IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMGEN INC., One Amgen Center Drive Thousand Oaks, CA 91320-1799, Plaintiff, v. THOMAS E. PRICE, M.D., in his official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W. Washington, DC 20201, and SCOTT GOTTLIEB, M.D., in his official capacity as COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Defendants.	Civil Action No. _____

VERIFIED COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND OTHER RELIEF

Plaintiff Amgen Inc. brings this Complaint against Defendants Thomas E. Price, M.D., in his official capacity as Secretary of the Department of Health and Human Services (HHS), and Scott Gottlieb, M.D., in his official capacity as Commissioner of Food and Drugs, head of the Food and Drug Administration (FDA or the agency), and alleges as follows:

PRELIMINARY STATEMENT

1. This is an action to compel the FDA to comply with statutory obligations by accepting Amgen's study reports and extending the additional six months of pediatric exclusivity for its drug SENSIPAR® (cinacalcet hydrochloride).[1]

2. To encourage drug sponsors to develop critical information about the safety and efficacy of drugs in pediatric populations, Congress requires FDA to grant six months of additional market exclusivity and patent protection to drugs for which pediatric studies were conducted in response to the agency's written request. 21 U.S.C. §§ 355a(b)(1), (c)(1). FDA is required to accept the study reports and recognize this so-called pediatric exclusivity so long as the studies "fairly respond" to the written request and are conducted in accordance with commonly accepted scientific principles and protocols, and the study reports are submitted in accordance with agency filing requirements. *Id.* § 355a(d)(3). That objective statutory mandate arguably is unique for what it does *not* require: the studies need not demonstrate that the drugs are (or are not) actually safe and effective in children to warrant pediatric exclusivity, nor must they be adequate to support a pediatric indication on the drug product's labeling, nor must the studies even "*fully* respond" to the written request. Congress's goal was simply to encourage drug sponsors to conduct pediatric studies in the first place.

3. In May 2010, FDA issued a Written Request to Amgen, asking the company to conduct studies to investigate the use of one of its drugs, SENSIPAR, in pediatric patients on dialysis with chronic kidney disease and secondary hyperparathyroidism (HPT). Individuals with secondary HPT have excess parathyroid hormone in the bloodstream due to an overactive

[1] As a technical matter, pediatric exclusivity attaches to the active moiety (cinacalcet hydrochloride), not the brand (SENSIPAR®). That distinction does not affect the disposition of this case.

parathyroid gland—the gland that regulates calcium in the blood. Among other indications, SENSIPAR is used to treat secondary HPT in adults who are on long-term dialysis for kidney disease. Although there was not a pediatric indication for SENSIPAR, SENSIPAR was often prescribed off label to the pediatric population. FDA's request acknowledged that unmet medical need and thus asked the company to investigate the drug's use in the corresponding pediatric population.

4. Amgen complied with FDA's request. And after devoting significant resources to that effort, Amgen submitted reports containing complete data for three out of the four studies requested. The final study—Study 3—was particularly challenging, because it tested the drug in secondary HPT patients receiving dialysis between the ages of 28 days and 6 years—a total population of approximately 300 patients nationwide. In February 2013, after a report of a fatality in Study 2 (studying patients in the 6 to 18 year age group), FDA placed a "partial clinical hold" on the pediatric program, including Study 3, for 14 months and requested changes to the testing protocol.

5. Amgen recommended discontinuing the pediatric program in September 2013. FDA disagreed with Amgen's recommendation, stating that the program was "very important to understand how to use this drug in the pediatric population." FDA, Meeting Minutes of September 4, 2013 Teleconference at 5 (Oct. 5, 2013) (a true and correct copy of which is attached as "Exhibit 1"). So Amgen continued on. But despite the company's best efforts, a combination of factors outside of Amgen's control (including the extremely small population size, the young ages of patients, the delays caused by the clinical hold, and additional testing requirements after the hold was lifted) resulted in a smaller number of patients completing Study 3 than had been projected.

6. Despite Amgen's compliance with FDA's instructions to continue, despite its best efforts possible, despite its continual efforts to work with the FDA, despite its efforts to amend the terms of FDA's request, and despite the significant data Amgen had managed to adduce, FDA notified Amgen on May 22, 2017 that the agency was denying pediatric exclusivity. FDA, Pediatric Exclusivity Denial Letter (May 22, 2017) (a true and correct copy of which is attached as "Exhibit 2"). According to FDA, though Amgen had "met the literal terms of the [Written Request] for Studies 1, 2, and 4," the failure to meet one element of one study included in the Written Request meant "that Amgen has failed to fairly respond." *Id.* at 7, 10.

7. Throughout its denial letter, FDA made clear that it was evaluating the responsiveness of Amgen's reports based on whether those reports contained sufficient information to make a labeling determination about SENSIPAR's safety in pediatric populations. *See, e.g.*, *id.* at 10 (observing that "Amgen's failure to provide sufficient safety data in the 28 day to < 6 year old age group prevents FDA from drawing any conclusions about the safety of the product" and that, had "the totality of safety information Amgen submitted . . . provided an appropriate safety assessment in younger children and supported a label description."). But the statute contemplates no such showing of safety; it only requires that the studies "fairly respond" to the Written Request.

8. Because the Amgen studies "fairly respond[ed]" to the Written Request, FDA's refusal to accept the study reports and its denial of pediatric exclusivity violate the plain language of the statute and the agency's previous treatment of similarly-situated entities. FDA's conduct therefore is unlawful, arbitrary, capricious, and contrary to law. 5 U.S.C. § 706(2)(A).

9. The statute provides that FDA *shall not* grant pediatric exclusivity "if the determination" to accept the study reports "is made later than 9 months prior to the expiration" of

existing patent rights. 21 U.S.C. § 355a(b)(2), (c)(2). One of the key patents covering SENSIPAR, U.S. Patent No. 6,011,068 (the '068 Patent), is due to expire on March 8, 2018. As a result, the preclusive effect of the '068 Patent will not be extended by pediatric exclusivity granted any later than June 8, 2017. FDA did not issue its decision denying pediatric exclusivity until May 22 2017, just 17 days before exclusivity must be granted, Amgen is compelled to seek immediate injunctive relief from this Court two days in advance of the statutory deadline (by **June 6, 2017**), to ensure that the company does not lose its statutory rights.

PARTIES

10. Plaintiff Amgen Inc. is a biotechnology company incorporated under Delaware law and headquartered at One Amgen Center Drive, Thousand Oaks, CA 91320-1799. Amgen is the sponsor of NDA 021688, the approved new drug application for SENSIPAR, and the sponsor of NDA 2099062, the new drug application under which the pediatric reports and request for pediatric exclusivity were submitted.

11. Defendant Thomas E. Price, M.D., is the Secretary of HHS and is responsible for administering and enforcing the Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 *et seq.* Defendant Price maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201.

12. Defendant Scott Gottlieb, M.D., is the Commissioner of Food and Drugs and is responsible for supervising the activities of FDA, an administrative agency within HHS. Defendant Gottlieb maintains offices at 10903 New Hampshire Avenue, Silver Spring, MD 20993.

JURISDICTION AND VENUE

13. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331, in that this civil action arises under the laws of the United States; 28 U.S.C. § 1346, in that this case involves claims against the federal government; 5 U.S.C. § 702, in that Amgen seeks judicial review of an agency action from which the company has suffered a legal wrong, has been adversely affected, and has been aggrieved; 28 U.S.C. § 1361, in that this is an action to compel an officer of the United States to perform his duty; and 28 U.S.C. §§ 2201–2202, in that there exists between Amgen and the Defendants an actual justiciable controversy as to which Amgen requires a declaration of its rights by this Court and temporary, preliminary and permanent injunctive relief to prohibit the Defendants from violating laws and regulations.

14. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (e) because this is a civil action in which the Defendants are officers of the United States acting in their official capacities and one of the Defendants maintains his office and conducts business in this judicial district. Moreover, a substantial part of the events giving rise to the claims occurred within this judicial district.

15. Amgen has standing to bring this lawsuit because it is suffering and faces imminent actual injury as a result of FDA's decision to deny pediatric exclusivity for SENSIPAR and because it is within the zone of interest of the relevant statutory provisions providing for that exclusivity.

FACTUAL BACKGROUND

Statutory Framework

16. The Food, Drug, and Cosmetic Act (FDCA) mandates that all new prescription drugs obtain FDA approval before they can be marketed. 21 U.S.C. § 355(a). Manufacturers of

brand name (also known as "pioneer" or "innovator") drugs must demonstrate the safety and effectiveness of their products in order to gain FDA approval. Companies typically accomplish that by conducting pre-clinical and clinical studies and submitting the resulting data to FDA in a new drug application (NDA). 21 U.S.C. § 355(b)(1).

17. Upon approval, a pioneer drug may be entitled to periods of marketing exclusivity and patent-related protections. After any such periods of exclusivity and patent protections expire, FDA may approve competing manufacturers' generic drugs, which are essentially copies of the already approved innovator product.

Six-month Pediatric Exclusivity

18. Most drugs are designed for and tested exclusively in adult populations. This is the result of a number of factors, including that conducting clinical trials in pediatric populations is a daunting task. Pediatric patient populations are often small, there are fewer experts with the requisite experience to run pediatric testing (such as the pediatric nephrologists involved in the studies at issue here), trial participation can be difficult for small children, parents are often reluctant to subject their children to the repeated blood draws and tests associated with clinical studies, potential liability is higher because of larger lifetime-damages awards, and there are unique consent and ethical issues at play. For all of these reasons and others, drugs approved for use in the United States have long lacked sufficient pediatric information for drug-labeling purposes. *See* Karena J. Cooper, *Pediatric Marketing Exclusivity—As Altered by the Best Pharmaceuticals for Children Act of 2002*, 57 Food & Drug L.J. 519, 520 (2002). This lack of information has, in turn, resulted in the persistent reality that most drugs are prescribed to children "off label" and without dosing instructions, which poses risks to pediatric patients.

Without data from clinical studies in children, healthcare providers often are effectively forced to wing it when it comes to determining pediatric dosing.

19. Once generic versions of a drug enter the marketplace, it is even less likely that pediatric testing will be performed. Because of limits imposed on generic manufacturers under the federal drug-labeling laws, clinical data informing labeling decisions is virtually always provided by the manufacturers of innovator drugs alone. And innovators lack the financial incentive to conduct pediatric testing following the launch of a generic drug.

20. As noted in the legislative history for the pediatric exclusivity statute: "[T]here is little incentive for drug sponsors to perform studies for medications which they intend to market primarily for adults and whose use in children is expected to generate little additional revenue. Pediatric studies pose ethical and moral issues relating to using new unapproved drugs in young patients. Second, there are substantial product liability and medical malpractice issues. Third, pediatric patients are more difficult to attract into studies. Fourth, for some drugs, pediatric use represents more difficult issues of drug administration and patient compliance than adult use." S. Rep. No. 105-43, at 51 (1997).

21. For these reasons, before the 1990s, only 20 percent of the drugs prescribed for children in the United States had been tested and approved for use in children, leaving individual pediatricians to rely on their individual judgments in prescribing drugs for their patients. Pamela Politis, *Transition from the Carrot to the Stick: The Evolution of Pharmaceutical Regulations Concerning Pediatric Drug Testing*, 12 Widener L. Rev. 271 (2005) (citing S. Rep. No. 107-79, at 1 (2001)). This lack of information and disuniformity became a major focus of healthcare reform efforts throughout the 1990s and early 2000s.

22. To remedy these deficiencies, Congress enacted the Best Pharmaceuticals in Children Act (BPCA), which created an incentive for sponsors to undertake vital testing in pediatric populations by adding six months to the term of the marketing exclusivities and patent-related protections for eligible drug products. *Id.* § 355a(b)(1), (c)(1). It is FDA's denial of "pediatric exclusivity" under the BPCA for Amgen's SENSIPAR that gives rise to the Complaint.

23. Under the BPCA, FDA issues a written request for pediatric studies if the agency "determines that information relating to the use of a … drug in the pediatric population may produce health benefits in that population." *Id.* § 355a(b)(1), (c)(1). The request, which is to be developed "after consultation with the sponsor" must be written, must include a timeframe for the studies," and must "request [that] … the sponsor … propose pediatric labeling resulting from such studies." *Id.* § 355a(d)(1)(A).

24. If a sponsor conducts the studies sought by FDA in the written request and submits reports of the study results to FDA, the agency has 180 days to either accept or reject the reports. FDA's "only responsibility" in accepting or rejecting the reports is to determine whether (1) "the studies fairly respond to the written request," (2) the studies "have been conducted in accordance with commonly accepted scientific principles and protocols," and (3) the studies "have been reported in accordance with the requirements of the [agency] for filing." *Id.* § 355a(d)(3). If each of the criteria is met, FDA must accept the reports, at which point the six-month extension of exclusivity and patent protection automatically applies. *Id.* at §§ 355a(b)(1), (c)(1) (exclusivities and patent protection extended if pediatric study reports are "accepted").

25. Whether the studies ultimately *support* an indicated use for children—that is, whether they successfully demonstrate (or refute) safety and efficacy—is irrelevant and

inapplicable to FDA's decision to accept the studies and recognize the six additional months of pediatric exclusivity. *See id.*; *see also id.* § 355a(j) (directing FDA to "order the labeling" of a drug to include, among other things, "information about the results of" a BPCA pediatric study if the agency determines that the study "does or does not demonstrate that the drug ... is safe and effective, including whether such study results are inconclusive, in pediatric populations or subpopulations"). As the relevant statutory provisions make clear, the purpose of the BPCA incentive of pediatric exclusivity is to generate additional data about the effects of the drug in pediatric patients for use in the labeling—whether or not those data entitle the sponsor to a new indication for pediatric use, or even conclusively demonstrate whether the product is safe and effective in the studied pediatric population. *Id.*

Amgen's Pediatric Clinical Studies for SENSIPAR

26. FDA first approved SENSIPAR in March 2004. The product currently is approved for use in adult patients for treating (i) secondary HPT in patients with chronic kidney disease on dialysis; (ii) hypercalcemia (too much calcium in the blood) in patients with parathyroid carcinoma, a malignancy of the parathyroid glands; and (iii) severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy—the surgical removal of one or all of the parathyroid glands. FDA, Approval Letter for NDA 21-688 (Mar. 8 2004); FDA, Supplemental Approval Letter for NDA 021588/S-015 (Feb. 25, 2011).[2]

27. There was and remains an unmet medical need to treat secondary HPT in children, *i.e.*, patients younger than eighteen years old. Left untreated, secondary HPT in children can lead to bone fractures, bone pain, bone deformities, decreased bone mass, and overall retarded growth. FDA estimated that there were approximately 2,200 pediatric patients

[2] Available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/21-688_Sensipar.cfm; https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021688s015ltr.pdf.

with chronic kidney disease who rely on dialysis in the United States as of 2007. Current treatment options for children with secondary HPT are very limited and often associated with hypercalcemia and hyperphosphatemia, which are of particular concern to younger CKD patients whose skeletal and vascular systems are still developing.

28. For three years (from May 2007 to May 2010), Amgen and FDA engaged in discussions about the appropriateness of pediatric studies for SENSIPAR. In May 2010, FDA issued a Written Request to Amgen to conduct pediatric studies for SENSIPAR. FDA, Written Request Letter (May 5, 2010) (a true and correct copy of which is attached as "Exhibit 3"). Over the next five years, that request was amended five times based on frequent exchanges of information about the ongoing clinical studies between Amgen and FDA. FDA, Revised Written Request Letter (Dec. 14, 2010) (a true and correct copy of which is attached as "Exhibit 4"); FDA, Revised Written Request Letter (Mar. 25, 2011) (a true and correct copy of which is attached as "Exhibit 5"); FDA, Revised Written Request Letter (July 29, 2014) (a true and correct copy of which is attached as "Exhibit 6"); FDA, Revised Written Request Letter (Apr. 9, 2015) (a true and correct copy of which is attached as "Exhibit 7"); FDA, Revised Written Request Letter (Oct. 14, 2015) (a true and correct copy of which is attached as "Exhibit 8").

29. As finally amended, FDA's Written Request asked Amgen to perform the following four pediatric studies:

a. *Study 1*: A single-dose pharmacokinetics/pharmacodynamics (PK/PD)[3] study in pediatric patients ages 28 days to < 6 years with chronic kidney disease and secondary HPT receiving dialysis.

[3] Pharmacokinetics is the "branch of pharmacology that deals with the movement of drugs within the body," and in particular the "quantitative aspects of their absorption, distribution, metabolism, etc." *Pharmacokinetics*, Oxford English Dictionary (2017). Pharmacodynamics refers to the "branch of pharmacology that deals with the actions of drugs" and "the

b. *Study 2*: A 30-week, randomized, double-blind, placebo-controlled, safety and efficacy study with a 30-week, open-label, safety extension in pediatric patients ages 6 years to < 18 years with chronic kidney disease and secondary HPT receiving dialysis.

c. *Study 3*: A 26-week or time-until-transplantation (whichever comes first), open-label, safety study in pediatric patients ages 28 days to < 6 years.

d. *Study 4*: A 20-week, randomized, open-label, controlled study in pediatric subjects between the ages of 6 and < 18 years, with secondary HPT and chronic kidney disease who are receiving either hemodialysis or peritoneal dialysis.

Ex. 8.

30. FDA set November 25, 2016 as the deadline for Amgen to submit reports from the studies. Ex. 6.

31. Amgen not only responded to FDA's Written Request for pediatric studies by that date; it far exceeded the scope of FDA's request. To begin with, Amgen conducted the four studies described in the Written Request, enrolling a total of 130 patients between the four studies and administering SENSIPAR to 76 patients, including 64 patients in the safety and efficacy studies. Amgen Inc., SENSIPAR NDA 209962 § 1.9.3, Request for Pediatric Exclusivity Determination at 7, tbl. 2 (Nov. 23, 2016) (a true and correct copy of which is attached as "Exhibit 9").

32. The Written Request also called for Amgen to develop a protocol to extend Study 4 as an open-label study, where patients receive treatment with SENSIPAR and are monitored to

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characteristics of the action of a particular drug." *Pharmacodynamics*, Oxford English Dictionary (2017). PK/PD data in children are important to making dosing decisions for pediatric patients.

assess long-term safety but are not given a placebo. The Written Request specified that submission of final results for Study 4 was "not a term of the Written Request." Ex. 3. Amgen went beyond the Written Request requirements; it included the option for the extension study to enroll patients from both Study 3 *and* Study 4, and ultimately submitted data from 18 patients who had received SENSIPAR in the extension study. Ex. 9 at 7, tbl. 2.

33. But Amgen also went beyond the Written Request by conducting a retrospective review and a prospective cohort study of pediatric patients with end-stage kidney disease—including 113 children that had been treated with SENSIPAR—to better understand the safety of the drug and patient outcomes both with and without treatment. Ex. 9 at 7, tbl. 2. These retrospective studies of patient registries and charts are tools widely used in medical research that provide targeted, patient-level datasets without the need for independent clinical testing. Because of the limitations on pediatric testing described above, this real-world data is often all the information that is available for healthcare professionals when making critical treatment decisions. Amgen also conducted three pharmacokinetic studies in three different age groups, including one more than the Written Request required, to develop a dosing regimen in pediatric patients.

34. In total, Amgen performed *nine* studies over the span of roughly eleven years, together covering 103 pediatric patients who received at least one dose of SENSIPAR in interventional clinical trials, along with an additional 113 patients who received SENSIPAR in either a registry or chart review. *Id.* The size of these studies is particularly remarkable, given the rarity of secondary HPT in the U.S. pediatric population and the fact that kidney transplantation is typically the preferred course of action for pediatric patients; fewer than 1,000 minors nationally are estimated to be affected and on dialysis. Amgen Inc., Formal Dispute

Resolution Request at 4 & n.13 (May 5, 2017) (a true and correct copy of which is attached as "Exhibit 10").

35. In addition to the clinical studies, Amgen also performed a number of PK and PK/PD modeling studies and a Bayesian analysis (which combines observed data and prior beliefs to estimate the relative probabilities of a given treatment's likelihood of success) to extrapolate the qualitative and quantitative PK, efficacy, and safety of SENSIPAR. Amgen Inc., Annotated Written Request for Pediatric Exclusivity Determination (Nov. 23, 2016) (a true and correct copy of which is attached as "Exhibit 11").

36. As to the four studies enumerated in FDA's Written Request, Amgen successfully completed Study 1, Study 2, and Study 4 precisely according to the terms of the agency's Written Request, even over-enrolling one study as permitted. *See id.* All of these studies were completed by June 23, 2016.

37. The only aspect of the Written Request that Amgen did not meet was the target number of completers for Study 3.

38. At any one time, there are only approximately *300* pediatric patients under the age of 6, nationwide, that are estimated to be on dialysis within the United States. Additionally, pediatric patients—especially those under six years old, comprising Study 3's population—are routinely prioritized for kidney transplants, which made identifying eligible patients for the study even more challenging. Relatedly, based on feedback from the study sites, many of these very young pediatric patients' parents focused their efforts on finding a donor rather than beginning the cumbersome process of enrollment in a clinical study, including the repeated blood draws associated therewith. Recruitment was additionally challenging because general nephrologists will not treat pediatric patients, and there are few pediatric nephrologists. Amgen Inc., General

Correspondence: Type C Meeting Request to Discuss the Pediatric Program and Written Request Requirements (Dec. 3, 2015) (a true and correct copy of which is attached as "Exhibit 12").

39. FDA's Written Request asked that Study 3 involve a minimum of 15 patients between the ages of 28 days and 6 years old who would be treated for either 26 weeks or, if a patient received a kidney transplant during the study, 12 weeks prior to transplant. Ex. 8. Amgen enrolled 18 patients in the study. However, a December 2012 report of the death of a child in Study 2 led FDA in February 2013 to temporarily suspend further dosing in pediatric patients with secondary HPT. Ex. 11. During that partial clinical hold, which lasted through April 2014, Amgen was prohibited from enrolling new patients, and already enrolled patients could not be dosed with the drug. FDA also made additional safety-related changes to the Written Request in force at the time. Ex. 6.

40. The clinical hold made an *almost* impossible task *actually* impossible. Following the start of the clinical hold, during which enrolled patients were not receiving treatment, six of the eight then-enrolled patients left Study 3. Four of those who discontinued treatment left as a result of the partial clinical hold, another received a kidney transplant, and the sixth patient withdrew on the day of enrollment without receiving a dose of cinacalcet. And while Amgen was able to enroll another 10 patients after the hold was lifted, by the end of the study only three patients had stayed enrolled throughout the required 26-week treatment period and one other completed the minimum 12 weeks' treatment before receiving a kidney transplant. At the end of the day, a total of 11 patients were on study for at least 12 weeks in the study, but only four of those enrollees ultimately met all completion criteria. Ex. 10.

41. Notwithstanding these challenges, Amgen made every effort to reach the target number of completing patients in Study 3. Amgen held the enrollment period open for more

than three years (from January 2012 to June 2016, not counting the fourteen-month clinical hold). The company also implemented a comprehensive recruitment and retention program that involved initiating a large number of study sites, engaging site-management organizations, offering home healthcare services for the benefits of enrolled patients, providing extensive support services, collaborating with the North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) organization, organizing additional investigator meetings, and simplifying the protocol in response to feedback from site personal. Ex. 9 at 5. But even with these Herculean efforts, the factors inherent in the pediatric group being studied as well as the practical impact of the clinical hold were simply too much to overcome. Amgen was unable to enroll sufficient completing patients to meet FDA's target.

42. Nevertheless, FDA stated that Amgen should continue with the study program. In a September 2013 teleconference—during the clinical hold—Amgen asked whether FDA agreed with Amgen's recommendation to discontinue the studies altogether. FDA responded: "No we do not agree, we continue to believe that cinacalcet can be useful for the management of secondary [HPT] in the pediatric population and that the cinacalcet pediatric program should continue with enhanced titration and monitoring safeguards." Ex. 1 at 4. The official meeting minutes from that conference (prepared by FDA) also recount that: "FDA stated that this pediatric program was very important to understand how to use this drug in the pediatric population." *Id.* at 5. The agency noted: "We have learned a lot from the analysis of the clinical data collected during the pediatric program." *Id.* at 7.

43. After receiving the agency's instruction to continue, and for the next two and a half years, Amgen continued to pour resources into the pediatric studies. All told, to the best of Amgen's knowledge, the company invested approximately $10 million to $15 million over the

space of eleven years to conduct the pediatric studies requested by FDA. In the fall of 2015, Amgen requested that FDA amend its Written Request to accommodate the effects of the clinical hold on Study 3 and meet with the company to discuss the rationale for the requested amendments. FDA, however, refused to meet with Amgen to discuss the issue. In its December 2015 denial of Amgen's request for a meeting to discuss amending the Written Request regarding Study 3, FDA said "we will not have any more discussion on this" and directed Amgen to "use [its] discretion moving forward." FDA, Meeting Denied Letter (Dec. 24, 2015) (a true and correct copy of which is attached as "Exhibit 13").

44. On multiple occasions, Amgen approached the agency to inform FDA of the unique challenges the study (and the hold) raised and to seek corresponding modifications to completing patient enrollments. FDA, Meeting Preliminary Comments (Sept. 2, 2013) (a true and correct copy of which is attached as "Exhibit 14"). DA refused to revise the requirements for patients completing Study 3. Amgen Inc. Memorandum of Meeting Minutes (Sept. 21, 2016) (a true and correct copy of which is attached as "Exhibit 15"); Ex. 13. FDA's refusal to amend the Written Request , or even discuss the issue with Amgen, is all the more surprising in light of the fact that information that FDA routinely makes public demonstrates that the agency has allowed other companies the ability to amend written requests six or more times.[4]

45. Following the directives Amgen consistently and continuously received throughout the years, Amgen pressed ahead to complete all of the studies, doing everything it could to address the particularly daunting enrollment challenges associated with Study 3. Among other efforts, Amgen worked with the NAPRTCS, which studies pediatric patients with end-stage renal disease, to identify members of the small population of children under 6

[4] Available at https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ucm049997.htm

requiring dialysis for kidney failure who might be eligible to participate in clinical studies. Amgen also supplemented the study data with two studies analyzing real-world treatment evidence from pediatric patients administered SENSIPAR. One was a prospective cohort study of 538 pediatric patients with end-stage renal failure (including 90 children who received SENSIPAR), which described and analyzed the course of treatment, both among those who had used SENSIPAR and those who had not, as an additional source of data about the drug. The other was a review of the medical charts of 23 patients aged 0 to 6 years old who had received SENSIPAR. This additional real-world treatment evidence provided additional information about the safety of the drug, including in young pediatric patients. Ex. 9 at 7, tbl. 2.

46. On November 23, 2016—two days before the filing deadline set by FDA—Amgen submitted reports of the results of the requested pediatric studies in line with FDA's filing requirements, via a supplement to the SENSIPAR NDA. Taken together, the pediatric studies Amgen undertook in response to FDA's Written Request generated a vast amount of data for the agency, including:

a. Chemistry, manufacturing, and controls information for an age-appropriate formulation developed for pediatric use (in dosages of 1, 2.5, and 5 milligrams).

b. Reports from two juvenile toxicity studies conducted upon FDA recommendation (although not specified in the written request).

c. A bioavailability and bioequivalence study report comparing doses of 5 milligram, administered by sprinkling onto applesauce or swallowed whole with applesauce, with the 30-milligram SENSIPAR tablet, swallowed whole with applesauce, in healthy adult subjects.

d. Final clinical study reports for Studies 1, 2, 3, and 4, including information on the representation of pediatric subjects of ethnic and racial minorities, and an interim clinical study report for the extension protocol for Studies 3 and 4.

e. A summary of demographic and drug-use data drawn from a national registry with more than 6,000 registered pediatric dialysis patients, which included an evaluation of safety information for 538 pediatric dialysis patients, including 90 patients treated with SENSIPAR.

f. Population PK and PK/PD exposure-response analyses that relate the time course of plasma cinacalcet concentrations with the changes in serum calcium and parathyroid hormone levels—which demonstrate the drug's safety and efficacy—and support dosing recommendations for pediatric patients.

g. A Bayesian extrapolation analysis that models, based on treatment data from adult populations, the effect of SENSIPAR on the parathyroid hormone and calcium levels for pediatric patients between the ages of 28 days and 6 years with chronic kidney disease and secondary hyperparathyroidism who are receiving dialysis.

h. A summary of the published literature on the use of SENSIPAR in pediatric patients.

i. A summary report evaluating all pediatric postmarketing adverse event reports regarding SENSIPAR available to Amgen.

j. Datasets from Studies 2, 3, and 4, and a study of the open-label protocol, as well as datasets supporting Amgen's integrated summary of safety and Bayesian analysis.

Id. at 4–5.

47. The data and information Amgen provided to FDA were useful to the agency—not just for Study 1, Study 2, and Study 4, but also for Study 3. In Study 3, the primary safety endpoint was to determine the proportion of patients whose serum calcium levels were below a certain target (9.0 mg/dL for patients under 2 years and 8.4 mg/dL for patients 2-6 years). Pooling data from Study 1 (N = 14 SENSIPAR-treated children < 6 years of age), Study 3 (N=17 SENSIPAR-treated children < 6 years of age), the retrospective chart review (N=23 SENSIPAR-treated children < 6 years of age), and the prospective cohort study (which included 9 SENSIPAR-treated children < 6 years of age), Amgen submitted safety data from 63 patients under age 6 who received SENSIPAR. This was a remarkable accomplishment. Given that there are fewer than 300 patients under age six receiving dialysis in the entire *country*, Amgen's results meant that the company had managed to painstakingly gather data from over 20 percent of the entire patient subpopulation. Ex. 9 at 1.

FDA's Denial of Pediatric Exclusivity

48. When it first became clear that FDA was poised to deny pediatric exclusivity on May 1, 2017, Amgen sought to invoke the administrative review process by submitting an administrative appeal to the agency on May 5th and requesting expedited review. Ex. 10. FDA rejected that request by letter dated May 19th, taking the position that Amgen could not invoke the dispute resolution process until after FDA's May 22nd denial. FDA, Not Accepted—Dispute Resolution Request (May 19, 2017) (a true and correct copy of which is attached as "Exhibit 16").

49. On the following Monday, May 22, 2017, the agency denied Amgen's request for pediatric exclusivity. Ex. 2. The denial letter admitted that "Amgen has met the literal terms of the [Written Request] for Studies 1, 2, and 4." *Id.* at 7. But the letter cited the "failure to meet

an important element of the written request"—the number of completers in Study 3— resulted in the lack of sufficient safety data for pediatric patients < 6 years of age with secondary HPT and CKD receiving dialysis." *Id.* at 10. The agency concluded that because "this criterion was not met," Amgen "has failed to fairly respond" to the Written Request. *Id.*

The denial letter also made clear that FDA considered whether Amgen's studies were "sufficient" to demonstrate safety (or the absence thereof) as part of its pediatric exclusivity analysis. *Id.* at 2, 3, 10. According to FDA, Amgen's "failure to provide sufficient safety data" in the youngest pediatric group "*prevent[ed] FDA from drawing any conclusions about the safety of the product*" in that population. *Id.* at 10 (emphasis added). As the agency saw it, "[i]f the totality of safety information Amgen submitted had provided an appropriate safety assessment in younger children *and supported a label description*—even if the exact minimum number of patients had not been met [ ]—this element of the [written response] could have been adequately satisfied and Amgen's response could be considered a fair response." *Id.* (emphasis added). Thus, because the agency found insufficient "safety information" pertaining to the youngest group studied, Amgen "failed to fairly respond." *Id.*

FDA's Conduct Was Unlawful, Arbitrary and Capricious

50. FDA's refusal to accept Amgen's study reports violates the plain language of the statute. Congress explicitly instructed that FDA's "*only* responsibility" in determining whether to accept the reports is to confirm that (1) "the studies fairly respond to the written request," (2) the studies "have been conducted in accordance with commonly accepted scientific principles and protocols," and (3) the studies "have been reported in accordance with the requirements of the Secretary for filing." 21 U.S.C. § 355a(d)(3) (emphasis added). Once the

reports meet those standards and are accepted, the six-month extension of exclusivity and patent protection automatically applies. *Id.* at §§ 355a(b)(1), (c)(1).

51. And yet here, FDA denied pediatric exclusivity because *one* of the four studies failed to meet *one* requirement—and that in the face of insurmountable challenges. That position runs afoul of the clear meaning of "fairly respond."

52. FDA's denial of pediatric exclusivity also violated the plain language of the statutory scheme governing pediatric exclusivity by improperly conflating the agency's "only responsibility" in assessing whether a sponsor's reports of pediatric studies "fairly respond to the written request," 21 U.S.C. § 355a(d)(3), with the discrete and more rigorous standard used by the agency to make labeling determinations assessing a drug's safety based on the underlying data, *id.* § 355a(j).

53. For example, FDA's denial letter took the position that the pediatric exclusivity provision "attempts to ensure that when pediatric exclusivity is granted for studies, FDA *also* may approve labeling describing the results of the studies and providing adequate information for use of the drug in relevant pediatric populations." Ex. 2 at 2 (emphasis added).

54. The denial letter also admitted that the agency considered, as part of its exclusivity analysis, whether the data generated by Amgen's studies was "sufficient" to demonstrate safety: "In determining whether a submission 'fairly responds' to a [written request], FDA considers whether the submission is sufficient to enable it to approve pediatric labeling (including negative pediatric labeling) for all of the age groups and indications requested based on the studies conducted." *Id.* at 3.

55. On the very last page of the letter, FDA stated:

> In summary, Amgen's failure to provide sufficient safety data in [Study 3] *prevents FDA from drawing any conclusions about the safety of the product* in

> patients <6 years of age when used as intended.
>
> If the totality of safety information Amgen submitted had provided an *appropriate safety assessment* in younger children *and supported a label description*—even if the exact minimum number of patients had not been met in study 3—*this element of the WR could have been adequately satisfied* and Amgen's response could be considered a fair response to the WR as a whole.

Id. at 10 (emphases added). On that same page, FDA lamented the lack of a "robust source of safety information". *Id.* And it concluded: "Amgen's failure to meet an important element of the [Written Request] also resulted in *the lack of sufficient safety data* for pediatric patients < 6 years of age with secondary HPT and CKD receiving dialysis. The *lack of sufficient safety data in this population has led to the inability to clearly establish the safety profile* of the drug for pediatric patients in accordance with objectives of the amended WR. Accordingly, [pediatric exclusivity] is denied for cinacalcet." *Id.* (emphasis added).

56. The statute does not permit FDA to assess the sufficiency of safety data in determining whether to accept pediatric studies. The only question is whether the studies "fairly respond" to the Written Request. Here, FDA performed a qualitatively different—and therefore statutorily impermissible—inquiry.

57. FDA's denial of pediatric exclusivity to Amgen reflects an abrupt and unexplained departure from the agency's past treatment of similarly situated entities. To the best of Amgen's knowledge, FDA previously has determined that a sponsor's failure to meet a single requirement of the written request—including the number of patients completing one study—does not mean the submitted studies do not "fairly respond" to the agency's written request.

58. In fact, even where there were *multiple* differences between the conducted studies and the written request—including low patient enrollment—FDA found the studies to "fairly respond" to the written request. This was the case with AstraZeneca's Zomig® (zolmitriptan)

tablets, which received pediatric exclusivity even though the sponsor submitted data that (as FDA acknowledged) deviated from the terms of two of the four studies contained in the agency's written request. FDA, Original Pediatric Written Request, Clinical Review, NDA 020768 (March 26, 1999).[5] FDA requested that a clinical study be conducted on 300 to 600 patients who suffer from an average of two or more headaches a year, but AstraZeneca submitted data on only 42 qualifying patients treated for at least one year and another 151 patients treated for at least 326 days—less than 200 patients total. *Id.* at 33, 38. FDA's written request had also sought an open-label, single-dose, parallel-group inpatient PK study in adolescents and adults with a history of migraine, and AstraZeneca instead submitted three non-conforming PK studies, one of which did not require enrollees to have a history of migraines, another that lacked adolescent enrollees, and the third without a foundation to conclude that only otherwise-healthy patients would be enrolled and that used a different dosage form than specified in the written request (nasal spray instead of oral tablets). *Id.* at 9–14.

59. Similarly, FDA granted pediatric exclusivity for Ortho-McNeil's Ortho Tri-cyclen® (ethinyl estradiol; norgestimate) tablets, having concluded that reported data from studies deviating from the terms of the written request nonetheless "fairly responded" to the request. FDA, Clinical Review, NDA 019697 (May 6, 2005).[6] There, the sponsor submitted data on 26 patients, when the written request required at least 40 patients and suggested that 60 would be preferable. Moreover, the agency's reviewer concluded that the "[r]esults of this study were confounding"; among other things, the study was supposed to have a "single-trough

[5] *Available at* https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM400085.pdf.

[6] *Available at* https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM343856.pdf.

sampling design" and "very few [patients] had true trough concentrations." FDA, Clinical Pharmacology And Biopharmaceutics Review, NDA 021690 at 1 (March 8, 2004).[7]

60. FDA also granted pediatric exclusivity to Bristol-Myers Squibb's Orencia® (abatacept) injection, even though the reviewer expressly acknowledged that Bristol-Myers Squibb had not satisfied the written request's enrollment instructions due to lower than expected recruitment success and higher than expected discontinuation rates. *See* Dr. Keith Hull, Addendum to Primary Clinical Review of Supplement 211, BLA 125118, at 7 (March 24, 2017) ("[T]he data submitted in this supplement, while not technically meeting the specifics of the [pediatric written request], are adequate and fulfills the intent of the Pediatric Written Request.").[8]

61. FDA's acceptance of these studies should not be surprising, considering FDA has granted exclusivity to all but 18 of the drug products that were the subject of an exclusivity determination, out of a total of 239—fully 93% of sponsoring companies.[9]

62. There can be no doubt that the Amgen studies "fairly respond" to the Written Request from FDA requirement here. After devoting 11 years to the clinical studies, Amgen presented study reports that matched FDA's requested parameters for three of the four requested studies. Even for Study 3, which was impossible to complete in accordance with the requested parameters, Amgen did everything reasonably possible to obtain the target number of patients completing the studies and provide informative data. And Amgen provided additional information from several other sources, including a retrospective chart review specifically

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[7] *Available at* https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM343859.pdf

[8] *Available at* https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/%20DevelopmentResources/UCM552563.pdf.

[9] *See* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm050005.htm

targeting children under 6 years of age, to supplement the data it was able to glean from Study 3. And there can be no dispute that FDA received useful information as a result of Amgen's pediatric studies; FDA officials admitted as much in the 2013 correspondence regarding the clinical hold. Ex. 1.

63. FDA got the benefit of its bargain. But Amgen was denied the *quid pro quo* promised by the statute for the studies the company laboriously performed. FDA's failure to recognize Amgen's statutory right is a serious matter not only for Amgen, but for the public health. An important part of the pediatric exclusivity scheme is the incentive system designed to ensure that it is worth drug sponsors' while to devote resources toward studying their drugs in pediatric patients. FDA's conduct threatens the balance created by the statutory program, because it dis-incentivizes drug sponsors from devoting resources to studying their drugs in the pediatric population—a population that offers significant study challenges and yet offers little in the way of financial rewards, given the small population sizes often at play. And once the window for pediatric exclusivity closes, the opportunity is lost for good—once generic drug products enter the market, innovator drug sponsors would have no financial incentive whatsoever to perform studies in pediatric patients. In turn, medical professionals would once again, despite Congress's clear intention to the contrary, be deprived of critical information to guide their dosing determinations.

64. FDA also acted arbitrarily and capriciously by refusing to consider the problems created by the clinical hold and by refusing to meet with Amgen despite its repeated requests for an amendment to the Written Request.

65. For all of these reasons, FDA's denial of pediatric exclusivity was unlawful, arbitrary, capricious, and otherwise violates the APA.

Amgen Will Suffer Irreparable Harm Absent Immediate Judicial Relief

66. Absent immediate judicial relief, FDA's improper denial of pediatric exclusivity threatens Amgen with irreparable harm.

67. In addition to the 180 day deadline for responding to a request for exclusivity, the BPCA also sets another deadline: FDA "shall not extend" an underlying patent or regulatory exclusivity period to reflect pediatric exclusivity "if the determination made under subsection (d)(3) is made later than 9 months prior to the expiration of" the underlying patent exclusivity. *Id.* §§ 355a(b)(2), (c)(2). Because a key patent covering SENSIPAR (the '068 Patent) is set to expire on March 8, 2018, that statutory deadline is June 8, 2017. If the agency continues to reject Amgen's study reports (thus denying Amgen's right to pediatric exclusivity) by this date, there is a very real risk that Amgen will be forever deprived of a its statutory entitlement—for which there is no clear legal mechanism to make Amgen whole. Because of this June 8, 2017 deadline, Amgen is seeking preliminary injunctive relief by **June 6, 2017**, to maintain the status quo and to preserve this Court's ability to render appropriate relief upon the conclusion of this case.

Amgen Lacks An Opportunity for Administrative Review

68. FDA has an internal dispute resolution procedure available to applicants denied pediatric exclusivity.[10] FDA's stated goal for resolving such appeals is 30 days.[11]

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[10] U.S. Food and Drug Administration, Formal Dispute Resolution: Appeals Level Guidance for Industry and Review Staff at 4–5 (Sept. 2015), *available at* https://www.fda.gov/downloads/drugs/guidances/ucm343101.pdf.

[11] U.S. Food and Drug Administration, *PDUFA Reauthorization Performance Goals and Procedures: Fiscal Years 2013 through 2017 at Part V.A.* (September 15, 2016), *available at* https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf

69. Because of the timing of FDA's exclusivity decision, Amgen cannot pursue that procedure without incurring the substantial risk of losing the full benefit of its statutory entitlement. As noted, FDA's deadline for granting pediatric exclusivity for a critical Amgen patent is June 8, 2017. Amgen submitted its pediatric study reports in advance of the deadline contained in the Written Request, and sufficiently before expiration of the '068 Patent for FDA to accept the reports in time for the '068 Patent to benefit from the six-month extension conveyed by pediatric exclusivity. Because FDA's decision on pediatric exclusivity was not issued until May 22, it is a virtual certainty that FDA would not resolve any administrative appeal by June 8—let alone in sufficient time to permit Amgen to seek judicial review of an adverse decision by that date.

70. Nonetheless, in an abundance of caution, Amgen filed an administrative appeal to the agency on May 5, based on communications with the agency earlier that week suggesting that the agency might be poised to deny pediatric exclusivity. Ex. 10. Amgen specifically requested expedited review proceedings. FDA responded to Amgen's May 5th letter on May 19, 2017 and denied the company's request for agency dispute resolution. Ex. 16.

71. Any further efforts to pursue administrative review would be futile, based on the agency's positions to date, and because such administrative review will not be completed in time to preserve Amgen's rights before the statutory deadline. While Amgen intends to pursue those administrative appeals anyway, it nonetheless needs this Court to step in and preserve the status quo by ordering FDA to accept the studies pending either (a) further order of this Court; or (b) a favorable resolution on administrative appeal.

72. FDA's decision to deny Amgen pediatric exclusivity constitutes final agency action for which Amgen has no other adequate remedy within the meaning of 5 U.S.C. § 704. It

would be futile for Amgen to avail itself of any remaining administrative review, given the time pressures at play here.

73. Both Amgen and the public would be irreparably harmed if FDA's decision were allowed to stand, as it undermines the incentive system Congress put in place to encourage drug sponsors to make the expensive, time-consuming, and risky decision to perform additional pediatric studies, and the data and information derived from those studies inform pediatric use of drugs, which is very much in the public interest.

74. Amgen is without an adequate remedy at law because FDA's improper denial of pediatric exclusivity, if uncorrected, would deny Amgen a statutory entitlement that money damages could not remedy.

75. The intent of Congress will be served by an Order directing FDA to grant Amgen pediatric exclusivity for SENSIPAR. In addition, the public interest will be served by such an order.

COUNT I
(Administrative Procedure Act: FDA's Conduct Was Unlawful, Arbitrary, Capricious, an Abuse of Discretion, and Contrary to Law)

76. Amgen re-alleges, reasserts, and incorporates by reference each of the foregoing allegations in the Complaint, as though set forth fully herein.

77. The Administrative Procedure Act prohibits FDA from implementing its statutory mandate in a manner that is unlawful, arbitrary, capricious, an abuse of discretion, or contrary to law. 5 U.S.C. § 706(2).

78. FDA's refusal to accept Amgen's pediatric studies violates the agency's governing statute in violation of the APA.

79. FDA's denial of Amgen's request for pediatric exclusivity violates the agency's governing statute, in violation of the APA.

80. FDA's decision to deny Amgen pediatric exclusivity was unlawful because it stemmed from an improper interpretation of the agency's governing statute.

81. FDA's refusal to accept the study reports and its decision to deny Amgen pediatric exclusivity was arbitrary, capricious, an abuse of discretion, and contrary to law because Amgen fairly responded to FDA's Written Request for pediatric studies, conducted the studies in accordance with commonly scientific principles and protocols, and reported those studies in accordance with the agency's filing requirements.

82. FDA's decision to deny Amgen pediatric exclusivity is arbitrary, capricious, an abuse of discretion, and contrary to law because it conflicts with the agency's treatment of similarly situated entities.

83. FDA's decision to deny Amgen pediatric exclusivity is arbitrary, capricious, an abuse of discretion, and contrary to law because it departs from the agency's own stated policies and long-standing practice, without adequate explanation.

84. FDA's decision to deny Amgen pediatric exclusivity is arbitrary, capricious, an abuse of discretion, and contrary to law because it reflects a failure of reasoned decisionmaking.

85. FDA's decision to deny Amgen pediatric exclusivity constitutes final agency action for which Amgen has no other adequate remedy within the meaning of 5 U.S.C. § 704. It would be futile for Amgen to avail itself of any remaining administrative review, given the aforementioned time constraints.

86. Both Amgen and the public would be irreparably harmed if FDA's decision were allowed to stand, as it undermines the incentive system Congress put in place to encourage drug

sponsors to make the expensive, time-consuming, and risky decision to perform additional pediatric studies.

87. Amgen is without an adequate remedy at law because FDA's improper denial of pediatric exclusivity, if uncorrected, would deny Amgen of a statutory entitlement that money damages could not remedy.

88. The intent of Congress and the public interest will be served by an Order directing FDA to grant Amgen pediatric exclusivity for SENSIPAR.

COUNT II
(Fifth Amendment to the U.S. Constitution: FDA Unconstitutionally Deprived Amgen of Procedural Due Process, in Violation of the Administrative Procedure Act)

89. Amgen re-alleges, reasserts, and incorporates by reference Paragraphs 1 through 75 alleged above in the Complaint, as though set forth fully herein.

90. FDA's failure to give Amgen fair notice about its newfound (and erroneous) interpretation of 21 U.S.C. § 355a, under which Amgen would be deprived of its statutory entitlement to pediatric exclusivity, violates the procedural due process guarantees of the Fifth Amendment to the United States Constitution, in violation of the APA.

PRAYER FOR RELIEF

For these reasons, Amgen respectfully prays for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that FDA's refusal to accept Amgen's study reports and its decision to deny Amgen its statutory right to six months of pediatric exclusivity violated the BPCA and was otherwise unlawful, arbitrary, capricious, an abuse of discretion, and contrary to law;

B. Temporary, preliminary, and permanent injunctive relief (i) vacating FDA's decision to deny pediatric exclusivity; (ii) requiring FDA to accept Amgen's study reports; and (iii) requiring FDA to recognize the pediatric exclusivity to

which SENSIPAR is entitled, before June 8, 2017;

C. An order awarding Amgen its costs, expenses, and attorneys' fees incurred in these proceedings pursuant to 28 U.S.C. § 2412; and

D. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

Catherine E. Stetson (DC Bar # 453221)
Susan M. Cook (DC Bar # 462978)
HOGAN LOVELLS US LLP
555 Thirteenth Street, NW
Washington, DC 20004
Telephone: 202-637-5491
Fax: 202-637-5910
cate.stetson@hoganlovells.com
susan.cook@hoganlovells.com

Counsel for Plaintiff Amgen Inc.

Dated: May 25, 2017

VERIFICATION

I, the undersigned, having read the allegations of the foregoing Verified Complaint, hereby declare under penalty of perjury and pursuant to 28 U.S.C. § 1746 that the factual allegations asserted in the Verified Complaint are true and correct.

Executed this 24th day of May 2017.

Laura Bloss, PhD
Executive Director, Global Regulatory Affairs