UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMGEN INC.,

Plaintiff,

v.

ERIC D. HARGAN, Acting Secretary, Department of Health and Human Services, *et al.*,

Defendants,

and

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Intervenor-Defendants.

Civil Action No. 17-1006 (RDM)

MEMORANDUM OPINION AND ORDER

The matter is before the Court on two motions: Amgen Inc.'s motion to complete or to supplement the administrative record, Dkt. 38, and Amneal Pharmaceuticals LLC's ("Amneal") unopposed motion to intervene as a defendant, Dkt. 33. For the reasons that follow, the Court will deny Amgen's motion and will grant Amneal's motion, subject to one condition. In addition, the Court reaffirms its earlier decision granting Watson Laboratories, Inc. ("Watson") leave to intervene, subject to that same condition. *See* Minute Order (Aug. 15, 2017).

I. BACKGROUND

The Court recites only those facts relevant to the pending motions.

A. Facts Relevant to Amgen's Motion To Supplement the Administrative Record

In March 2004, the Food and Drug Administration ("FDA") approved a New Drug Application ("NDA") for Sensipar (cinacalcet hydrochloride) for the treatment of (1) secondary hyperparathyroidism in adult patients with chronic kidney disease on dialysis; (2) hypercalcemia in adult patients with parathyroid carcinoma; and (3) severe hypercalcemia in adult patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy. Dkt. 1 at 10 (Compl. ¶ 26). Amgen, the sponsor of the NDA, holds several patents for Sensipar. One of those patents, which Amgen describes as a "key patent[] covering Sensipar," is due to expire on March 8, 2018. *Id.* at 4–5 (Compl. ¶ 9).

The present dispute centers on whether Amgen is entitled to an additional six months of market exclusivity for Sensipar (and other drugs containing the same active moiety) under 21 U.S.C. § 355a, an amendment to the Federal Food, Drug, and Cosmetic Act that Congress enacted to "provide[] an incentive for a drug patent holder to conduct pediatric studies of a drug which the FDA believes may have beneficial pediatric use." *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1276 (D.C. Cir. 2004). Subject to certain exceptions not relevant to the pending motion, § 355a provides an additional six-month period of "pediatric exclusivity" for qualifying drugs. It does so by, among other things, precluding the FDA from approving any Abbreviated New Drug Application ("ANDA") for a follow-on drug for "a period of six months after the date the patent expires (including any patent extensions)," subject to detailed rules relating to the timing of the pediatric studies and the term, scope, and validity of the patent. 21 U.S.C. § 355a(b)(1)(B)(i); *see also* 21 U.S.C. § 355(b)(2)(A)(ii)–(iv) (describing certification of ANDA

applicant that the patent has expired, will expire, is invalid, or will not be infringed); 21 U.S.C. § 355(j)(2)(A)(vii)(II)–(IV) (same).

Before an applicant may qualify for this additional period of exclusivity, however, five events must occur: (1) the FDA must determine "that information relating to the use of [the] drug in the pediatric population may produce health benefits in that population;" (2) the FDA must make a "written request for pediatric studies;" (3) the applicant must agree to that request; (4) the studies must be "completed using appropriate formulations for each age group for which the study is requested within [the specified] timeframe;" and—most importantly for present purposes—(5) the reports from those studies must be "submitted [to] *and accepted*" by the FDA. 21 U.S.C. § 355a(b)(1) (emphasis added). In deciding whether to accept or reject the studies, the FDA's "only responsibility [is] to determine . . . whether the studies *fairly respond* to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with" the FDA's filing requirements. 21 U.S.C. § 355a(d)(4) (emphasis added).

Amgen submitted a proposed pediatric study request for Sensipar in May 2007, and after extensive back and forth, the FDA finally issued a written request for pediatric studies of the drug in May 2010. Dkt. 1 at 11 (Compl. ¶ 28); Dkt. 1-2 at 4. The back and forth then continued over the next several years, while Amgen performed—or attempted to perform—various studies. Dkt. 1 at 11 (Compl. ¶ 28). Ultimately, however, the FDA concluded in May 2017 that Amgen's studies failed to "fairly respond" to the agency's written request. *Id.* at 20–21 (Compl. ¶ 49). Amgen, then, brought this action to challenge that decision, asserting claims under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), and the Due Process Clause of the Fifth Amendment. *Id.* at 29–31 (Compl. ¶¶ 76–90). Amgen simultaneously moved for a

temporary restraining order ("TRO") and preliminary injunction, Dkt. 3, and the Court held a hearing on Amgen's motion, *see* Minute Entry (June 2, 2017). At the same time that Amgen brought suit, it also sought formal dispute resolution before the FDA. Dkt. 52-2 at 154 (FDA reconsideration decision). The FDA declined to accept Amgen's request for formal dispute resolution while the company was actively pursuing litigation on the same matter. *Id.* Following the TRO hearing, however, the parties stipulated to stay this action pending completion of the administrative process and further agreed that, in light of their stipulation, Amgen's motion for a TRO was moot. Dkt. 14.

The Court agreed to stay the action and denied Amgen's motions for a TRO and preliminary injunction as moot in light of the FDA's agreement to reconsider its decision. Minute Order (June 5, 2017); Dkt. 15. In pursuing its request for reconsideration, Amgen challenged the FDA's initial denial of pediatric exclusivity on several grounds, including one ground that bears on the present motion: that the FDA ignored its own precedent in denying Amgen's application for pediatric exclusivity. Although far from exhaustive of the FDA's pediatric exclusivity decisions, the FDA and Amgen focused their analysis and arguments on eight "comparator" drugs. Dkt. 38-1 at 3–4, 7–9. The FDA rejected Amgen's contention that the agency had ignored its own precedent, and, indeed, concluded that its prior decisions were consistent with its decision denying Amgen's application for pediatric exclusivity. Dkt. 52-2 at 154–75.

The dispute, then, returned to this Court. The Court lifted the stay and set an agreed-upon, expedited schedule for cross-motions for summary judgment. Dkt. 25. Pursuant to that schedule, the FDA proceeded to compile the administrative record. It did not, however, provide the full complement of pediatric exclusivity documents for each of the eight comparator drugs;

rather, the FDA included only one document for most of those drugs. Dkt. 38-1 at 8. According to Amgen, although the relevant documentation may vary from case to case, a complete set of pediatric exclusivity documents for each drug generally should have included the Pediatric Exclusivity Board meeting minutes, the completed pediatric exclusivity checklist, Review Division memoranda, and the annotated Written Request. *Id.*

In September, Amgen moved to complete or supplement the administrative record with "documents that were before [the] FDA and [were] necessarily considered by the agency in connection with its pediatric exclusivity decision for Sensipar." Dkt. 38-1 at 2. Amgen argued that the FDA should be required to supplement the administrative record with three categories of documents: (1) "the Pediatric Review Board meeting minutes for Sensipar;" (2) "documents reflecting FDA's consideration of the requests for pediatric exclusivity for the eight comparator drugs;" and (3) "any other documents reflecting the 'consistency' of FDA's application of its 'fairly respond' standard." *Id.* at 3–5. Amgen asked the Court to order the FDA to produce the missing documents or to "certify that no such documents exist." Dkt. 38-2 at 2.

Nine days after the parties completed briefing on the relevant issues, *see* Dkt. 38; Dkt. 40; Dkt. 41, the Court held a hearing in an effort to expedite resolution of the issue. As explained at the hearing and reflected in a minute order entered that same day, the Court denied Amgen's motion with respect to the first and third categories of documents. *See* Minute Order (Sept. 20, 2017). With respect to the first category, the Pediatric Review Board meeting minutes for Sensipar, the Court denied Amgen's request as moot. *Id.* In responding to Amgen's motion, the FDA represented that the minutes that Amgen sought did not exist, and it further asserted that any *draft* minutes that may have been prepared were deliberative and, thus, were properly excluded from the administrative record. *See* Dkt. 40 at 5. Because Amgen acknowledged that

the FDA had included all of the relevant documents relating to Sensipar, all agreed that there was nothing further for the Court to decide with respect to Pediatric Review Board meeting minutes. Dkt. 58 at 4 (Transcript of Hearing).

The Court also denied Amgen's request with respect to the third category—"any other documents reflecting the 'consistency' of FDA's application of its 'fairly respond' standard"—on the ground that Amgen had failed to carry its burden of demonstrating that these documents were before the FDA when it made its decision or that unusual circumstances otherwise justified inclusion of the documents in the administrative record. *See* Minute Order (Sept. 20, 2017); *see also Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 55 (D.C. Cir. 2015). As the FDA clarified at the hearing, the agency "did not pull other files or . . . look at other files" beyond those pertaining to the eight comparators when it rendered its decision. Dkt. 58 at 7 (Transcript of Hearing). Nothing in the APA or in the case law requires an agency to include in the administrative record any and all documents reflecting the consistency—or inconsistency—of its application of a statute where there is no basis to conclude that the agency actually considered those materials.

This, then, left the second category of documents that Amgen sought to compel the FDA to include in the administrative record—that is, documents relating to the FDA's pediatric exclusivity decisions for the eight comparator drugs. As the FDA explained at the hearing, it affirmatively introduced one of these comparators, Actiq, into the case by pointing to it as a relevant precedent at the hearing on Amgen's motion for a TRO. Dkt. 58 at 7 (Transcript of Hearing). Both parties, moreover, had previously addressed a second drug, Mevacor, because it was the subject of a relevant decision from this Court. *See id.*; *see also Merck & Co. v. FDA*, 148 F. Supp. 2d 27 (D.D.C. 2001). The remaining six examples were raised by Amgen in

connection with its request that the FDA reconsider the denial of Amgen's application for pediatric exclusivity for Sensipar. Dkt. 58 at 7–8 (Transcript of Hearing). Although the administrative record contains certain documents relating to each of these drugs, Amgen identified a number of additional documents that it contends the "FDA must have considered" in deciding that it had consistently applied the "fairly respond" standard. Dkt. 38-1 at 7.

With respect to this category of documents, the FDA clarified at the hearing that the additional documents that Amgen would have it include in the administrative record were not "before" the agency in the sense that anyone involved in the decision-making process actually thought about them; the agency disavowed any suggestion that it considered the documents or that it declined to include them in the administrative record merely because they were not cited in its decision. Dkt. 58 at 8, 15–17 (Transcript of Hearing). Rather, the FDA explained, once the agency found documents sufficient to understand the basis for its application of the "fairly respond" standard in the comparator cases, it saw no need to dig deeper and to locate or to review other potentially relevant documents. *Id.* at 15–17 (Transcript of Hearing).

The FDA conceded at the hearing, however, that an agency is required to include in the administrative record not only those materials that it "directly" considered, but also those that it "indirectly considered," and it further acknowledged that documents "that elucidate and explain the documents that were [directly] considered" fall into the latter category when necessary to understand the documents that were directly considered. Dkt. 58 at 39 (Transcript of Hearing). The FDA thus offered that, if "there [were] specific instances where [Amgen were to] say ['L]ook, we don't understand what this phrase means['] or [that] something . . . needs to be explained," and Amgen could "explain how the record needs to be supplemented," it would be "open to hearing those arguments." *Id.* at 39–41 (Transcript of Hearing). The Court,

accordingly, ordered that the parties meet and confer regarding whether the administrative record should be supplemented regarding the eight comparators. Minute Order (Sept. 20, 2017). The Court explained that the parties should discuss whether any of the documents that Amgen seeks to add to the administrative record "are necessary to discern the meaning of specific, material references contained in the [a]dministrative [r]ecord," and further ordered that, if necessary, the parties file a joint status report with the Court describing any unresolved requests on specific documents. *Id.*

In response to the Court's Order, Amgen narrowed its request to twenty-five documents, all of which the FDA declined to add to the record. *See* Dkt. 53 at 2. The parties submitted a joint status report setting forth their respective positions on whether each document was necessary to make sense of "specific, material references" in the record. *See* Dkt. 53-2. Given the expedited briefing schedule, the Court issued a minute order on October 11, 2017, resolving this dispute and explaining that the Court would issue a subsequent opinion setting forth the reasons for the Court's decision.[1]

B. Facts Relevant to Amneal and Watson's Motions To Intervene

Meanwhile, Teva Pharmaceuticals USA, Inc. ("Teva"), Barr Laboratories, Inc., and Watson filed an unopposed, joint motion to intervene in this matter as defendants pursuant to Rule 24. Dkt. 26; *see* Fed. R. Civ. P. 24. All three companies are indirectly owned by Teva Pharmaceuticals Industries Ltd., a publicly traded corporation. Dkt. 26-2 at 1. The proposed intervenors noted that FDA had already "granted tentative approval" to Teva's and Barr's ANDAs, allowing them to market generic versions of Sensipar in the future. Dkt. 26-1 at 8. The

[1] In light of the Court's minute order, Amgen's renewed motion to supplement the administrative record, Dkt. 59, is **DENIED** as moot.

proposed intervenors further noted that Watson's ANDA was "under active review." *Id.* at 8. The Court granted the motion to intervene. Minute Order (Aug. 15, 2017).

Shortly after the Court granted that motion, Amneal filed an unopposed motion to intervene as a defendant. Dkt. 33. Amneal noted that, although its ANDA had "not yet received tentative approval," the application was currently under review and that "recent activity by [the] FDA indicates that approval will be granted, at the latest, by March 8, 2018," when Amgen's patent is currently due to expire. *Id.* at 9. Amneal also asserted that its interest in this litigation was "no different from" Watson's. *Id.* at 8.

In response to Amneal's motion, the Court entered an Order highlighting its independent duty to satisfy itself that it has jurisdiction. Dkt. 37 at 1. The Court further noted, moreover, that (1) the Supreme Court has recently suggested that a separate showing of Article III standing might not be required when a proposed intervenor seeks the same relief sought by a party with standing; (2) existing D.C. Circuit precedent, however, expressly requires that a party seeking to intervene as of right have Article III standing; and (3) the D.C. Circuit has reserved on the question whether a party moving for permissive intervention must demonstrate an independent basis of Article III standing. *Id.* at 2. The Court, accordingly, ordered that both Amneal and Watson "submit evidence" demonstrating that tentative approval of their ANDAs was "more than merely speculative." *Id.* at 3. Amneal and Watson, in response, filed supplemental memoranda and declarations in support of intervention. *See* Dkt. 44-1 (Amneal's redacted supplemental memorandum); Dkt. 49 (Watson's redacted supplemental memorandum). Although invited to address the jurisdictional issue, FDA continues to "take no position" on Amneal and Watson's motions to intervene. Dkt. 56 at 1.

II. ANALYSIS

A. Amgen's Motion To Supplement the Administrative Record

In the usual course, judicial review under the APA is "based on the full administrative record that was before the [agency] at the time [it] made [its] decision." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971). Indeed, this limitation is inherent in the very nature of judicial review: "To review more than the information before the [agency decision-maker] at the time she made her decision" opens the door to "post hoc rationalizations," *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984), to consideration of facts and arguments that were not presented to the decision-maker, *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1297–98 (D.C. Cir. 2004), and to the Court substituting its judgment for that of the agency, *see Citizens to Preserve Overton Park, Inc.*, 401 U.S. at 416. Two qualifications, however, temper this rule.

First, as the FDA concedes, "[t]he 'whole' administrative record . . . [consists of] 'all documents and materials directly *or indirectly* considered by agency decision-makers and include[es] evidence contrary to the agency's position.'" *Holy Land Found. for Relief & Dev. v. Ashcroft*, 219 F. Supp. 2d 57, 65 (D.D.C. 2002) (quoting *Thompson v. Dep't of Labor*, 885 F.2d 551, 555 (9th Cir. 1989)) (emphasis added); *see also Dist. Hosp. Partners, L.P., v. Sebelius*, 971 F. Supp. 2d 15, 20 (D.D.C. 2013); *Stainback v. Sec'y of the Navy*, 520 F. Supp. 2d 181, 185 (D.D.C. 1989). Although it is not entirely clear what it means to *indirectly* consider documents or materials, for present purposes the parties agree that this concept captures materials that are necessary to understand the documents that the agency *directly* relied upon. Dkt. 58 at 37–40. Second, the D.C. Circuit has held that a district court should permit supplementation of the administrative record if the moving party "can demonstrate unusual circumstances justifying

departure from th[e] general rule." *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1002 (D.C. Cir. 2008). The Court of Appeals has identified three such "unusual circumstances":

> (1) the agency deliberately or negligently excluded documents that may have been adverse to its decision; (2) the district court needed to supplement the record with "background information" in order to determine whether the agency considered all of the relevant factors; or (3) the agency failed to explain administrative action so as to frustrate judicial review.

Id. (internal quotation marks, citations, and alterations omitted); *see also Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 55 (D.C. Cir. 2015).

Applying these standards, the Court concludes that Amgen has failed to carry its burden of rebutting the "strong presumption" that the agency "properly designated the administrative record." *Dist. Hosp. Partners, L.P.*, 971 F. Supp. 2d at 20 (internal quotation marks and citation omitted). Amgen contends that the twenty-five documents that it seeks to add to the administrative record were "indirectly" considered because they are "necessary to discern the meaning of specific, material statements in the [a]dmnistrative [r]ecord about the basis for the exclusivity determinations [the] FDA has cited as examples of 'consistent' application of its otherwise unpublished interpretation of the statutory 'fairly responds' standard." Dkt. 53 at 2. As Amgen further explains, six of the documents it seeks to add to the record—the annotated written requests for six drugs—are "necessary to explain [the] FDA's unsubstantiated conclusions in the Sensipar dispute resolution document that each of the . . . comparat[or] drug sponsors either did or did not 'meet the terms' of their [w]ritten [r]equest, and if not, the reasons that it failed to do so." *Id.* at 3. It seeks to add thirteen more documents—the Pediatric Exclusivity Board minutes and pediatric exclusivity checklists for several drugs—on a similar theory, explaining that the documents would likely disclose "whether the requested studies" for those drugs "provided data sufficient for an indication or dosing" label amendment and "whether

the sponsor 'fairly respond[ed]' to the written request." *Id.* at 5 (internal quotation marks omitted). And, finally, Amgen seeks to add six documents—the clinical reviews and summary reviews for three drugs—to understand "whether the . . . comparator drugs' studies produced 'meaningful labeling.'" *Id.* at 7.

As an initial matter, the Court notes that, for most of these comparator drugs, it was not the FDA, but Amgen, that placed the comparisons in issue. As to one of the drugs, it is true, the FDA pointed to a letter or memorandum during the TRO proceeding to rebut Amgen's contention that the FDA had not previously articulated the standard that it applied in this case. Dkt. 58 at 7 (Transcript of Hearing); *see* Dkt. 18 at 67–68 (Transcript of TRO Hearing). And, as to another drug, both parties pointed to an earlier decision from this Court regarding the relevant standard. For the most part, however, it is Amgen that has raised the question whether the FDA has consistently applied that standard, and Amgen submitted evidence on this question to the FDA in an effort to substantiate its claim of inconsistent treatment. The FDA, in turn, has relied on and produced agency records that it contends rebut Amgen's contention and show that, in fact, it has acted in a consistent manner.

Amgen is free to argue that the existing record fails to provide adequate support for that conclusion. What Amgen seeks to do now, however, goes beyond that, and, in essence, amounts to a request for discovery in an APA case in the hopes of finding some inconsistency. The twenty-five excluded documents are not needed to explain the meaning of the documents the FDA actually considered or to understand or to elucidate the agency's Sensipar decision. Instead, Amgen seeks the documents in order to test the FDA's conclusion that no inconsistency exists between its Sensipar decision and its earlier decisions; that is, it hopes to disprove the FDA's conclusion with documents that the agency did not consider, that were not otherwise

before the relevant decision-makers, and that Amgen itself has never seen because they are not publicly available. Under these circumstances, it is a stretch too far to contend that the FDA "indirectly considered" these documents in rendering its decision. Indeed, if the present facts satisfy the "indirectly considered" standard, it is difficult to discern what, if anything, would prevent APA litigants from obtaining what can only fairly be considered discovery in virtually any APA case in which the plaintiff asserts that the agency has applied the governing standard in an inconsistent manner.

Nor has Amgen carried its burden of showing that supplementation is justified by "unusual circumstances." First, there is no evidence that the FDA "deliberately or negligently excluded documents that may have been adverse to its decision," *Kempthorne*, 530 F.3d at 1002 (citation omitted); rather, as required, the FDA included only those documents that were directly or indirectly considered by agency decision-makers. Second, at least on the present record, the Court is not convinced that it needs additional "background information in order to determine whether the [FDA] considered all of the relevant factors" in deciding whether to grant Amgen pediatric exclusivity. *Id.* (citation omitted). Again, Amgen is free to argue that the administrative record does not support the FDA's decision or that the agency's failure to consider certain documents was, itself, arbitrary and capricious. Amgen does not need the twenty-five documents, however, to address whether the FDA failed to consider relevant factors. Finally, the FDA has not "failed to explain [its decision] so as to frustrate judicial review." *Id.* (citation omitted). The agency has already produced all the materials on which it directly or indirectly relied in denying Amgen pediatric exclusivity; nothing more was required to permit the Court to determine whether that decision comports with the APA. *See Camp v. Pitts*, 411 U.S. 138, 140–43 (1973).

For these reasons, the Court has **DENIED** Amgen's motion to complete or supplement the Administrative Record, Dkt. 38.

B. Amneal and Watson's Motions To Intervene

Under controlling D.C. Circuit precedent, a movant seeking to intervene as of right pursuant to Rule 24(a) must possess Article III standing. *See Roeder v. Islamic Republic of Iran*, 333 F.3d 228, 233–34 (D.C. Cir. 2003); *Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 731–32 (D.C. Cir. 2003). Article III, in turn, requires that the movant demonstrate that an unfavorable decision would cause it to suffer an injury in fact that is "actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016) (quoting *Lujan*, 504 U.S. at 560); *see Fund for Animals*, 322 F.3d at 733.

Amneal and Watson argue that tentative approval of their ANDAs is not a prerequisite to standing. *See* Dkt. 44-1 at 10; Dkt. 49 at 3–5. The Court agrees that tentative approval is not a *sine qua non* for standing. Rather, Article III requires a case-by-case assessment of whether the proposed intervenor can "demonstrate a substantial probability that [it] will be injured" if not afforded the relief sought. *Nat. Res. Def. Council v. EPA*, 464 F.3d 1, 6 (D.C. Cir. 2006) (internal quotation marks omitted). If Amgen prevails in this action, the earliest possible date on which Amneal and Watson will be able to begin marketing generic versions of Sensipar will be delayed by six months. That delay, however, will make a difference only if Amneal and Watson's ANDAs would otherwise be approved before the expiration of that six-month period. The "principal question," therefore, is whether Amneal and Watson have established a "substantial" probability that their ANDAs will receive tentative or final approval before that six-month period would expire. *Attias v. Carefirst, Inc.*, 865 F.3d 620, 626 (D.C. Cir. 2017).

Amneal asserts that tentative approval of its ANDA is "imminent" and "contingent only upon" a successful reinspection of the facility where its contractor will manufacture the active ingredient in Sensipar. Dkt. 44-1 at 5–6. In support of this contention, Amneal proffers the declaration of Candis Edwards, Amneal's Senior Vice President for Regulatory Affairs. *Id.* at 14 (Edwards Decl. ¶ 2). According to Edwards, the site in question is "ready for re-inspection," and Amneal expects "an FDA approval action by March 2018." *Id.* at 17 (Edwards Decl. ¶¶ 11–12).

Watson, too, argues that "FDA approval of Watson's ANDA" is "likely to occur soon, and certainly in time for this litigation to affect Watson's legal and commercial interests." Dkt. 49 at 6. Watson has also submitted a declaration from its parent company's Vice President for Regulatory Affairs, Scott Tomsky. Dkt. 49-1 (Tomsky Decl.). After describing the current status of Watson's efforts to secure tentative approval, Tomsky attests that "FDA is likely to approve (on a tentative or final basis) Watson's ANDA on or before March 8, 2018." *Id.* at 3 (Tomsky Decl. ¶ 9).

The FDA has not taken a position on whether either Amneal or Watson has accurately predicted that their ANDAs will receive tentative approval in the near future, nor would the Court expect the agency to announce its likely decision before completing the required process. Although not surprising, that leaves an uncontested factual record in which Amneal and Watson have produced credible evidence that they are likely to obtain tentative approval before long. Under these circumstances, the Court finds that both companies have carried their burden of establishing that they have Article III standing.

At the same time, however, the Court recognizes that the predictions of both companies are nothing more than that—predictions of what is likely to happen. It is not unusual, moreover, for predictions of this type to evolve based on factual and regulatory developments. The Court

will, accordingly, condition Amneal and Watson's intervention on their obligation to keep the Court informed of any significant developments that may have material bearing on the likelihood that their ANDAs will receive tentative approval in the near future.[2] If, for example, the reinspection of the facility where Amneal's contractor will manufacture the active ingredient in its version of Sensipar were not to go as expected, Amneal should so inform the Court.

On the present record, however, the Court is satisfied that Amneal and Watson are likely to receive tentative or final approval for their ANDAs before the period of pediatric exclusivity that Amgen seeks in this case would expire, and, on that basis, the Court concludes that both companies have Article III standing to intervene. Their motions, moreover, are unopposed. The Court, accordingly, hereby **GRANTS** Amneal's motion to intervene as of right, Dkt. 26, and confirms its prior decision granting Watson leave to intervene as of right, Minute Order (Aug. 15, 2017), subject to the condition described above.

SO ORDERED.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: October 24, 2017

[2] Amneal and Watson may seek leave to file any such update containing confidential information under seal.