Paper No. 7
Filed: August 4, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, INC. AND KASHIV BIOSCIENCES, LLC,
Petitioners,

v.

GENENTECH, INC. AND NOVARTIS PHARMACEUTICALS CORP.,
Patent Owners.

Case IPR2026-00260
U.S. Patent No. 12,030,959

PATENT OWNERS' REQUEST FOR DISCRETIONARY DENIAL

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42 U.S.C. § 262(*l*) 1, 2, 3, 6, 7, 8, 9, 11, 12, 13, 14, 15

LIST OF EXHIBITS

Exhibit	Description
2001	Amneal, *Amneal Announces BLA Submission of Biosimilar Candidate to XOLAIR® (omalizumab)* (Sep. 26, 2025), available at https://tinyurl.com/rj4akbpm
2002	Non-Confidential Excerpt of Kashiv's 42 U.S.C. § 262(*l*)(3)(B) Contentions
2003	Memorandum from Acting Director re Interim Processes for PTAB Workload Management (Mar. 26, 2025)
2004	Global Food Consumers, *FDA Approves Groundbreaking Drug Xolair to Prevent Severe Food Allergic Reactions* (Feb. 22, 2024), available at https://tinyurl.com/56ez33x6
2005	Aleyna Rentz, *Life-changing food allergy management drug made possible by NIH funding*, Johns Hopkins University Hub (June 17, 2025) available at https://tinyurl.com/4dcf6hbh
2006	FDA, *Approval Letter for BLA 761399* (Mar. 7, 2025), available at https://tinyurl.com/mthrfxca
2007	Stanton Mehr, *Celltrion Gains First Omalizumab Biosimilar Approval*, Biosimilars Review & Report (Mar. 11, 2025), available at https://tinyurl.com/p3etbafn
2008	ClinicalTrials.gov, *Study NCT05413161: To Compare the PK, PD, Safety & Immunogenicity of ADL-018 in Healthy Subjects*, available at https://tinyurl.com/y8e3vnyc

I. INTRODUCTION

Far too many children suffer from food allergies, some so severe that a trip to the hospital could arise from a simple mistake in a preschool cafeteria. U.S. Patent No. 12,030,959 (the "'959 Patent") helps prevent these disasters and claims methods of treating food allergies in pediatric patients by administering omalizumab, the active ingredient in Genentech's and Novartis's XOLAIR® product, according to dosing regimens calibrated to a patient's body weight and baseline serum IgE levels. Ex. 1001, claims 1, 12, 17, 25. Developing medicine for children is notoriously difficult. These innovations are the product of years of research, clinical trials, and regulatory investment, culminating in the FDA's approval of XOLAIR® for the treatment of food allergies, the first and only biologic therapy approved for this indication. Ex. 1001, 7:43–56.

The Director should exercise his discretion to deny institution of this IPR under 35 U.S.C. § 314(a) for a straightforward reason: Amneal Pharmaceuticals, Inc. ("Amneal") and Kashiv BioSciences, LLC ("Kashiv") (together, "Petitioners") filed this Petition *after* the parties began the patent dispute resolution process Congress created in the Biologics Price Competition and Innovation Act (the "BPCIA"). The BPCIA established a comprehensive, step-by-step process colloquially known as the "Patent Dance" through which biosimilar applicants and reference product sponsors identify, narrow, and resolve patent disputes. 42 U.S.C. § 262(*l*)(2)–(6). Congress

designed this process to be the mechanism through which disputes like this one are filtered and adjudicated. The Supreme Court has described the BPCIA as setting forth a "carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement," one that "facilitates litigation during the period preceding FDA approval so that the parties do not have to wait until commercial marketing to resolve their patent disputes." *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 7-8 (2017). The Court further has recognized that the BPCIA's "carefully crafted and detailed enforcement scheme" reflects Congress's considered judgment about how these disputes should proceed and provides "strong evidence" that Congress did not intend for parties to route around those procedures. *Id.* at 16.

When Petitioners filed this IPR on May 26, 2026, the parties were deep into the Patent Dance. While some aspects of these exchanges are confidential by statute, Amneal announced in September 2025 that Kashiv had submitted its omalizumab BLA. Ex. 2001 at 1-2. After FDA accepts the BLA, the biosimilar applicant has 20 days to decide whether to begin the Patent Dance by producing to the reference product sponsor (here, Genentech) its BLA and manufacturing information. 42 U.S.C. § 262(*l*)(2). Genentech then was required within sixty days to serve a list identifying potentially infringed patents, 42 U.S.C. § 262(*l*)(3)(A), and Kashiv then was required within sixty days to serve contentions, 42 U.S.C. § 262(*l*)(3)(B). Exhibit 2002 is a non-confidential excerpt of Kashiv's Patent Dance invalidity

contentions as to the '959 Patent.[1] As Exhibit 2002 makes clear, Kashiv's arguments in the two forums are *identical*. Ex. 2002 at 7 (arguing in § 262(*l*)(3)(B) Patent Dance contentions that "for the same reasons as set forth in the IPR Petition (IPR2026-00260, Paper 1), all claims of the '959 Patent are invalid as anticipated and/or obvious"). There is not a single issue relating to validity that differs between the two proceedings.

Petitioners' decision to file this IPR *after* beginning the Patent Dance transforms what Congress designed as a narrowing exercise into an expanding one. If the IPR is instituted, a final written decision would not issue until late 2027 at the earliest. By that time, the parties will be in the middle of BPCIA district court litigation, far into fact discovery if not already expert discovery. And it is reasonable to infer from the filing date of Kashiv's BLA and the service of Kashiv's invalidity contentions under 42 U.S.C. § 262(*l*)(3)(B) that FDA approval will occur before then too, meaning that a preliminary injunction motion likely will have been decided. This IPR represents Petitioners' proverbial "second bite at the apple," but such second bites are out of step with Congressional intent reflected in the BPCIA and precisely the kind of redundant, resource-wasting challenge that the Director's

[1] Genentech and Novartis have redacted from Exhibit 2002 information relating to Kashiv's non-infringement contentions.

policies are meant to prevent. Ex. 2003 at 2-3; *cf. Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 6–12 (P.T.A.B. Mar. 20, 2020) (precedential).

II. BACKGROUND

A. The '959 Patent Protects Genentech's and Novartis's Investment in Developing the First and Only FDA-Approved Biologic for Food Allergies.

Omalizumab, marketed by Genentech and Novartis under the trade name XOLAIR®, is a recombinant, humanized IgG1 antibody that selectively binds to immunoglobulin E ("IgE"), a key mediator of the body's immune response to allergens. Ex. 1001, 24:35–40. The '959 Patent claims methods of treating food allergies in pediatric patients. Ex. 1001, claims 1, 12, 17, 25.

The innovations protected by the '959 Patent are the result of XOLAIR®'s extensive clinical development program, including the OUtMATCH study, a multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical trial that evaluated omalizumab monotherapy for food allergies in patients aged 1–55 years. Ex. 1001, 32:34–44:16. The trial was sponsored and funded by the National Institute of Allergy and Infectious Diseases and supported by Genentech and Novartis. In February 2024, the FDA approved XOLAIR® for the reduction of allergic reactions to foods, including the reduction of risk of anaphylaxis, in patients aged one year and older, making it the first and only FDA-approved treatment for food allergies that can protect against allergic reactions to more than one food simultaneously. Ex.

1001, 7:43–56. The significance of this work was roundly recognized by the food allergy community, which praised the drug as a "breakthrough," Ex. 2004 at 1, and celebrated the OUtMATCH trial results as having "changed the landscape of food allergy management," Ex. 2005 at 3.

The patent issued on July 9, 2024. Ex. 1001, at [1]; Ex. 1004, 186. No one filed a petition for post-grant review of the patent, even though Genentech had identified the patent as one that would be infringed by the first omalizumab biosimilar filer, Celltrion, and had listed it in the Purple Book.[2] The FDA approved Celltrion's biosimilar omalizumab in March 2025, Ex. 2006, but Celltrion announced that it would not launch its biosimilar until September 1, 2026 as a result of its settlement with Genentech and Novartis. Ex. 2007 at 2. During this time, Kashiv had been developing its omalizumab biosimilar for years. Ex. 2008 at 3 (indicating Kashiv started testing its biosimilar omalizumab in humans in 2022). Kashiv could have sought post-grant review at that time—after all, Genentech had announced via the Purple Book that the patent covered omalizumab biosimilars, and Celltrion had settled and elected to wait more than a year to launch its product out of respect for the patent. But Kashiv chose to wait.

[2] https://purplebooksearch.fda.gov/index.cfm?event=patentlist

B. The Parties Are Engaged in the BPCIA Patent Dance.

The BPCIA provides an abbreviated pathway for the regulatory approval of biosimilars (highly similar copies of biologic products). 42 U.S.C. § 262(k). To balance that abbreviated approval pathway against the interests of companies like Genentech and Novartis that develop innovative biologics and related intellectual property, Congress provided a structured, sequential information-exchange process for identifying, narrowing, and efficiently resolving patent disputes, commonly called the "Patent Dance." 42 U.S.C. § 262(*l*).

While the BPCIA imposes mandatory obligations on the reference product sponsor once the Patent Dance begins, it does not compel the biosimilar applicant to initiate the Dance in the first place. *Sandoz*, 582 U.S. at 18. A biosimilar applicant may decline to produce its BLA under § 262(*l*)(2)(A), and if it does, the only consequence is that the reference product sponsor may immediately bring a declaratory judgment action. *Id.*; 42 U.S.C. § 262(*l*)(9)(C). But if the biosimilar applicant *elects* to engage in the Patent Dance—as Petitioners did here—then the statute's framework governs the resolution of any patent disputes. At a general level, that framework provides for the exchange of information about the biosimilar product and any patents that may cover it, competing positions on infringement and validity, and identification of which patents will be litigated, all before the reference product sponsor may file suit. With certain limited exceptions, only after the parties

complete this exchange does the statute permit the dispute to proceed to district court. In this way, the Patent Dance is designed to narrow and focus any eventual patent litigation rather than allow disputes to proceed on multiple fronts at once. 42 U.S.C. § 262(*l*)(2)–(6); *see also Sandoz*, 582 U.S. at 6–12.

In view of the Patent Dance's overall purpose and structure, the specific steps proceed as follows. First, following FDA acceptance of a biosimilar application, the applicant must provide the reference product sponsor with a copy of its application and information describing the manufacturing process. 42 U.S.C. § 262(*l*)(2)(A). Second, the reference product sponsor must identify patents for which it believes a claim of infringement could reasonably be asserted. 42 U.S.C. § 262(*l*)(3)(A). Third, the parties exchange detailed contentions regarding infringement and validity. 42 U.S.C. § 262(*l*)(3)(B)–(C). Fourth, the parties identify which patents will be litigated immediately. 42 U.S.C. § 262(*l*)(4)–(5). Finally, the reference product sponsor must bring an infringement action within 30 days or lose its right to obtain a remedy other than a reasonable royalty. 42 U.S.C. § 262(*l*)(6); 35 U.S.C. § 271(e)(6)(A)–(B).

Here, Kashiv BioSciences, LLC filed a BLA for ADL-018, its proposed omalizumab biosimilar. *See, e.g.*, Pet., 1. And, as noted above, Patent Owners have attached to this Request a non-confidential excerpt of Kashiv's Patent Dance invalidity contentions as to the '959 Patent, served by Kashiv pursuant to 42 U.S.C.

§ 262(*l*)(3)(B). Ex. 2002. The parties' Patent Dance thus is actively underway. Following receipt of Kashiv's contentions, Genentech must provide its own infringement and validity contentions under § 262(*l*)(3)(C), and the parties then must work to identify patents for immediate litigation under the processes set forth in § 262(*l*)(4)–(5). These exchanges will culminate in the filing of a complaint for patent infringement in district court. 42 U.S.C. § 262(*l*)(6); 35 U.S.C. § 271(e)(6)(A)–(B). Genentech and Novartis will file updated mandatory notices identifying this proceeding promptly after its filing, which pursuant to the Patent Dance's timelines likely will occur in the next few months.

III. ARGUMENT

A. Petitioners' Decision to File this Duplicative IPR After Having Already Initiated the Patent Dance Expands Rather Than Narrows Disputes and Warrants Discretionary Denial.

The purpose of the BPCIA's Patent Dance is to narrow. This IPR does not. Because Congress specifically created the BPCIA's Patent Dance to provide an efficient mechanism for parties to narrow and resolve their infringement disputes and because Kashiv has chosen to initiate that statutory process, the Patent Dance and subsequent BPCIA litigation are the appropriate vehicles to address Petitioners' patentability challenges. Permitting a biosimilar applicant that already has made the affirmative decision to initiate the Patent Dance to then open a second front before

the PTAB and fight a near identical battle there would create enormous inefficiency and a risk of inconsistent decisions.

1. Petitioners' attempt to mount a parallel, substantively identical AIA proceeding is inconsistent with the design of the BPCIA and Congressional intent.

The BPCIA provides a structured framework for resolving patent infringement disputes arising from the approval of biosimilar drugs: the Patent Dance. 42 U.S.C. § 262(*l*). Parties exchange detailed validity and infringement contentions, narrowing and focusing the scope of any eventual patent litigation. 42 U.S.C. § 262(*l*)(3)–(6). This process culminates with the filing of a district court complaint. 42 U.S.C. § 262(*l*)(6). The Supreme Court explained that the BPCIA "sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement," under which the parties "exchange information to identify relevant patents and to flesh out the legal arguments that they might raise in future litigation." *Sandoz*, 582 U.S. at 8.

Congress intended this process to be the primary vehicle for resolving patent disputes arising from biosimilar applications when the applicant elects to engage in it. Once a biosimilar applicant makes that election and initiates the Dance, Congress ensured that any patent disputes would be resolved comprehensively and efficiently through a single statutory framework and single litigation forum (the federal district

courts), rather than in piecemeal fashion.[3] This design reflects a considered legislative choice—the BPCIA provides a "carefully crafted and detailed enforcement scheme." *Sandoz*, 582 U.S. at 16. That design and Congressional intent counsel against permitting an applicant that already has chosen to initiate the Patent Dance to then pursue simultaneous, duplicative review before the Board.

2. Institution would be highly inefficient, ensuring that identical challenges to the '959 Patent are heard in two fora.

Having opted into the Patent Dance, Kashiv has triggered a series of statutory deadlines that effectively will force the parties into district court litigation on a compressed timeline, *regardless of whether an IPR is instituted*. A reference product

[3] A reference product sponsor cannot strategically omit certain patents from the Patent Dance process, at least without suffering draconian penalties. As the Federal Circuit has explained, "the statute penalizes sponsors that decline to participate in the BPCIA's information exchanges because under 35 U.S.C. § 271(e)(6)(C), a sponsor that fails to list a patent that should have been included in the list described in [paragraph (*l*)(3)(A)] . . . may not bring an action under this section for infringement of the patent with respect to the biological product." *Amgen Inc. v. Hospira, Inc.*, 866 F.3d 1355, 1361 (Fed. Cir. 2017) (internal quotation marks omitted).

sponsor must provide its (*l*)(3)(A) list identifying relevant patents within 60 days of receiving the applicant's disclosures, 42 U.S.C. § 262(*l*)(3)(A); the applicant must provide its invalidity and noninfringement contentions within the following 60 days, 42 U.S.C. § 262(*l*)(3)(B); the reference product sponsor must provide its validity and infringement contentions within the following 60 days, 42 U.S.C. § 262(*l*)(3)(C); and the parties then must determine which patents will be litigated in the first phase of district court litigation, 42 U.S.C. §§ 262(*l*)(4)–(5). Most importantly, the reference product sponsor must bring an infringement action within 30 days of completing the patent identification processes set forth in §§ 262(*l*)(4)–(5) or forfeit its right to seek any remedy other than a reasonable royalty. 42 U.S.C. § 262(*l*)(6); 35 U.S.C. § 271(e)(6)(A)–(B).

Here, the district court forum Congress specifically designated for biosimilar patent disputes already is on a path to adjudicate the infringement and validity of the '959 Patent, and there is no scenario in which a favorable outcome for Petitioners in this IPR will avoid BPCIA litigation. Given that Kashiv already has served its contentions under 42 U.S.C. § 262(*l*)(3)(B), any BPCIA case regarding the '959 Patent is likely to be filed by the end of 2026, approximately a year before any final written decision would issue in this IPR. By the time of a final written decision, the district court case likely will have progressed through much of fact discovery as well

as critical preliminary injunction proceedings that will have required a court to reach at least tentative conclusions regarding the validity of the '959 Patent.

Compounding this inefficiency is the fact that Petitioners' challenge to the '959 Patent in this IPR is *identical* to the validity challenge it intends to present in BPCIA litigation. Kashiv's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) merely "incorporate[s] . . . by reference" the IPR Petition and supporting expert declaration, stating that "for the same reasons as set forth in the IPR Petition (IPR2026-00260, Paper 1), all claims of the '959 Patent are invalid as anticipated and/or obvious." Ex. 2002 at 7. Kashiv asserts anticipation by MacGinnitie, obviousness over MacGinnitie, anticipation by Bégin, obviousness over Bégin, and obviousness over the combination of OUtMATCH-V26, PI2021, and Arasi. *Id.* These are the same five grounds, relying on the same prior art references, and challenging the same claims, that Petitioners present in their IPR Petition.

Where, as here, "substantially identical prior art arguments" are presented before a district court and the PTAB, "concerns of inefficiency and the possibility of conflicting decisions [are] particularly strong." *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 12 (P.T.A.B. Mar. 20, 2020) (precedential). "Accordingly, if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial." *Id.* The discretionary denial decision in *Mylan Laboratories*

Ltd. v. Janssen Pharmaceutica NV, IPR2020-00440, Paper 17 (P.T.A.B. Sept. 16, 2020) is instructive. The Board there denied institution because the petition relied on substantially the same prior art references and arguments that the patent owner's litigation adversaries were already asserting against the same patent in parallel district court proceedings. IPR2020-00440, Paper 17 at 20–21 (P.T.A.B. Sept. 16, 2020). As Kashiv concedes in its own § 262(*l*)(3)(B) statement, the same will be true here.

B. This Case Is Distinguishable from *Amgen v. BMS* Because the Parties Here Are Actively Engaged in the Patent Dance

Petitioners may contend that *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, Paper 9 (P.T.A.B. July 24, 2025) controls and requires the Director decline to exercise his discretion to deny institution of their IPR. That decision is not precedential, nor did it address facts similar to those presented here. The *Amgen v. BMS* decision differs from this case in a critical respect—the existence of an *ongoing* Patent Dance.

Amgen v. BMS arose out of three IPR petitions that Amgen filed challenging patents covering a BMS biologic product. BMS sought discretionary denial, and the parties briefed whether the BPCIA's Patent Dance provisions supported denial under 35 U.S.C. § 314(a). The Director denied institution of two of Amgen's three petitions in view of the patent owner's strong settled expectations in patents that had

been in force for six and seven years. *Id.* at 3. As to the third petition, and as to the BPCIA arguments generally, the Director found those arguments "not persuasive." *Id.* At the time of that decision, however, Amgen had not yet filed a BLA for its biosimilar product, the BPCIA process had not been triggered, no Patent Dance exchanges had occurred, and there was no active parallel proceeding of any kind. *See* IPR2025-00601, Paper 8 at 4, 17, 21-22 (P.T.A.B. July 10, 2025). Critically, the Director indicated that it was the still-inchoate and speculative nature of any BPCIA proceedings in that case—rather than some inherent flaw in BMS's argument—that drove the outcome. The Director explained that "the parties are not currently engaged in a parallel proceeding involving the challenged patents," and that, "[a]s a result, there is currently no concern of inconsistent outcomes and duplication of efforts resulting from two proceedings operating in parallel." IPR2025-00601, Paper 9 at 2 (P.T.A.B. July 24, 2025). In other words, the Director's rejection of the BPCIA arguments in *Amgen v. BMS* was not a rejection of the Patent Dance as a basis for discretionary denial—it was a recognition that the putative Patent Dance there had never begun.

This case presents the opposite situation in every material respect. First, unlike in *Amgen v. BMS*, where Amgen had not yet filed a BLA, Kashiv has filed BLA No. 761505. Second, whereas no § 262(*l*)(2)(A) production had occurred in *Amgen v. BMS*, Kashiv plainly has opted into the Patent Dance here, given its service

of invalidity contentions under § 262(*l*)(3)(B). Third, whereas no party had served an (*l*)(3)(A) list in *Amgen v. BMS*, it is known here that the parties have reached an even more advanced stage of the Patent Dance. Fourth, whereas the Director found in *Amgen v. BMS* that the parties were "not currently engaged in a parallel proceeding," the parties here are actively engaged in the Patent Dance. And fifth, whereas the risk of duplicative proceedings was entirely speculative in *Amgen v. BMS* because the BPCIA process had not started, here such proceedings are a certainty.

Indeed, the "active parallel proceeding" absent from *Amgen v. BMS* already has commenced here. Once Kashiv elected to participate in the Patent Dance, strict statutory deadlines kicked in. Genentech was required to provide its list of patents under § 262(*l*)(3)(A) within 60 days. And upon completion of the Patent Dance exchanges, Genentech must bring suit within 30 days of completing negotiations under § 262(*l*)(4)-(5). There is no option to delay. There is no opportunity to wait for an IPR. District court litigation is not merely possible; it is statutorily compelled. *Amgen v. BMS* confirms what matters: the presence of an active parallel proceeding, and that is exactly what exists here. Having chosen to avail itself of the Patent Dance, Kashiv has set the BPCIA boulder rolling, and it will proceed downhill through the remainder of the Dance and into district court litigation, without regard for this IPR. If IPR is instituted, the parties will find themselves simultaneously

litigating the ’959 Patent and *identical* alleged prior art and invalidity theories in this proceeding and in district court. That is neither prudent nor an efficient use of the PTAB’s resources. *Fintiv*, IPR2020-00019, Paper 11 at 12.

IV. CONCLUSION

For all the reasons discussed above, the Director should exercise his discretion to deny institution of Kashiv’s request for inter partes review of the ’959 Patent.

Respectfully submitted,

Dated: August 4, 2026

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CERTIFICATE OF COMPLIANCE PURSUANT TO 37 C.F.R. § 42.24

Pursuant to 37 C.F.R. § 42.24(d) and Interim Director Discretionary Process (§ II.C.iii), I, Thomas S. Fletcher, certify that PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL complies with the 20-page limit, excluding those portions identified in 37 C.F.R. § 42.24(a), (b). This paper also complies with the typeface requirements of 37 C.F.R. § 42.6(a)(ii) and the type style requirements of § 42.6(a)(iii)&(iv).

Dated: August 4, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned hereby certifies that a true and correct copy of the foregoing Patent Owners' Request for Discretionary Denial was served on August 4, 2026, by delivering copies via electronic mail on the following counsel of record for the Petitioner:

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