble fraction results in a total 8.95% of binder, which exceeds the "about 5%" weight limitation in the '405 patent. (D.I. 355 at 535:15-22). When Zydus raised this point with Dr. Davies, he shifted infringement theories yet again, stating that Zydus' product literally

[16] Zydus product has 11% of pregelatinized starch. (PTX 395 at 27). Dr. Davies claims that 13.1% of pregelatinized starch is a cold water soluble portion. (D.I. 354 at 253:17-254:20; PTX 202). Therefore, 13.1% x 11% = 3.97%

infringed the binder limitation, because there was "at least one" binder from the Markush group in Zydus' product that was within the about 1% to about 5% weight limitation: the 4.98% of hydroxy propyl cellulose. (*Id*. at 539:4-540:12). This testimony is not consistent with the court's controlling claim construction. (*See* D.I. 300; D.I. 357).

The same problems with Dr. Davies' fractions opinion appeared again when Amgen tried to apply it to the pregelatinized starch in the Example of the '405 patent. Dr. Davies claimed that the cold water soluble fraction of the pregelatinized starch in the Example functions as a binder. (D.I. 354 at 315:22-316:11). The Example has 33.378% of pregelatinized starch, of which 4.373% purportedly acts as a binder.[17] (JTX 2 at 11:22-23). Dr. Davies further testified that the 2.044% of povidone in the Example also functions as a binder. (*Id*. at 315:8-13). Adding these two binder amounts together (4.373% of a cold water soluble fraction and 2.044% of povidone) results in 6.417% of binder total. Thus, under Dr. Davies' fractions opinion, the Example would not meet the "from about 1% to about 5%" weight limitation for binders. This issue is avoided, however, if the court adopts Dr. Davies' prior testimony that the pregelatinized starch in the Example is acting only as a diluent. (D.I. 354 at 312:3-23).

The only evidence Amgen presented to corroborate Dr. Davies' fractions opinion is unpersuasive. Amgen relies on a single sentence in the Handbook of Pharmaceutical Granulation Technology stating: "The water-soluble fraction [of pregelatinized starch] acts as a binder, whereas the remaining fraction facilitates the tablet disintegration process." (PTX 439 at 62; D.I. 359 at 19; D.I. 354 at 471:22-472:12). Reading this sentence in the context of the Handbook and the record as a whole, it appears that Amgen imparts too much meaning to the

[17] As stated previously, Dr. Davies claims that 13.1% of pregelatinized starch is a cold water soluble portion. (D.I. 354 at 253:17-254:20; PTX 202). Therefore, 13.1% x 33.378% = 4.373%.

word "acts" in the phrase "acts as a binder." Nowhere else besides that one word does the Handbooks itself or any other scientific literature in the record suggest that only the cold water soluble fraction of pregelatinized starch is acting as the binder. As Aurobindo's expert pointed out, when that same Handbook advises the percentage amount of binders to use in a formula, it advises using 2-5% of "pregelatinized starch," not 2-5% of "the cold water soluble fraction of pregelatinized starch." (PTX 439 at 61; D.I. 356 at 962:3-963:10). If anything, the sentence on which Amgen relies can be reasonably construed to mean that the cold water soluble fraction of pregelatinized starch imparts properties that improve its binding capabilities. The sentence itself makes this suggestion when it addresses the water soluble fraction and the remaining native starch fraction in parallel: It states that the water soluble fraction "acts" as a binder, and the native starch fraction "facilitates" the disintegration process. (PTX 439 at 62). "Facilitates" means "[t]o make easy or easier." Am. Heritage Dictionary (4th ed. 2009).

Ultimately, Dr. Davies consistently asserted, and other experts agreed, that the particular function of pregelatinized starch in any given formulation "depends on the context," including the amount of pregelatinized starch, the other excipients present, and the manufacturing process. (D.I. 354 at 268:21-269:3; *Id*. at 309:21-22; D.I. 355 at 506:15-507:17; *Id*. at 510:2-11; *Id*. at 511:4-512:5). And yet Amgen did not have its expert give testimony that applied those same contextual factors to each specific defendant. On the defense side, however, Aurobindo's expert, Dr. Fassihi, credibly explained how the amount of pregelatinized starch in a particular formulation will dictate its function.[18] (D.I. 356 at 955:21-960:1). As Dr. Fassihi explained and scientific literature confirmed, the theory of percolation holds that when pregelatinized starch is

[18] Similarly, Amneal's expert, Dr. McConville, explained how the manufacturing process affected the function of the pregelatinized starch in Amneal's product. *See*, *supra*, Section III(B)(2).

included in a wet granulation formulation in an amount in excess of about 20% by weight, the pregelatinized starch functions as a diluent. (*Id*. at 961:11-18; DTX 228 at 112-14). When, however, the pregelatinized starch in a wet granulation formulation is between 5% and 10%, the pregelatinized starch functions as a tablet binder. (PTX 438 at 692; *see also* PTX 454 at 408 ("[S]olution binders … are included in the formulation at relatively low concentrations, typically 2-10% by weight.")). When evaluating the ANDA products for Amneal, Piramal, and Zydus, the percolation theory provides the consistency lacking in Dr. Davies' opinion. For example, Amneal and Zydus use over 20% by weight of pregelatinized starch which is consistent with the diluent function identified in their ANDAs. (PTX 183 at 42; PTX 395 at 27). Piramal uses 11% of pregelatinized starch which is consistent with the binder function identified in its ANDA. (PTX 494 at PIR 229). Finally, the Example uses 33.378% of pregelatinized starch which is consistent with a diluent function that would result in the '405 patent covering the Example. (JTX 2 at 11:22-23).

Given all of the foregoing, I find that Amgen has not proven by a preponderance of the evidence that pregelatinized starch should be artificially divided into two fractions, with each fraction alone serving a different function. As a result, Zydus cannot defeat Amgen's assertions of literal infringement by adopting Dr. Davies' opinion that the cold water soluble fraction of pregelatinized starch functions as a binder. Zydus' ANDA product literally infringes claim 1 to the extent the claim is found valid and enforceable.

2. Conclusion

Amgen has asserted claims 1-4, 6, 8-9 and 15-20 of the '405 patent against Zydus. (D.I. 293, Ex. 2 at ¶¶ 41-42). Because I found above that Zydus' ANDA product literally infringes claim 1, I also find per the parties' stipulation that Zydus' ANDA product literally infringes

claims 2-4, 8-9, 15-17, and 19, to the extent each claim is found valid and enforceable. (D.I. 336 at ¶ 5). This leaves for resolution claims 6, 18, and 20. Amgen argues that the use of crospovidone in Zydus' ANDA product literally satisfies claim 6. (D.I. 359 at 16 n. 8). I agree, but only to the extent the claim is found valid and enforceable. Finally, Amgen had the burden to prove by a preponderance of the evidence that Zydus infringed asserted claims 18 and 20, yet for reasons unknown to the court, Amgen neither presented argument on these claims nor entered into a stipulation covering these claims. Accordingly, Amgen has not carried its burden as to claims 18 and 20.

IV. CONCLUSION

For the foregoing reasons, I find that Amgen has not proven infringement as to Amneal, Watson, and Piramal. As to Zydus, Amgen has proven infringement of claims 1-4, 6, 8-9, 15-17, and 19 to the extent the claims are valid and enforceable, but Amgen has not proven infringement of claims 18 and 20. Currently pending before the court is Amneal's motion pursuant to Fed. R. Civ. P. 52(c) for judgment and Zydus' motion pursuant to the same rule for partial judgment. (D.I. 325, D.I. 337). A decision on those motions will be forthcoming.

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

UFCW Local 1500 Welfare Fund, on behalf of itself and all others similarly situated

(b) County of Residence of First Listed Plaintiff Nassau County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Ned Weinberger
Labaton Sucharow LLP, 300 Delaware Avenue, Suite 1340, Wilmington, Delaware 19801 Tel.: (302) 573-2540

DEFENDANTS

Amgen Inc., Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Actavis Inc., and Actavis Pharma Inc.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ❒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	**PERSONAL INJURY**	**PERSONAL INJURY**	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	❒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		**PROPERTY RIGHTS**	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	☒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	**PERSONAL PROPERTY**	**LABOR**	❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 835 Patent - Abbreviated New Drug Application	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	❒ 840 Trademark	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	**SOCIAL SECURITY**	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 861 HIA (1395ff)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 790 Other Labor Litigation	❒ 862 Black Lung (923)	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 791 Employee Retirement Income Security Act	❒ 863 DIWC/DIWW (405(g))	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise				❒ 864 SSID Title XVI	❒ 890 Other Statutory Actions
				❒ 865 RSI (405(g))	❒ 891 Agricultural Acts
					❒ 893 Environmental Matters
					❒ 895 Freedom of Information Act
REAL PROPERTY	**CIVIL RIGHTS**	**PRISONER PETITIONS**		**FEDERAL TAX SUITS**	❒ 896 Arbitration
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	**Habeas Corpus:**		❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee		❒ 871 IRS—Third Party 26 USC 7609	❒ 950 Constitutionality of State Statutes
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence			
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty	**IMMIGRATION**		
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	**Other:**	❒ 462 Naturalization Application		
	❒ 448 Education	❒ 540 Mandamus & Other	❒ 465 Other Immigration Actions		
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
15 U.S.C. §§ 1, 2, 26

Brief description of cause:
Unlawful agreement to restrain competition of branded and generic Sensipar

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Leonard P. Stark DOCKET NUMBER 1:19-cv-00044

DATE 02/21/2019

SIGNATURE OF ATTORNEY OF RECORD /s/ Ned Weinberger (Bar No. 5256)

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RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE