BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: Denosumab Patent Litigation	MDL No.:

BRIEF IN SUPPORT OF MOTION FOR TRANSFER TO THE DISTRICT OF NEW JERSEY PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED PRETRIAL PROCEEDINGS

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INTRODUCTION

This motion arises from patent-infringement litigation under the Biologics Price Competition and Innovation Act ("the BPCIA"), Pub. L. No. 111-48, §§ 7001–03, 124 Stat. 119, 804–21 (2010), involving eleven defendants in four actions that are presently proceeding on parallel tracks in three jurisdictions. To avoid duplicative and potentially inconsistent litigation of the same patent claims, Amgen Inc. and Amgen Manufacturing Limited LLC (together, "Amgen") request that the Panel establish a multidistrict litigation pursuant to 28 U.S.C. § 1407. Amgen further requests that the MDL be established in the District of New Jersey before Judge Christine P. O'Hearn, who is currently presiding over the first two of the four pending actions, and who also presided over an earlier (fifth) related case, now resolved, that included a six-day evidentiary hearing on three overlapping patents.

Each of the four cases that are the subject of this motion is an action for patent infringement arising out of a pharmaceutical company's filing of an abbreviated Biologic License Application ("BLA"), by which the defendants in each case have sought approval to manufacture and sell biosimilar versions of Amgen's Prolia® and XGEVA® drug products. In each case, Amgen asserts infringement of patents that cover the denosumab antibody itself, pharmaceutical compositions comprising denosumab, and innovative methods of manufacturing therapeutic proteins like denosumab at a consistent quality and scale for use in patients. Amgen has asserted 21 patents common to all of the pending actions, including three patents that were the subject of the six-day evidentiary hearing before Judge O'Hearn in the earlier, now-settled case.

Given the complexities of BPCIA patent litigation and the common issues of fact and law across the four pending cases, consolidation of the actions and any tag-along actions in the District of New Jersey "will be for the convenience of parties and witnesses and will promote the

just and efficient conduct of such actions." 28 U.S.C. § 1407(a). The Panel has repeatedly recognized that "actions involving the validity of complex pharmaceutical patents and the entry of generic versions of the patent holder's drugs are particularly well-suited for transfer under Section 1407." *In re Sitagliptin Phosphate ('708 & '921) Pat. Litig.*, 402 F. Supp. 3d 1366, 1367 (J.P.M.L. 2019) (quoting *In re Alfuzosin Hydrochloride Pat. Litig.*, 560 F. Supp. 2d 1372, 1374 (J.P.M.L. 2008)). And the Panel has recently extended this principle to actions involving the entry of biosimilar products under the BPCIA. *See In re Aflibercept Pat. Litig.*, 2024 WL 1597512, at *1 (J.P.M.L. Apr. 11, 2024). The Panel should grant Amgen's motion.

BACKGROUND

I. Amgen's Prolia and XGEVA Drug Products and Patented Technologies.

Amgen manufactures and sells Prolia and XGEVA for patients seeking treatment for certain types of bone disease. Prolia is prescribed to treat patients with a high risk of bone loss, such as patients suffering from osteoporosis. XGEVA is prescribed to prevent skeletal-related events (*e.g.*, fractures or spinal cord compression) in cancer patients whose cancer has spread to the bone, and also to treat certain types of tumors.

The active ingredient in both Prolia and XGEVA is an antibody called denosumab. Amgen scientists spent decades elucidating the biology of bone remodeling, creating the denosumab antibody, and developing Prolia and XGEVA. To support its portfolio of complex biological products such as Prolia and XGEVA, Amgen scientists have also made significant advancements in manufacturing processes for biological products that enhance product yield, consistency, and quality. After creating denosumab, Amgen continued to innovate. Indeed, once denosumab was on the market, Amgen's ongoing investments spurred Amgen scientists to invent improvements applicable to the broader field of commercial manufacturing of antibody therapeutics.

The patents Amgen has asserted in these actions cover the antibody denosumab itself, pharmaceutical formulations comprising it, and innovative methods of manufacturing therapeutic proteins (like denosumab) at a consistent quality and scale for use in patients. Amgen has asserted 47 patents in total, with 21 patents that are common to all four pending actions. There is even more overlap when considering the patents common to at least two pending suits. The common patents across all four pending actions include three that were at issue in a prior six-day evidentiary hearing before Judge O'Hearn—U.S. Patent Nos. 7,364,736 (the "Boyle '736 Patent"), 7,928,205 (the "Dillon '205 Patent"), and 11,434,514 (the "Huang '514 Patent").

II. Amgen's Efforts to Vindicate Its Patent Rights.

This motion seeks to coordinate pretrial proceedings across four cases in which Amgen has brought claims for patent infringement based on the filing of applications seeking approval to market biosimilar versions of Amgen's Prolia and XGEVA products under the BPCIA. As the Panel has recognized, the BPCIA "was enacted to expedite the entry of follow-on biologic drugs into the market," *Aflibercept*, 2024 WL 1597512, at *1 n.1, by creating an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. *See* 42 U.S.C. § 262(k) (sometimes referred to as the "subsection (k) pathway"). Subject to certain conditions, this abbreviated pathway permits a biosimilar applicant to rely on the prior clinical tests, data, and results, and the prior licensure and approval status, of the innovative (or "reference") biological product to secure licensing of a biosimilar version of the reference biological product.

To date, Amgen has filed five patent infringement suits against pharmaceutical companies seeking to market biosimilar versions of Amgen's Prolia and XGEVA products. Amgen filed the first such case last year against Sandoz Inc. and certain Sandoz affiliates in the District of New Jersey. *See Amgen Inc. et al. v. Sandoz Inc. et al.*, No. 1:23-cv-02406-CPO-EAP (D.N.J.). The *Sandoz* case proceeded before Judge O'Hearn, who worked closely with Magistrate Judge

Elizabeth A. Pascal to manage discovery in the expedited proceedings. The parties in *Sandoz* engaged in significant discovery with active involvement by the court in preparation for a six-day evidentiary hearing in late 2023 before Judge O'Hearn on Amgen's motion for a preliminary injunction. That hearing involved live testimony from roughly a dozen witnesses relating both to patented technologies—as claimed in the Boyle '736 Patent, the Dillon '205 Patent, and the Huang '514 Patent—and the market for Amgen's Prolia and XGEVA products. Discovery was not bifurcated during the expedited proceedings. To prepare for the evidentiary hearing, Judge O'Hearn also held a technology tutorial to better understand the proposed Prolia and XGEVA biosimilar products and the manufacturing processes and technologies involved in producing them. At the end of January 2024, the case was narrowed to focus on thirteen of the asserted patents. The *Sandoz* case was resolved by settlement a few months later, before Judge O'Hearn rendered a decision on the preliminary injunction motion.

Each of the four pending cases was filed on the heels of the *Sandoz* litigation, between May and November of this year. Two of those cases are currently pending in the District of New Jersey before Judge O'Hearn and Magistrate Judge Pascal. *See Amgen Inc. et al. v. Celltrion, Inc.*, No. 1:24-cv-06497-CPO-EAP (D.N.J.); *Amgen Inc. et al. v. Samsung Bioepis Co., Ltd. et al.*, No. 1:24-cv-08417-CPO-EAP (D.N.J.). Both pending New Jersey cases involve allegations of infringement of the 21 patents common to all four cases, including the three that were the subject of preliminary-injunction proceedings in *Sandoz*. With the court's active assistance in managing early, expedited discovery issues—including discovery from a third-party supplier, following a motion to enforce a subpoena that was transferred to New Jersey[1]—the parties in the

[1] *See* Memorandum Order, Dkt. 59, *In re Subpoena to FujiFilm Irvine Scientific*, No. 24-cv-8830-CPO-EAP (D.N.J. Sept. 13, 2024).

Celltrion case are currently focused on pursuing fact discovery and working on a proposed schedule that will ensure the efficient resolution of the proceedings, with an eye toward a potential expedited trial in early 2025.[2] In the *Samsung Bioepis* case, the defendants have responded to the complaint, and the parties are similarly engaged in preliminary fact discovery.

Each of the two pending cases outside of New Jersey is in its infancy. Last month, Amgen filed suit against Fresenius Kabi and certain affiliates in the Northern District of Illinois. *See Amgen Inc. et al. v. Fresenius Kabi USA, LLC, et al.*, No. 1:24-cv-09555 (N.D. Ill.). Judge John R. Blakey is presiding over the *Fresenius* case, in which defendants have not yet filed a response to the complaint. And earlier this week, Amgen brought suit against Accord and certain affiliates in the Eastern District of North Carolina. *See Amgen Inc. et al. v. Accord Biopharma, Inc., et al.*, No. 5:24-cv-00642 (E.D.N.C.). The *Accord* case has been assigned to Chief Judge Richard E. Myers II. In both *Fresenius* and *Accord*, Amgen has asserted infringement of (among others) the 21 overlapping patents identified above, including the three at issue in the *Sandoz* preliminary-injunction proceedings.

All four of these pending actions will require the courts to manage related discovery, construe patent claims, and resolve similar pretrial issues relating to the infringement of Amgen's patents relating to the denosumab antibody itself, pharmaceutical compositions comprising denosumab, and innovative methods of manufacturing therapeutic proteins like denosumab at a consistent quality and scale for use in patients. As is common in BPCIA patent litigation, other biosimilar drug manufacturers have also announced plans to develop proposed biosimilars to

[2] Another related matter in which Amgen seeks discovery for use in a foreign proceeding pursuant to 28 U.S.C. § 1782 is pending in the New Jersey District Court and has been assigned to Judge O'Hearn. *See In the Matter of the Application of Amgen Inc. for Assistance Before a Foreign Tribunal*, No. 24-09052-CPO-EAP (D.N.J.).

Amgen's Prolia and XGEVA products, such that further related actions may arise in the future. *See, e.g.*, *Aflibercept*, 2024 WL 1597512. A recent Cardinal Health report identified roughly a dozen proposed biosimilar candidates to Amgen's Prolia and XGEVA therapeutics in clinical trials beyond those that are the subject of the pending litigations.[3] These candidates suggest a meaningful possibility of potential tag-along actions that would be best managed through centralization with the pending cases.

ARGUMENT

This Panel has routinely centralized pharmaceutical patent-infringement cases, recognizing that "actions involving the validity of complex pharmaceutical patents and the entry of generic versions of the patent holder's drugs are particularly well-suited for transfer under Section 1407." *Alfuzosin Hydrochloride*, 560 F. Supp. 2d at 1374; *see also Aflibercept*, 2024 WL 1597512, at *2 ("Even if there is some variation among defendants' defenses to certain patents, it seems far more efficient to allow a single court to construe the patents at issue and to decide whether injunctive relief is warranted" in BPCIA litigation.). Consistent with this established practice, the Panel should order the transfer of the Illinois *Fresenius* action and the North Carolina *Accord* action for consolidation with the cases before Judge O'Hearn and Magistrate Judge Pascal in the District of New Jersey.

Pretrial consolidation is appropriate because: (1) the actions involve "one or more common questions of fact," (2) transfer to New Jersey "will be for the convenience of parties and witnesses," and (3) transfer "will promote the just and efficient conduct of [the] actions." 28 U.S.C. § 1407(a). New Jersey is the most appropriate venue for consolidation because it is a

[3] Cardinal Health, "Biosimilars Landscape," May 8, 2024, https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/cardinal-health-biosimilar-launches.pdf (last visited Nov. 1, 2024).

conveniently located district where two of the four current actions are pending, and because the court, and Judge O'Hearn in particular, has substantial experience and familiarity with Amgen's patents, its Prolia and XGEVA products, and the BPCIA. In addition, Magistrate Judge Pascal has worked closely with Judge O'Hearn and has managed discovery in each of the three Prolia and XGEVA patent infringement actions filed in New Jersey (*i.e.*, *Sandoz*, *Celltrion*, and *Samsung Bioepis*). In contrast, the cases in Illinois and North Carolina are in their infancies, and the assigned judges have not yet had occasion to meaningfully engage with the substantive and discovery-related issues likely to arise in the Prolia and XGEVA patent infringement cases.

I. The Related BPCIA Actions Involve Common Questions of Fact.

The *Fresenius* and *Accord* actions should be transferred to the District of New Jersey for consolidation with the other two BPCIA actions pending there because of the common questions of fact necessary to resolve each case. Where, as here, an innovator "alleges that the defendant[s] infringed a common set" of patents covering its drug, "by submitting aBLAs and seeking to market their follow-on biologic products," the Panel has before concluded that "[c]ommon factual questions will include whether the proposed biosimilar products infringe the patents, the evidence related to claim construction, and patent validity considerations such as the level of ordinary skill in the art, the scope and content of the prior art, and obviousness." *Aflibercept*, 2024 WL 1597512, at *1. If the BPCIA actions are not consolidated, the courts will be forced to address these matters in parallel, contravening this Panel's well-established view that "it seems far more efficient to allow a single court to construe the patents at issue." *Id.* at *2. Given the common questions of fact, "[c]entralization will avoid the risk of duplicative discovery and prevent inconsistent rulings as to claim construction, patent validity, and other issues." *Id.* at *1.

Beyond technical patent-related issues, the co-pending BPCIA actions are likely to involve common questions of fact relating to remedies. For example, in each complaint, Amgen

seeks injunctive relief, which raises questions relating to the irreparable harm Amgen faces from infringing conduct, the balance of equities, and the public interest. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008) (preliminary injunction standard); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (permanent injunction standard). Like the patent issues, resolving the parties' disputes regarding these equitable standards will involve complex analysis and expert discovery, including discovery relating to the market in which proposed biosimilars to Prolia and XGEVA may compete. Similar overlapping factual questions will arise in connection with any claims for damages. All parties benefit by having one judge oversee these overlapping factual matters pre-trial.

The BPCIA patent litigation context presents an added layer of complexity (and urgency)—not present in the context of generic drugs—that further underscores the benefits of centralization. In litigation involving generic drugs, there is typically a so-called "thirty-month stay" of FDA approval pending litigation, which allows courts to resolve the parties' patent disputes expeditiously without concerns about addressing a potential launch during the litigation.[4] There is no such automatic stay of FDA approval in the context of biosimilar products, which is why motions for preliminary injunctions (as Amgen sought in the earlier *Sandoz* case before Judge O'Hearn), stipulated preliminary injunctions,[5] and orders for expedited

[4] *See* 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii); Meredith H. Boerschlein et al., "Intricacies of the 30-Month Stay in Pharmaceutical Patent Cases," Am. Pharm. Rev., Mar. 25, 2018, https://www.americanpharmaceuticalreview.com/Featured-Articles/348913-Intricacies-of-the-30-Month-Stay-in-Pharmaceutical-Patent-Cases/.

[5] *See, e.g.*, Consent Preliminary Injunction, Dkt. 95, *Immunex Corp. v. Sandoz Inc.*, No. 16-cv-01118 (D.N.J. Aug. 11, 2016); *see also* Scheduling Order, Dkt. 58 at 2, *Amgen Inc. v. Samsung Bioepis Co.. Ltd. et al.*, No. 24-cv-08417 (D.N.J. Nov. 6, 2024) (directing Samsung Bioepis to inform the court whether it will agree to a consent injunction).

trial[6] arise more frequently in the BPCIA context than in Hatch-Waxman cases. BPCIA cases benefit from active and careful management and often need to move quickly, which further supports centralization. *See In re Kerydin (Tavaborole) Topical Sol. 5% Pat. Litig.*, 366 F. Supp. 3d 1370, 1371 (J.P.M.L. 2019) (ordering consolidation of actions in part based on "the need for swift progress in litigation involving the potential entry of generic drugs into the market").

II. Transfer and Consolidation Will Serve the Convenience of Parties and Witnesses.

Consolidation will best serve the convenience of the parties and witnesses by allowing the court to "avoid the risk of duplicative discovery" otherwise caused by parallel proceedings. *Aflibercept*, 2024 WL 1597512, at *1. Witnesses whose testimony is likely to be sought in multiple cases will not need to appear for a series of duplicative depositions or evidentiary hearings in different courts, nor will their attorneys have to expend resources preparing for otherwise duplicative proceedings. Centralization in New Jersey would not meaningfully impact Celltrion or Samsung Bioepis, the defendants that have already been litigating in New Jersey for the past several months. And any burden of a transfer on Fresenius or Accord, which is minimal, is substantially outweighed by the opportunity to proceed with efficient discovery that builds on the New Jersey court's experience in these Prolia and XGEVA patent infringement matters, to the parties' and witnesses' convenience.

Consolidation further aids the court's ability to manage multiple proceedings in which parties in one litigation may attempt to seek confidential information disclosed by parties in another. Indeed, this challenge has already arisen in multiple actions: the *Celltrion* defendants

[6] *See, e.g.*, Scheduling Order, Dkt. 87, *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 22-cv-00061 (N.D. W. Va. Oct. 25, 2022) (setting two-week trial for less than a year after filing of BPCIA patent infringement complaint); *see also* Text Order, Dkt. 173, *Amgen Inc. et al. v. Celltrion, Inc.*, No. 1:24-cv-06497 (D.N.J. Nov. 5, 2024) (directing parties to submit a proposed schedule that accounts for an expedited trial in late February 2025).

and the *Samsung* defendants have separately requested the disclosure of confidential information from other Prolia and XGEVA patent infringement matters. *See, e.g.*, Dkt. 448, *Amgen Inc. et al. v. Sandoz Inc. et al.*, No. 1:23-cv-02406 (D.N.J. Aug. 13, 2024) (letter from Sandoz to the court explaining Celltrion's request for confidential information in parallel litigation). Resolving disputes relating to such requests and the best means by which to protect confidential information among the various parties is best handled by a single court managing the proceedings in each case, for the benefit of all parties involved.

III. Transfer and Consolidation Will Promote the Just and Efficient Conduct of These Actions.

Consolidation will not only be convenient for the parties, it will also be convenient for the courts and promote just and efficient resolution of all of the Prolia and XGEVA patent litigations. There is no reason to have multiple federal judges invest their time in resolving common pretrial factual and legal questions in four separate cases, and possible tag-along cases, with the accompanying risk of reaching inconsistent conclusions. The Panel has explained that § 1407 enables multiple actions to be assigned to "a single judge who can ensure that pretrial proceedings are conducted in a streamlined manner leading to the just and expeditious resolution of all actions to the overall benefit of all parties and the courts." *In re Armodafinil Pat. Litig.*, 755 F. Supp. 2d 1359, 1360 (J.P.M.L. 2010). Doing so in patent cases helps to "prevent inconsistent pretrial rulings (particularly on claim construction issues), and conserve the resources of the parties, their counsel and the judiciary." *Id.*

Indeed, recent experience in the pending *Celltrion* case regarding third-party discovery underscores the value of centralization in these Prolia and XGEVA patent litigations. There, Amgen had sought discovery from a supplier of certain cell-culture media used in the manufacture of Celltrion's proposed Prolia and XGEVA biosimilar denosumab products. The

supplier moved to quash Amgen's subpoena in the Central District of California, but that court found "exceptional circumstances" warranted transfer of the supplier's motion to quash the subpoena to the District of New Jersey, including due to a "heightened risk of inconsistent orders," along with a recognition of the "active role" the New Jersey court has taken in "managing the case." Order, Dkt. 24, *In re Subpoena to FujiFilm Irvine Scientific in Amgen, Inc. v. Celltrion USA, Inc., et al.*, No. 8:24-mc-00024 (C.D. Cal. Aug. 28, 2024). The same principles that led the California court to transfer the third-party discovery dispute to New Jersey likewise support centralization here: these are complex cases with overlapping issues that present a risk of inconsistent rulings, and the just and efficient conduct of the proceedings will be best promoted through centralization before a court prepared to actively manage the cases. And having one court available to resolve any further potential third-party discovery disputes would be advantageous as well.

The fact that Amgen seeks to consolidate only four actions pending in three districts does not change the analysis. The statute permits transfer so long as there are at least two actions pending in two districts. *See* 28 U.S.C. § 1407(a). The Panel has accordingly rejected the argument that "centralization is not appropriate" when there are a "relatively small number of involved actions," declaring that argument "not persuasive." *Aflibercept*, 2024 WL 1597512, at *2. For good reason. Consolidating even just a small number of actions promotes judicial efficiency where, as here, the actions have substantial overlap. Moreover, as mentioned above, there are roughly a dozen other companies reported to be pursuing a proposed biosimilar to Amgen's Prolia and XGEVA therapeutics, which raises a possibility of additional suits that would benefit from consolidation. *See In re Metoprolol Succinate Pat. Litig.*, 329 F. Supp. 2d 1368, 1370 (J.P.M.L. 2004) (explaining consolidation under § 1407 has "the salutary effect of

assigning the present actions and any future tag-along actions to a single judge who can formulate a pretrial program that ensures that pretrial proceedings will be conducted in a manner leading to the just and expeditious resolution of all actions to the overall benefit of the parties and the courts").

In recognition of the benefits of consolidation, the Panel has "frequently centralized litigation comprised of only two Hatch-Waxman Act cases." *In re Nebivolol Pat. Litig.*, 867 F. Supp. 2d 1354, 1355 & n.4 (J.P.M.L. 2012) (consolidating Hatch-Waxman cases from two forums) (citing *Armodafinal*, 755 F. Supp. 2d 1359 (same); *In re Brimonidine Pat. Litig.*, 507 F. Supp. 2d 1381 (J.P.M.L. 2007) (same); *Metoprolol*, 329 F. Supp. 2d 1368 (same)). It should do so again here, in the analogous BPCIA context. *See Aflibercept*, 2024 WL 1597512, at *2 (rejecting defendants' argument opposing consolidation on the basis that BPCIA litigation is "significantly different from litigation under the Hatch-Waxman Act that the Panel typically centralizes").

IV. The District of New Jersey is the Most Appropriate Transferee Forum.

If the Panel concludes that consolidation is appropriate, consistent with its precedent in pharmaceutical patent-infringement cases, it should order the Northern District of Illinois and Eastern District of North Carolina actions transferred to District of New Jersey, the forum of the first-filed action. *See In re Fenofibrate Pat. Litig.*, 787 F. Supp. 2d 1352, 1354 (J.P.M.L. 2011) (ordering transfer to a certain court in part because "[t]he first-filed action … is pending in this district"); *Metoprolol*, 329 F. Supp. 2d at 1370 (ordering transfer to "the location of the first-filed action").

New Jersey is an ideal forum for this litigation. It is already the primary forum for Prolia and XGEVA patent infringement litigation, as it is where three of the five actions filed to date have proceeded, including the concluded *Sandoz* action and the pending *Celltrion* and *Samsung*

Bioepis actions. The Illinois and North Carolina actions, by contrast, each involve just one set of applicants, and each of these non-New Jersey cases was filed in the past month. It makes more sense to have the defendants in the two non-New Jersey actions transferred to New Jersey—the center of the Prolia and XGEVA patent infringement litigations to date—rather than having three actions transferred to Illinois or North Carolina. *See Armodafinil*, 755 F. Supp. 2d at 1360 ("We are persuaded that the District of Delaware is an appropriate transferee district … [because] most parties are already litigating there"); *In re Mirtazapine Pat. Litig.*, 199 F. Supp. 2d 1380, 1381 (J.P.M.L. 2002) (ordering transfer to the district in which "five of the six constituent actions and two potential tag-along actions are pending").

The District of New Jersey, and specifically Judge O'Hearn, is also particularly well-suited to take on this case as a multi-district litigation. The District of New Jersey has long been recognized as a "premier" district for pharmaceutical patent litigation, behind only the District of Delaware in terms of the number of Hatch-Waxman cases it has adjudicated, for example.[7] Last year, aside from Delaware, New Jersey had more new and pending generic drug suits than all other districts combined.[8] And though there have been fewer BPCIA cases since the statute's enactment in 2010, New Jersey has emerged as one of the top venues for BPCIA litigation as well.[9] Moreover, unique among the three relevant districts here, New Jersey has even crafted

[7] Matthew Bultman, "Hatch-Waxman Post-*TC Heartland*: What You Need to Know," May 24, 2018, Law360, https://www.sternekessler.com/app/uploads/2022/09/Hatch_Waxman-Post_TC-Heartland_What-You-Need-To-Know.pdf (last accessed Nov. 2, 2024).

[8] Christina D. Brown-Marshall *et al.*, "Hatch-Waxman 2023 Year in Review," Feb. 5, 2024, https://fr.com/insights/thought-leadership/articles/hatch-waxman-2023-year-in-review-2/ (last accessed Nov. 2, 2024) (reporting 23% of all "Open ANDA Cases" in New Jersey, compared to 12% anywhere else other than Delaware, and 35% "New 2023 ANDA Cases," compared to 8% anywhere else other than Delaware).

[9] Philip Chen *et al.*, "Biosimilar Litigation Review: Ongoing BPCIA District Court Cases To Watch," Biosimilar Development, Jan. 14, 2020, https://www.biosimilardevelopment.com/doc/

local rules specific to litigation under the Hatch-Waxman Act, including disclosure requirements regarding any communications with the FDA regarding a pending application for approval of a generic drug. *See* D.N.J. L. Pat. R. 3.6(j). Although the Hatch-Waxman rules do not apply directly in BPCIA cases, New Jersey judges (including Judge O'Hearn and Magistrate Judge Pascal) have adopted similar disclosure requirements, informed by the district's experience with its local Hatch-Waxman rules. *See, e.g.*, Order, Dkt. 56, *Amgen Inc. et al. v. Celltrion, Inc. et al.*, No. 1:24-cv-06497 (D.N.J. July 3, 2024) (ordering defendant to "submit any and all communications sent to and received from the Food and Drug Administration within seven days of submission or receipt"); Scheduling Order, Dkt. 58 at 1–2, *Amgen Inc. v. Samsung Bioepis Co., Ltd. et al.*, No. 24-cv-08417 (D.N.J. Nov. 6, 2024) (ordering production of FDA correspondence within 14 days).

Beyond this general experience with pharmaceutical cases in the district, Judge O'Hearn has significant experience managing the specific issues at the heart of this litigation, having presided in the entire *Sandoz* matter and, in close coordination with Magistrate Judge Pascal, presided over discovery issues in *Sandoz* as well as the currently-pending *Celltrion* and *Samsung Bioepis* actions. This experience gives Judge O'Hearn a critical advantage, given the time pressures that frequently arise in BPCIA litigation, discussed above. In contrast, assigning the four pending cases to one of the recently assigned judges in Illinois or North Carolina—where the pending cases are each in their infancies—would put the transferee court at a significant disadvantage, as it would be forced to get up to speed on not only the technical and discovery

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issues common to all cases but also on decisions already made in *Sandoz*, *Celltrion*, and *Samsung Bioepis*, potentially on a tight or accelerated timeframe.

CONCLUSION

Transfer of the Illinois and North Carolina actions to the District of New Jersey for coordinated pretrial proceedings with the two pending New Jersey actions will reduce duplicative discovery, serve the convenience of the parties and witnesses, and promote judicial economy. Amgen respectfully requests that the Panel grant the Motion to Transfer and centralize the pending Prolia and XGEVA patent infringement litigations in the District of New Jersey, pursuant to 28 U.S.C. § 1407.

Date: November 18, 2024

Respectfully submitted,

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