IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: THE APPLICATION OF AMGEN INC.	)	Civil Action No. 24-59-CJB
		REDACTED VERSION

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MEMORANDUM OPINION

May 22, 2025
Wilmington, Delaware

Christopher J. Burke
BURKE, United States Magistrate Judge

Presently pending before the Court is Petitioner Amgen Inc.'s ("Amgen") Second Application Pursuant to 28 U.S.C. § 1782 for an Order Authorizing Discovery for Use in a Foreign Proceeding ("Application"). (D.I. 2) The Application is opposed by Respondent Sandoz, Inc. ("Sandoz"). (D.I. 22) For the reasons set forth below, the Court HEREBY ORDERS that the remaining unresolved portions of Amgen's Application are DENIED for the reasons set forth below.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. Relevant Entities

Amgen sells the biologic drug products Prolia® and XGEVA®, which are used to treat a variety of bone conditions, and which contain the active ingredient denosumab. (D.I. 4 at 3) Sandoz is a U.S.-based commercial organization that is a part of the Sandoz Group AG list of companies. (D.I. 5, ex. 12 at 2; D.I. 22 at 3)

In February 2023, Sandoz announced that the United States Food and Drug Administration ("FDA") had accepted Sandoz's biologics license application ("BLA"), which sought authorization to make, use or sell denosumab biosimilars in the United States. (D.I. 5, ex. 6) In connection with Sandoz's FDA submission, Amgen and Sandoz engaged in an exchange of information pursuant to the Biologics Price Competition and Innovation Act ("BPCIA"); this process eventually led to Amgen filing a patent infringement suit against Sandoz in the United States District Court for the District of New Jersey. In that suit, Amgen asserted various of its patents, including United States Patent No. 11,098,079. (D.I. 4 at 4-5); *see also Amgen Inc v.*

Sandoz Inc., Civil Action No. 2:23-cv-02406, D.I. 1 (D.N.J. May 1, 2023) (the "BPCIA Proceeding").[1]

The Application relates to an effort by Amgen to seek discovery that it wished to use in then-anticipated preliminary injunction proceedings in Austria and Slovenia that Amgen intended to file against Sandoz GmbH and Lek Pharmaceuticals d.d. ("Lek"), respectively. (D.I. 4 at 1, 7-8) Pursuant to the Application, Amgen sought discovery not only in the physical possession of Sandoz, but also discovery that was in the physical possession of three other entities: Sandoz GmbH, Lek, and Novartis AG ("Novartis").

Sandoz GmbH and Lek are sister entities to Sandoz; all three companies are indirect subsidiaries of Sandoz Group AG. (D.I. 5, ex. 12 at 2) As for Novartis, prior to October 4, 2023, Sandoz Group AG had been its subsidiary and had served as Novartis' generic pharmaceutical and biosimilar division; on that date, Novartis spun off Sandoz Group AG (and, relatedly, its subsidiaries Sandoz, Sandoz GmbH and Lek) as a separate corporate organization (hereafter, the "spin-off"). (*Id.*, ex. 13; *see also* D.I. 4 at 6 n.11; D.I. 6 at ¶ 5) As part of the spin-off, Novartis and Sandoz Group AG [redacted]. (D.I. 22 at 4; D.I. 37, ex. C)

Following the spin-off, certain Novartis entities [redacted]: Novartis farmacevtksa proizvodnja d.o.o. (registered English name: Novartis Pharmaceutical Manufacturing LLC) in Slovenia and

[1] The BPCIA Proceeding was terminated in May 2024 pursuant to a stipulated order of dismissal and injunction. (*See* D.I. 62)

Novartis Pharmaceutical Manufacturing GmbH in Austria. (D.I. 79 at ¶ 5) [redacted]. (*Id.*)

B. The First Application

In May 2023, Amgen filed a first application (the "first application") seeking certain discovery from Sandoz for the anticipated European preliminary injunction proceedings; in September 2023, Chief United States District Judge Colm F. Connolly granted that application. *In Re: The Application of Amgen Inc.*, Civil Action No. 23-mc-258-CFC-CJB, D.I. 33 (D. Del. Sept. 26, 2023). In doing so, Chief Judge Connolly found that Amgen had "good reason to believe that Sandoz [was] about to engage or at least assist in the manufacture of a generic denosumab [biosimilar] in Austria and Slovenia." *Id.* at 9. Thereafter, Sandoz produced over 250,000 pages of documents in response to Amgen's requests that were part of the first application. (D.I. 37 at ¶ 6)

C. The Instant Litigation

Amgen filed the instant case on January 17, 2024. (D.I. 1) The case was referred to the Court to conduct all proceedings and determine all motions on January 25, 2024. On February 16, 2024, the parties consented to the Court's jurisdiction to conduct all proceedings in this matter. (D.I. 30)

The instant Application relates to two subpoenas that Amgen served on Sandoz; in these subpoenas, Amgen sought additional forms of discovery regarding Sandoz's denosumab

biosimilars, as well as in-line product samples relating thereto. (D.I. 5, exs. A-B)[2] At the time of the filing of the instant matter, Amgen believed that Sandoz GmbH and Lek, respectively, were and would be manufacturing a generic denosumab biosimilar for Sandoz, which Sandoz, in turn, planned to market in the United States and elsewhere. (D.I. 4 at 5-6, 19)[3] Amgen also believed that this foreign manufacturing would infringe at least its European Patent No. 3 334 747 B1 ("EP 747"), which issued in September 2023, the day after Chief Judge Connolly granted Amgen's first application. (*Id.* at 2, 6; D.I. 22 at 8) Amgen stated that it was then prepared to institute the above-referenced preliminary injunction proceedings in Austria (against Sandoz GmbH) and Slovenia (against Lek) in order to enforce EP 747. (D.I. 4 at 2, 7-8)[4] Through the subpoenas, Amgen was seeking to secure documentation that it might use in those or related proceedings. (*Id.* at 8)

Briefing on the Application was completed on February 16, 2024. (D.I. 31) On March 13, 2024, the Court held a hearing, during which it heard oral argument on the Application via videoconference. (D.I. 39 (hereafter "Tr.")) During the hearing, the parties agreed that there were four categories of documents at issue regarding the Application:

- Regulatory documents in the possession of Sandoz.
- Non-regulatory documents in the possession of Sandoz.

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[2] The first of the two subpoenas contained five document requests that are at issue, while the second subpoena seeks deposition testimony regarding six topics (topics that largely correspond to the document requests at issue in the first subpoena). (D.I. 5, exs. A-B)

[3] In May 2024, Sandoz publicly announced that it planned to commercially launch its denosumab biosimilar products on the European market in November 2025. (D.I. 62; D.I. 79 at ¶ 2 & ex. 1)

[4] As it turns out, Amgen never did seek the contemplated preliminary injunctions. (*See* D.I. 78 at 1; D.I. 84 at 1)

- Documents in the possession of Novartis.
- Documents in the possession of Sandoz GmbH and Lek.

(*Id.* at 10-14)[5]

At the end of the hearing, the Court ruled on part of the Application. It granted the Application as to Amgen's request for responsive regulatory and non-regulatory documents in the possession of Sandoz (i.e., as to the first two categories listed above)—except to the extent that production of such documents would violate a protective order issued in the BPCIA Proceeding. (*Id.* at 101-03)[6]

The Court also took under advisement the Application's request for the final two categories of documents listed above (i.e., as to documents in the possession of Novartis, and

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[5] To the extent that the subpoenas at issue request information other than documents, the Court means to include those items in its summary here of the sought-after materials; it simply uses "documents" for convenience, since most of the materials at issue are documentary in nature. (Tr. at 14-15)

Additionally, the Court notes that one of the requests in the first subpoena asks for [redacted] (D.I. 5, ex. A at ¶ 5) Sandoz represents that [redacted]). (D.I. 22 at 16; Tr. at 66) Amgen disagrees with that assertion. (D.I. 31 at 10) The Court need not separately address this dispute, because to the extent that [redacted]. (Tr. at 66-67) And in light of the Court's resolution, set out below, such samples need not be produced here.

[6] After the hearing, the parties raised a further dispute regarding the first two categories of documents. (D.I. 40) More specifically, Amgen requested that Sandoz be ordered to produce documents that Sandoz had received in the BPCIA Proceeding from Novartis, which had been designated "CONFIDENTIAL Discovery Material" pursuant to the Protective Order in effect in that proceeding. (*Id.* at 1) For the reasons set out by Sandoz, (*id.*), the Court DENIES that request. Any contrary order would be in direct contravention of the agreements made by the parties to that Protective Order. (*Id.*, ex. A at ¶ 26) And if any such order were ever to be justified, it should come from the Court that entered the Protective Order, not this Court. (D.I. 40 at 1 (citing cases))

those in the possession of Sandoz GmbH and Lek). (*Id.* at 103) Understanding that the need for a prompt decision on those issues might "depend on events that occur in the future" (i.e., on the status of then-anticipated foreign litigation or of future drug development efforts), the Court advised Amgen to inform it if further developments required "quicker action" on these remaining disputes. (*Id.* at 101) The Court did not hear from Amgen further in that regard.

The Court thereafter received various notices of subsequent developments from the parties. (D.I. 36; D.I. 44; D.I. 62; D.I. 63) It also has resolved two protective order/discovery dispute motions related to this matter. (D.I. 64; D.I. 92)

On January 31, 2025, Amgen filed a patent infringement suit against Sandoz GmbH in the Commercial Court Vienna in Austria in which it alleges infringement of EP 747. (D.I. 79 at ¶ 4; D.I. 87 at 2; Civil Action No. 23-mc-258-CFC-CJB, D.I. 76 at 3) That Austrian action relies in part on confidential materials produced in response to the first application and on materials produced in response to the instant Application. (D.I. 79 at ¶ 4; Civil Action No. 23-mc-258-CFC-CJB, D.I. 76 at 3) Amgen also reports that it plans to file further related European patent litigation in the near future. (D.I. 92)[7]

II. STANDARD OF REVIEW

Under 28 U.S.C. § 1782 ("Section 1782"), "[t]he district court of the district in which a person resides or is found may order him to give his testimony or statement or to produce a

[7] On March 21, 2024, Amgen had also filed suit in the Commercial Court in Vienna, Austria seeking a preliminary injunction to enjoin Sandoz GmbH from importing, commercially manufacturing, or exporting its denosumab biosimilar products or pharmaceutical compositions containing denosumab. (D.I. 44 at 1) That lawsuit was related to Sandoz's reliance on a European Regulation known as the SPC Manufacturing Waiver; Amgen asserted that the suit was unrelated to the contemplated litigations identified in this proceeding, and Amgen later withdrew this preliminary injunction request from the Austrian court. (D.I. 62 at 1-2)

document or other thing for use in a proceeding in a foreign or international tribunal. . . . The order may be made . . . upon the application of any interested person[.]" 28 U.S.C. § 1782(a). The aim of the statute is to "facilitate the conduct of litigation in foreign tribunals, improve international cooperation in litigation, and put the United States into the leadership position among world nations in this respect." *In re Bayer AG*, 146 F.3d 188, 191-92 (3d Cir. 1998).

For a court to compel discovery sought under Section 1782, the applicant must first demonstrate that three statutory requirements are met: (1) the party from whom discovery is sought must reside in or be found in the district; (2) the discovery must be "for use in a proceeding before a foreign or international tribunal[;]" and (3) the application must be made, *inter alia*, by an "interested person." *See* 28 U.S.C. § 1782(a); *In re Ex Parte Application of Eni S.p.A.*, No. 20-mc-334-MN, 2021 WL 1063390, at *2 (D. Del. Mar. 19, 2021); *see also In re Bayer*, 146 F.3d at 193. If a Court finds that the statutory factors have been met, then it has discretion to grant the application. *In re Application of Gilead Pharmasset LLC*, C.A. No. 14-mc-243 (GMS), 2015 WL 1903957, at *2 (D. Del. Apr. 14, 2015).

In determining how to exercise that discretion, courts look to four factors set forth by the Supreme Court of the United States in *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241 (2004): (1) whether "the person from whom discovery is sought is a participant in the foreign proceeding[;]" (2) "the nature of the foreign tribunal, the character of the foreign proceedings underway abroad, and the receptivity of the foreign government or the court or agency abroad to U.S. federal-court judicial assistance[;]" (3) whether the "request conceals an attempt to circumvent foreign proof-gathering restrictions or other policies of a foreign country or the United States[;]" and (4) whether the request is "unduly intrusive or burdensome[.]" 542 U.S. at 264-65; *see also Eni S.p.A.*, 2021 WL 1063390, at *2. These are known as the *Intel* factors.

III. DISCUSSION

There is no dispute that in filing its Application, Amgen has met the three Section 1782 statutory factors. (Tr. at 13-14; D.I. 31 at 1) And in opposing the Application here, Sandoz is not making an argument that, as to the first three discretionary *Intel* factors, Amgen's Application is wanting. (Tr. at 12-13; D.I. 31 at 1)

Instead, with regard to the two categories of responsive documents remaining in dispute, Sandoz puts at issue the fourth *Intel* factor. (D.I. 22 at 7) To that end, Sandoz asserts that in light of the spin-off, neither Sandoz GmbH or Lek are likely to have any of the remaining documents responsive to the Application, and that those documents will be [redacted] (*Id.* at 1, 3, 6, 12 (emphasis omitted)) And Sandoz's position is that requests for any such documents are unduly intrusive or burdensome, since the documents are not in Sandoz's physical possession or custody—nor are they in Sandoz's "control" pursuant to the meaning of Federal Rule of Civil Procedure 34(a)(1). (*Id.*)

Section 1782 says that unless "prescribe[d] otherwise" the "practice and procedure" by which a document is produced under the statute shall be "in accordance with the Federal Rules of Civil Procedure." 28 U.S.C. § 1782(a). Rule 34, in turn, governs the issuance of subpoenas in federal civil proceedings, and it states that a party may serve on another party a request to produce items that are in the receiving party's "possession, custody, or control[.]" Fed. R. Civ. P. 34(a)(1). The parties agree that for Amgen's remaining requests at issue to be granted, there would need to be a showing that Rule 34's requirements have been satisfied. Here, that means demonstrating that the remaining disputed categories of documents are in Sandoz's "control." If Sandoz does not have control over the documents at issue, then the Court's "[Section] 1782 analysis need go no further." *In re Boustany*, 23 Misc. 203 (LGS), 2024 WL 473569, at *2

(S.D.N.Y. Feb. 7, 2024); *see also In re FourWorld Event Opportunities Fund, L.P.*, No. 22-MC-330 (JPO), 2023 WL 3375140, at *1 (S.D.N.Y. May 11, 2023).

So who bears the burden of proof to demonstrate whether or not these documents are in Sandoz's control? In the Court's view, this is Amgen's burden to bear. This issue is a little confusing, because typically, the party resisting production (here, that is Sandoz) bears the burden of proof to demonstrate that, as to relevant evidence, certain facts warrant the denial of the Section 1782 application at issue. *In re Chevron Corp.*, 633 F.3d 153, 162 (3d Cir. 2011); *In re Selman*, Civil Action No. 23-895-CJB, 2024 WL 1092025, at *2 (D. Del. Mar. 13, 2024). Yet in the instant scenario, it makes sense that Amgen, not Sandoz, carries the burden. This is because, as noted above, Section 1782's text emphasizes the importance of following the Federal Rules of Civil Procedure when producing documents pursuant to the statute. Moreover, in this case, as noted above, the resolution of the parties' dispute as to the fourth *Intel* factor will turn on an analysis of Rule 34's "control" requirement. And when courts assess a Rule 34 "control" question, they do so by placing the burden of proof on the *party seeking production* of the documents—here, Amgen. *See, e.g.*, *Princeton Digit. Image Corp. v. Konami Digit. Ent. Inc.*, 316 F.R.D. 89, 90 (D. Del. 2016); *Playboy Ent. Grp., Inc. v. United States*, No. CIV. A. 96-94-JJF, 1997 WL 873550, at *3 (D. Del. Dec. 11, 1997); *see also* (Tr. at 85-88). Indeed, other courts evaluating a Rule 34 "control" issue in the context of Section 1782 litigation have come to the very same conclusion. *See, e.g.*, *In re Boustany*, 2024 WL 473569, at *2; *Doe Run Peru S.R.L. v. Trafigura AG*, No. 3:11mc77 (SRU), 2011 WL 13059042, at *1 (D. Conn. Aug. 24, 2011).

Amgen argues that it has met its burden to demonstrate "control" here. The Court will first analyze its showing as to Novartis. Then it will assess the issue as it relates to Sandoz GmbH and Lek.

A. Novartis

The Court first addresses the Application to the extent it seeks documents in the possession of Novartis.

In its opening brief, Amgen did not specifically seek any documents from Sandoz that were in Novartis' physical possession. (*See generally* D.I. 4) Indeed, Novartis was barely mentioned in that brief. Instead, other than seeking documents in Sandoz's own physical possession, Amgen only otherwise argued that it should be permitted to obtain documents that were in the physical possession of Sandoz GmbH and Lek. (*Id*. at 18-20) Amgen explained that the reason why Sandoz GmbH and Lek might have such relevant documents in their possession, custody or control was that those entities were the ones that ran denosumab manufacturing facilities in Austria and Slovenia, respectively—the facilities that, in turn, were expected to make and provide the drug product at issue to Sandoz for future distribution. (*Id*. at 6-7, 18-20)

However, when Sandoz filed its answering brief, it provided evidence that as of the time of the spin-off in Fall 2023, [redacted] (D.I. 22 at 10 [redacted]); *see also* D.I. 37, ex. B at SDZDENO1782-00108916-19 (August 2023 document titled [redacted]

[redacted] which indicates that [redacted]; the document also states that it is meant to reflect [redacted])[8] As a result, Sandoz argued, "[redacted] (D.I. 22 at 10; *see also* Tr. at 70-71) And in its reply brief, Amgen appeared to acknowledge that this evidence shows that, as of the January 2024 date that this proceeding was instituted: [redacted] (D.I. 31 at 4-5 (Amgen acknowledging that this evidence demonstrates [redacted] (citing D.I. 32, ex. 25 at 26 & ex. 26 at 146)))

In light of this, how could Amgen argue that as of the relevant date, Sandoz had "control" over any responsive documents in Novartis' possession? After all, at that point, Novartis was no longer Sandoz's corporate affiliate; it was simply a separate, independent corporate entity. (D.I. 22 at 10-11) And when it comes to adjudicating disputes over "control" for purposes of the Federal Rules of Civil Procedure (and otherwise), federal courts generally respect the corporate

[8] [redacted] (*See supra* at 3-4; D.I. 37, ex. B at SDZDENO1782-00108917-19) Neither party has suggested that this fact should impact the decision here, (Tr. at 68-69), and so the Court will simply refer to these as [redacted]

form. *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc*., 233 F.R.D. 143, 145 (D. Del. 2005) (noting that "separate and distinct corporate identities" are "not readily disregarded" in the "control" inquiry); *cf. ECB USA, Inc. v. Savencia, S.A*., Civil Action No. 19-731-GBW-CJB, 2024 WL 406437, at *5 (D. Del. Jan. 31, 2024) (citing *Harrison v. Soroof Int'l, Inc*., 320 F. Supp. 3d 602, 614 (D. Del. 2018)).

On this score, Amgen's argument was that Sandoz has control over any responsive documents in Novartis' physical possession because Sandoz has the "legal right or ability to obtain the documents from [Novartis] upon demand[.]" (D.I. 31 at 6 (quoting *Mercy Cath. Med. Ctr. v. Thompson*, 380 F.3d 142, 160 (3d Cir. 2004))); *see also Gerling Int'l Ins. Co. v. Comm'r*, 839 F.2d 131, 140 (3d Cir. 1988).[9] But Amgen did not meet its burden to demonstrate that this is so.

Indeed, it was Sandoz that produced evidence as to this issue, and that evidence indicates the opposite—i.e., that it does not have the legal right or ability to obtain the documents at issue from Novartis upon demand. In part, Sandoz did this by (as is set out above) providing evidence indicating that any documents at issue are now in Novartis' physical possession—and not in the physical possession of Sandoz.

But additionally, Sandoz cites in support to [redacted]. As to [redacted], Sandoz argued as

[9] As noted above, pursuant to the caselaw of the United States Court of Appeals for the Third Circuit, a party in Sandoz's position here must be shown to have the "legal right or ability" to obtain the documents in question from the third party "upon demand"—it is not sufficient for Amgen to demonstrate that Sandoz has the "practical ability" to obtain the documents. *See Cradle IP LLC v. Texas Instruments, Inc.*, Civ. No. 11-1254-SLR, 2013 WL 1794992, at *1 (D. Del. Apr. 29, 2013); *Inline Connection Corp. v. AOL Time Warner Inc.*, No. C A 02-272-MPT, C A 02-477-MPT, 2006 WL 2864586, at *2 (D. Del. Oct. 5, 2006); *Power Integrations*, 233 F.R.D. at 146.

follows: (1) [redacted] (2) [redacted] (3) [redacted] and (4) [redacted]

(D.I. 37, ex. C at 6, 39-40, 43 (emphasis added); *see also* D.I. 22 at 11; Tr. at 80-81) Because it is undisputed that Amgen seeks the information at issue here from Sandoz via civil subpoenas (and not, for example, via requests for production in a traditional civil litigation), Sandoz argues that [redacted]. Indeed, Sandoz's attorneys proffered during oral argument that since the spin-off, when they have sought documents in Novartis' possession, they have had to negotiate such requests with Novartis' legal team and abide by the conditions set out in [redacted]. (Tr. at 75-76, 82-83)

Amgen made three primary arguments in opposition to Sandoz's position, but none were availing.

First, Amgen disputed Sandoz's reading of [redacted].[10] But as Sandoz argued (above), [redacted]

[10] At the time of the hearing in this case, Sandoz had only produced a portion of [redacted], and Amgen was arguing that this should cause the Court to be skeptical of Sandoz's arguments about [redacted]. (D.I. 31 at 7, 9; Tr. at 48-49) But after the hearing, Sandoz produced a full copy of [redacted] for the Court. (D.I. 37, ex. C)

[redacted]—like the requests at issue here. (D.I. 37, ex. C at 43) In its reply brief, in attempting to push back on this conclusion, Amgen said only that [redacted] and that it [redacted] (D.I. 31 at 8) Yet it appears to the Court that [redacted]. And regardless of whether Novartis [redacted] the issue here is whether *Sandoz* has a *legal right* to *force Novartis* to produce documents to it on demand. It is not "preposterous" to the Court that no such right might exist as to third-party subpoena requests served on Sandoz.[11]

Second, Amgen argued that although Sandoz claimed that [redacted]

[11] In a post-hearing letter, Amgen seemed to make other, different arguments about the definition of [redacted] (and why that term's definition did not hurt its position here). There, for the first time, Amgen suggested that: [redacted] (D.I. 40 at 2) Whatever the merit of these arguments (and the Court is not sure that there is merit to them), because Amgen had the ability to make them in its reply brief, but did not, it has forfeited the ability to raise them belatedly in this letter.

[redacted] (*Id.* (citations omitted)) But as noted above, it is Amgen that has the burden to demonstrate control. And the Court cannot conclude that Amgen has met that burden by making reference to documents that are not of record (or by speculating that something in them might help Amgen's case).

Third, Amgen noted that in producing discovery in response to the first application, Sandoz turned over [redacted] (*Id.* at 6; D.I. 32 at ¶ 12) Amgen argued that this demonstrates that even after the spin-off, Sandoz still has the legal right or ability to obtain Novartis documents upon demand. But during oral argument, Sandoz's counsel represented that all of the Novartis documents that Sandoz produced in response to the first application were documents that Sandoz obtained from Novartis prior to the spin-off—i.e., at a time when Novartis was still a Sandoz affiliate entity (and a time when [redacted] was not in effect). (Tr. at 72-76) The Court has no reason to disbelieve this assertion, and Amgen has not challenged it. Therefore—and unlike when Sandoz came into possession of the Novartis documents it produced in response to the first application—now: (1) Novartis is no longer an affiliated entity to Sandoz; and (2) [redacted]. Therefore, Amgen's argument about the discovery process regarding the first application is not helpful to its position.

For all of these reasons, the Court concludes that Amgen has not met its burden to demonstrate that any responsive documents in the physical possession of Novartis are in

Sandoz's "control" pursuant to Rule 34(a)(1). Therefore, the Court denies the Application in this regard.

B. Sandoz GmbH and Lek

Similarly, the Court also concludes that the Application should be denied to the extent that Amgen seeks responsive documents from Sandoz GmbH and Lek.

Although the relevant facts are a little murky and not well set out by either side, for purposes of the Application, it seems to be undisputed that Sandoz GmbH and Lek are [redacted] (D.I. 36 at 1 & ex. A; D.I. 79 at ¶ 5; D.I. 84) The Court therefore assumes *arguendo* that Sandoz GmbH and/or Lek could be said to retain possession, custody or control of certain responsive documents.

Thus, the issue here is: Under what theory can Amgen argue that *Sandoz* has "control" over those documents? In its briefing, Amgen invoked only one way to make this showing, which is drawn from the Third Circuit's decision in *Gerling Int'l Ins. Co. v. Comm'r*, 839 F.2d 131 (3d Cir. 1988): i.e., that it can demonstrate that "the litigating corporation had acted with its sister in effecting the transaction giving rise to suit and is litigating on its behalf[.]" *Gerling*, 839 F.2d at 141; *see also* (D.I. 4 at 19). But Amgen's Application must also be rejected in this regard.

To explain why, as an initial matter, the Court must first address what is the "suit" at issue and who is the "litigating corporation"? In their briefing and during the hearing, the parties had different and varying views on the answer to this question—with both at times suggesting that the "suit(s)" at issue could be considered to be the then-anticipated foreign preliminary

injunction proceedings in Europe. (D.I. 22 at 13; D.I. 31 at 10; Tr. at 25-30, 89-95) Upon reflection, however, the Court concludes that this cannot be correct, and that the relevant "suit" has to be *this civil action*—i.e., the one in which Amgen has filed the pending Application. For one thing, that is how the Third Circuit and this Court have looked at this issue and have applied this law in the past. *See Gerling*, 839 F.2d at 141 (considering the "suit" in question to be the U.S.-based litigation before the Court—i.e., the litigation in which a party was seeking documents in the possession of a non-party); *Princeton Digit. Image Corp.*, 316 F.R.D. at 93 (same). And that approach makes sense, in that *this* "suit" is the only actual, instituted "litigati[on]" in which the undersigned Judge has the authority and jurisdiction to issue any order regarding Amgen's ability to compel production of documents from Sandoz. It has to be *that* type of "suit" that *Gerling* was referring to—i.e., not some contemplated foreign proceeding that is not before the Court and that, at the time of the filing of the Application, hadn't even been instituted.[12]

From there, the Court concludes that Amgen has not made a sufficient showing that Sandoz is "litigating on [] behalf" of Sandoz GmbH or Lek in this "suit." (Tr. at 93-94) The relevant caselaw makes clear that to demonstrate that this is occurring, the movant must show that the non-party sister corporation is playing some role in directing the course of this litigation, or is making important strategic decisions impacting this litigation, or is already participating in the litigation as if it were a party (or the like). *See, e.g.*, *Gerling*, 839 F.2d at 141 (noting that a corporation is "litigating on [] behalf" of its sister corporation where "the sister possessing the

[12] The Court acknowledges that this Section 1782 action is a different type of "suit" than the typical form of civil litigation in a federal district court. But even if the "suit" in question were considered to be any instituted or contemplated foreign patent litigation proceeding, the result of the Court's "control" analysis below would not differ.

documents had assisted its sibling in litigating the case") (citing *Alimenta (U.S.A.), Inc. v. Anheuser–Busch Companies*, 99 F.R.D. 309, 313 (N.D. Ga. 1983)); *see also Alimenta (U.S.A.), Inc.*, 99 F.R.D. at 313 (concluding that the defendant had established that the plaintiff (Alimenta USA) was a sister corporation of Alimenta BV, and that it was litigating on behalf of Alimenta BV, where counsel for the plaintiff had actively participated in various aspects of discovery in the instant case along with Alimenta BV representatives, and where there was other evidence that the plaintiff had "acted with and for" Alimenta BV). And any such showing cannot be "based on *what might possibly be* or *what one might assume to be* the relationship between [Sandoz and Sandoz GmbH or Lek] with regard to the [] litigation" at issue—the showing "has to be based on the *current record before the Court*, and what that record *actually demonstrates*." *Princeton Digit. Image Corp.*, 316 F.R.D. at 91 (emphasis in original).

Amgen has made no such showing as to this case. That is, there is no significant evidence that in this proceeding, one or both of the foreign sister entities has a role in directing the course of Sandoz's litigation, or making important strategic decisions on behalf of Sandoz in the case, or taking any other action that might be said to satisfy this requirement.[13] For this

[13] Perhaps the closest that Amgen comes to producing evidence on this point is to note that with regard to the first application, Sandoz stipulated and agreed to [redacted]. (D.I. 4 at 20; D.I. 5, ex. 21) In the Court's view, however, that stipulation is not enough to demonstrate that Sandoz is litigating on behalf of its sister corporations here. For one thing, the agreement came in a different civil litigation, not this "suit." For another, the stipulation itself specifically notes that Amgen and Sandoz "could not resolve" their dispute about whether documents in the possession of Sandoz GmbH and Lek were "within Sandoz['s] control" and that by "entering this stipulation, Sandoz[] does not waive or concede its position that Sandoz[] does not have control of Sandoz GmbH's and Lek's documents[.]" (D.I. 5, ex. 21 at 1-2) That Amgen was able to avoid further discovery hassles as to the first application [redacted]—and only pursuant to a stipulation that pointedly notes that Sandoz was not making any concessions as to this "control" issue—is not persuasive evidence that Sandoz is "litigating on [] behalf" of its sister entities in this case.

reason alone, the Application's request for documents in the possession of Sandoz GmbH or Lek must be denied. *See id*. at 91-93 (concluding that, in light of the absence of such evidence, the movant had not sufficiently demonstrated that a United States litigating corporation was litigating on behalf of its foreign sister company) (citing cases, including *Alimenta (U.S.A.), Inc.*); *Afros S.p.A. v. Krauss-Maffei Corp.*, 113 F.R.D. 127, 132 (D. Del. 1986) (concluding that KMC had control of the requested documents from its non-party parent corporation KMAG—but where the record demonstrated that "[t]he relationship between KMC and KMAG is very close" including that "KMC's Board consists of upper echelon KMAG employees who have substantial oversight responsibility in that corporation" and "[k]ey decisions regarding this litigation, primarily the assignment of patent rights and decision to counterclaim, were made by a KMAG employee with no direct connection to KMC"); *see also Provost v. Kia Motors Am.*, CIVIL ACTION NO. 05-36-D-M2, 2006 WL 8432836, at *5 (M.D. La. July 24, 2006) (denying the plaintiff's motion to compel the defendant ("KMA") to produce certain information in the possession of its foreign parent corporation ("KMC") where, *inter alia*, the plaintiff had not provided evidence demonstrating that "key decisions regarding this litigation have been made by employees of KMC[,] and/or that KMC has previously provided documents of the type requested in this matter voluntarily or with full cooperation in the interest of moving litigation forward") (internal quotation marks and citations omitted).[14]

IV. CONCLUSION

[14] Though the parties have not spoken to it, the Court notes that it seems likely that the stakes here may now be less significant—in that Amgen is currently suing Sandoz GmbH in Austria in a related litigation (wherein it may be able to obtain some or all of the types of documents it is seeking here).

For the reasons set forth above, the Court DENIES the unresolved portions of the Application. An appropriate Order will issue.

Because this Memorandum Opinion may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Memorandum Opinion. Any such redacted version shall be submitted no later than **May 28, 2025** for review by the Court. It should be accompanied by a motion for redaction that shows that the presumption of public access to judicial records has been rebutted with respect to the proposed redacted material, by including a factually-detailed explanation as to how that material is the "kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure." *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Opinion.