BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re Dupixent Products Liability Litigation **MDL-_____**

BRIEF IN SUPPORT PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407

Pursuant to 28 U.S.C. § 1407 and Judicial Panel on Multi-District Litigation ("JPML") Rule 6.2, Plaintiffs Wanda Nalls, John I. Mun, and Giovanni Fraioli (hereinafter, "Plaintiffs") respectfully move this Judicial Panel on Multi-District Litigation ("Panel") for an Order creating an MDL involving the use of the drug Dupixent and the injury of T-cell lymphoma and transferring the currently filed cases marked in the attached Schedule of Actions (collectively the "Actions"), as well as any cases subsequently filed involving similar facts or claims ("tag-along cases"), to the United States District Court for the Northern District of Georgia.

As described herein, transfer of these cases at issue is well within the scope of 28 U.S.C. § 1407. Each of the Actions involves common questions of fact and law that would benefit from resolution by one court. Additionally, consolidation would serve the convenience of the parties and witnesses, and consolidation would promote the just and efficient conduct of the litigation.

This litigation should be centralized in the Northern District of Georgia for several reasons. Twenty-five percent of the cases filed to date – the most actions of any district – are pending there. The district is centrally located, convenient and accessible, and it has the judicial resources and expertise to manage complex nationwide litigation.

I. BACKGROUND

This motion for transfer involves fifteen (15) pending cases in twelve (12) district courts asserting similar claims, with four (4) of the fifteen (15) Actions pending in the Northern District of Georgia. To date, eight (8) different law firms have filed cases.

The pending cases allege plaintiffs were prescribed and administered Dupixent (dupilumab), a biologic used to treat various inflammatory conditions, including atopic dermatitis, moderate-to-severe asthma, inadequately controlled chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, prurigo nodularis, chronic spontaneous urticaria, and bullous pemphigoid. The Plaintiffs used Dupixent for at least one of these Indications and subsequently developed various forms of T-cell lymphoma.

The Dupixent sold and administered to Plaintiffs was manufactured and sold pursuant to a Collaboration Agreement between the Defendants Regeneron Pharmaceuticals, Inc. (hereinafter "Regeneron) and Sanofi-Aventis U.S. LLC (hereinafter "Sanofi").[1] In accordance with that agreement, Regeneron and Sanofi have worked together to co-develop and then sell Dupixent. Moreover, Genzyme Corporation (hereinafter "Genzyme") is a wholly owned subsidiary of Sanofi that has worked extensively on the funding and dissemination of third-party research of Dupixent that it has thereafter used to market and sell Dupixent in the United States.[2]

[1] *See* Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.; Amendment No. 4 to Collaboration Agreement, by and between Sanofi-Aventis U.S., LLC (successor in interest to Aventis Pharmaceuticals, Inc.) and Regeneron Pharmaceuticals, Inc., effective as of January 31, 2006; License and Collaboration Agreement, dated as of November 28, 2007, by and among Aventis Pharmaceuticals Inc., Sanofi-Aventis Amerique Du Nord and Regeneron Pharmaceuticals, Inc.; Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009, by and among Aventis Pharmaceuticals Inc., Sanofi-Aventis Amerique Du Nord, and Regeneron Pharmaceuticals, Inc.

[2] *See* Am. Answer ¶¶ 46-47, Doc. 64 in *Immunex Corp. v. Sanofi*, No. 2:17-cv-02613, 2017 (C.D. Cal. Aug. 16, 2017) (Genzyme admitting its involvement in marketing and selling Dupixent in the United States and preparing and deploying a sales force to offer for sale and to sell Dupixent in the United States).

Recent epidemiological studies have shown a strong association between the usage of Dupixent and the development of T-cell lymphomas. Specifically, an analytical cohort study published in the Journal of the American Academy of Dermatology in 2024 found that Dupixent patients exhibited over a 300% increased risk of developing cutaneous T-cell lymphoma ("CTCL") compared to untreated subjects.[3] Another analytical cohort study published in June 2025 in the European Respiratory Journal found a nearly 400% increased risk of T-cell and NK-cell lymphomas among asthma patients taking Dupixent as compared to those taking inhaled corticosteroids or long-acting beta agonists.[4] This study also observed similar increases in risk (450-500%) for various T-cell lymphoma subtypes, including CTCL, peripheral T-cell lymphoma and Mycosis fungoides/Sézary syndrome. In total, to date seven epidemiologic studies have reported a strong and consistent increased risk of T-cell lymphomas with the use of Dupixent. These studies follow years of other literature reflecting that Dupixent use is involved in the development of T-cell lymphomas.

On January 15, 2025, the FDA notified Regeneron that it identified and began evaluating a newly identified safety signal (NISS) regarding "dupilumab therapy for atopic dermatitis being associated with increased risk of cutaneious [*sic*] T-cell lymphoma" on December 26, 2024. The FDA further noted that the agency had classified this NISS as a potential safety risk.[5,6] On March 31, 2025, the FDA published its quarterly report "Potential Signals of Serious Risks/New

[3] Hasan I, Parsons L, Duran S, Zinn Z. Dupilumab therapy for atopic dermatitis is associated with increased risk of cutaneous T cell lymphoma: A retrospective cohort study. J Am Acad Dermatol. 2024;91(2):255-258. doi:10.1016/j.jaad.2024.03.039

[4] Sheng-Kai Ma K, Brumbaugh B, Saff RR, et al. Dupilumab and lymphoma risk among patients with asthma: a population-based cohort study. Eur Respir J. 2025 (Ahead-of-Print). doi:10.1183/13993003.00139-2025

[5] Center for Drug Evaluation and Research. Manual of Policies and Procedures: MAPP 6700.9: FDA Posting of Potential Signals of Serious Risks Identified by the FDA Adverse Event Reporting System. U.S. Food and Drug Administration. September 9, 2019.

[6] Center for Biologics Evaluation and Research. Standard Operating Procedures and Policies: SOPP 8420: FDAAA Section 921: Posting of Potential Signals of Serious Risk. U.S. Food and Drug Administration. February 27, 2022.

Safety Information Identified by the FDA Adverse Event Reporting System (FAERS)" for the 4th quarter of 2024.[7] However, to this date, Defendants have yet to implement appropriate labeling revisions to add necessary information regarding the risk of CTCL or other T-cell lymphoma subtypes with Dupixent use or appropriate mitigation strategies to reduce or eliminate the risk of Dupixent-induced T-cell lymphoma.

A. Defendants

Regeneron invented Dupixent and is the current official sponsor of the Biologics License Application for Dupixent in the United States. Regeneron has worked pursuant to a Collaboration Agreement with Sanofi and its subsidiary Genzyme to collectively develop, market, and sell Dupixent in the United States.

B. Dupixent

Dupixent, chemical name dupilumab, is a biologic used to treat various inflammatory conditions, namely atopic dermatitis, moderate-to-severe asthma, inadequately controlled chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, prurigo nodularis, chronic spontaneous urticaria, and bullous pemphigoid. Dupixent is supplied in 200 mg and 300 mg single-dose prefilled syringes and single-dose prefilled pens. Dupixent is self-administered by patients or by caregivers through a subcutaneous injection in 1-, 2- or 4-week intervals depending on age, weight and therapeutic indication. Dupixent was initially approved in 2017 for the treatment of adult patients with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Additional indications for the conditions that are described herein followed thereafter.

[7] October - December 2024 | Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System (FAERS). U.S. Food and Drug Administration. March 31, 2025. https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/october-december-2024-potential-signals-serious-risksnew-safety-information-identified-fda-adverse

C. T-Cell Lymphoma

T-cell lymphomas, often classified together with NK-cell lymphomas,[8] represent a heterogenous group of aggressive non-Hodgkin lymphomas where cancer develops in the T-cell and natural killer white blood cells. There are multiple subtypes of T-cell lymphoma including CTCL, Mycosis fungoides, Sézary syndrome, peripheral T-cell lymphoma, anaplastic large cell lymphoma, subcutaneous panniculitis-like T-cell lymphoma, follicular helper T-cell lymphoma and extranodal natural killer/T-cell lymphoma.[9] T-cell lymphomas are extremely rare conditions estimated to affect fewer than 20 out of every 1 million people in the United States annually.[10] Many T-cell lymphomas are considered incurable, and accordingly, treatment generally aims to put the disease into remission, leaving the patient with fewer signs and symptoms.[11] Many patients will require several different types of treatments throughout their lifetime. T-cell lymphomas can cause a variety of severe symptoms which can significantly impair health-related quality of life, especially in later stages of the disease.[12] T-cell lymphomas can also metastasize to affect multiple tissues and organs. Survival rates vary greatly depending on disease subtype, site of involvement and stage at the time of diagnosis. Estimated 5-year survival rates in peripheral T-cell lymphoma are between 20% and 40%, while patients with moderate to advanced CTCL, Mycosis fungoides and Sézary syndrome also experience markedly reduced

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[8] Attygalle AD, Karube K, Jeon YK, et al. The fifth edition of the WHO classification of mature T cell, NK cell and stroma-derived neoplasms. J Clin Pathol. 2025;78(4):217-232. Published 2025 Mar 19. doi:10.1136/jcp-2025-210074

[9] Campo E, Jaffe ES, Cook JR, et al. The International Consensus Classification of Mature Lymphoid Neoplasms: a report from the Clinical Advisory Committee. Blood. 2022;140(11):1229-1253. doi:10.1182/blood.2022015851

[10] Stuver R, Epstein-Peterson ZD, Horwitz SM. Few and far between: clinical management of rare extranodal subtypes of mature T-cell and NK-cell lymphomas. Haematologica. 2023;108(12):3244-3260. doi:10.3324/haematol.2023.282717

[11] Olsen EA, Whittaker S, Willemze R, et al. Primary cutaneous lymphoma: recommendations for clinical trial design and staging update from the ISCL, USCLC, and EORTC. Blood. 2022;140(5):419-437. doi:10.1182/blood.2021012057

[12] Shinohara MM, Mahurin HM, Tarabadkar E, et al. Health-related quality of life in cutaneous T-cell lymphoma: A cross-sectional survey study. Skin Health Dis. 2021;1(3):e45. doi:10.1002/ski2.45

survival.[13,14]

II. ARGUMENT

Transfer to the Northern District of Georgia for consolidation and coordination of pretrial proceedings is appropriate and necessary as the Actions involve common questions of fact and law, the centralization of these Actions will serve the convenience of the parties and witnesses and will promote the just and efficient conduct of the litigation. 28 U.S.C. § 1407.

Transfer is not premature as there are a significant number of Dupixent cases involving the development of T-cell lymphoma already pending in multiple federal district courts; at least fifteen (15) cases on file in at least twelve (12) different federal district courts in nine (9) different states. It is anticipated that significantly more cases will be filed given that over 1,000,000 patients have been treated with Dupixent and given that to this day no warning exists in the prescribing information for Dupixent concerning T-cell lymphoma.[15]

Given the geographic variety of these cases, the lack of any discovery in any filed case (with each of the cases being so newly filed that Defendants have not yet filed an Answer or dispositive motion), and the expected number of future filings, these cases are ripe for consolidation before one transferee judge. Thus, transfer pursuant to 28 U.S.C. § 1407 will lead to a just and expeditious resolution of these Actions to the benefit of all parties.

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[13] Zackheim HS, Amin S, Kashani-Sabet M, McMillan A. Prognosis in cutaneous T-cell lymphoma by skin stage: long-term survival in 489 patients. J Am Acad Dermatol. 1999;40(3):418-425. doi:10.1016/s0190-9622(99)70491-3

[14] Kwong YL, Zhang H, Wang X, Tse E. Epidemiology of mature T-cell and NK-cell neoplasms: east and west. Lancet Reg Health West Pac. 2025;62:101646. doi:10.1016/j.lanwpc.2025.101646

[15] 9/27/2024 Regeneron Press Release: https://investor.regeneron.com/news-releases/news-release-details/dupixentr-dupilumab-approved-us-first-ever-biologic-medicine/

A. The Dupixent Cases Involve Common Questions of Fact and Law

The cases allege that the plaintiffs have received Dupixent manufactured, developed, marketed and sold by common defendants Regeneron, Sanofi, and Genzyme. Federal civil actions are eligible for transfer pursuant to 28 U.S.C. § 1407 if they involve "common questions of fact" subject to discovery. *See* 28 U.S.C. § 1407(a); *In re Kugel Mesh Hernia Patch Prods. Liab. Litig*., 493 F. Supp. 2d 1371, 1372-73 (J.P.M.L. 2007). The statute, however, does not require complete identification of common questions of fact to justify transfer. *In re Zyprexa Prods, Liab. Litig*., 314 F. Supp. 2d 1380, 1381 (J.P.M.L. 2004). Almost all personal injury cases involve individualized factual issues, such as questions of causation that are case-specific. However, the existence of such differences has not been an impediment to centralization in the past and does not negate the common factual issues. *See In re Xarelto (Rivaroxaban) Prods. Liab. Litig.,* 65 F. Supp. 3d 1402, 1404 (J.P.M.L. 2014); *In* re *Wright Medical Technology, Inc., Conserve Hip Implant Prods. Liab. Litig*., 844 F. Supp. 2d 1371, 1372 (J.P.M.L. 2012).

The Panel has regularly ordered transfer for coordinated or consolidated proceedings in instances involving the use of pharmaceuticals that were manufactured and distributed by common defendants. Prior MDLs involving pharmaceutical product liability and negligence claims include but are not limited to: *In re Valsartan Prods. Liab. Litig.*, C.A. 1:19-md-02875-RBK-JS; *In re Elmiron (Pentosan Polysulfate Sodium) Prods. Liab. Litig.*, C.A. 2:20-md-02973-BRM-ESK; *In re Proton-Pump Inhibitor Prods. Liab. Litig.*, C.A. 2:17-md-02789-CCC-MF; *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, C.A. 3:08-cv-00008-FLW; *In re Actos® (Pioglitazone) Prods. Liab. Litig.*, C.A. 6:11-MD-02299-RFD-PJH; *In re Zantac (Ranitidine) Prods. Liab. Litig.*, C.A. 9:20-md-02924-RLR-BER; *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, C.A. 2:16-md-02740-KDE-MBN; *In re Glucagon-Like Peptide-1 Receptor Agonists*

(GLP-1 RAS) Prods. Liab. Litig., C.A. 2:24-md-03094-KSM; *In re Depo-Provera (Depot Medroxyprogesterone Acetate) Prods. Liab. Litig.,* C.A. 3:25-md-03140-MCR-HTC.

Similarly, the cases presented here share a common core of operative facts. All Plaintiffs allege that Dupixent is defective, contains inadequate warnings, and all Plaintiffs have been diagnosed with a subtype of T-cell lymphoma. The cases involve a shared biomechanism of action as well as the same injury, T-cell lymphoma, and sequelae and treatment related thereto.

Among the common factual issues are the causal relationship between Dupixent and the associated increased risk of development of T-cell lymphoma and its subtypes, as well as the failure to warn of that risk in the label which continues to this date. Each Plaintiff alleges Defendants knew or should have known of the unreasonably high risk of developing T-cell lymphoma associated with Dupixent and yet failed to properly warn doctors and patients when they knew of the severe dangers associated with it. Cases that share core issues of fact concerning design, manufacture, testing, marketing, and labeling of a pharmaceutical product are appropriate for consolidation. *See In re Invokana (Canagliflozin) Prods. Liab. Litig.*, C.A. 3:16-md-02750- BRM-LHG; *see also In re Valsartan Prods. Liab. Litig.*, C.A. 1:19-md-02875-RBK-JS; *see also In re Elmiron (Pentosan Polysulfate Sodium) Prods. Liab. Litig.*, C.A. 2:20-md-02973-BRM-ESK; *see also In re Proton-Pump Inhibitor Prods. Liab. Litig.*, C.A. 2:17-md-02789-CCC-MF; *see also In re Xarelto (Rivaroxaban) Prod. Liab. Litig.*, C.A. 2:14-md-02592-EEF-MBN; *see also In re Zantac (Ranitidine) Prods. Liab. Litig.*, C.A. 9:20-md-02924-RLR-BER; *see also In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, C.A. 2:07-md-01871-CMR; *see also In re Tepezza Mktg, Sales Practices & Prods. Liab. Litig.*, C.A. 1:23-md-03568-TMD.

Plaintiffs have also asserted the same legal theories of liability, including negligence, failure to warn, strict liability, and fraud. Plaintiffs raise common questions of fact to support their theories of liability including: the association in the scientific literature between usage of Dupixent and development of T-cell lymphoma; how Dupixent is mechanistically involved in the development of T-cell lymphoma; when Defendants first should have learned of the harmful effects caused by Dupixent; whether, and for how long, Defendants concealed this knowledge from physicians and patients and continued to promote sales of Dupixent; whether Defendants failed to provide adequate warnings concerning Dupixent and the risk of T-cell lymphoma; whether Defendants engaged in fraudulent and negligent marketing practices regarding Dupixent; and the nature and extent of damages suffered by Plaintiffs as a result of their use of Dupixent. Moreover, Plaintiffs anticipate that Defendants will raise a common preemption defense concerning the labeling of Dupixent that will be most efficiently adjudicated by a single Court.

Accordingly, Plaintiffs respectfully request the Panel order coordinated or consolidated proceedings for cases involving the usage of Defendants' Dupixent and the development of T-cell lymphoma.

B. Consolidation of these Cases Would Serve the Convenience of the Parties and Witnesses

Pretrial coordination of these cases will serve the convenience of the parties and witnesses. When cases involve common issues of fact, consolidation will serve the convenience of the parties and witnesses by preventing the duplication of discovery as well as inconsistent or repetitive pretrial rulings. *See In re Meridia Prods. Liab. Litig.,* 217 F. Supp. 2d 1377 (J.P.M.L. 2002). It will also conserve the resources of the parties and the judiciary. *See id.* at 1378.

Plaintiffs' common theories of negligence, strict liability, and failure to warn run throughout each action and will reduce duplicative discovery and motion practice relating to those common theories. Consolidation will reduce the number of discovery requests and the costs associated with multiple productions in numerous district courts. Specifically, depositions of key witnesses can be coordinated. Additionally, Defendants can produce documents to one central location as opposed to producing documents to each individual plaintiff. If transfer is denied in this litigation, these cases will proceed on independent tracks, requiring duplicative discovery and repeated depositions of the same corporate personnel. Additionally, judicial resources will most efficiently be utilized by adjudicating Defendants' common preemption defense in a single court. In short, both Plaintiffs and Defendants would benefit from centralization and the economies of scale that it would bring.

Furthermore, as discussed more fully below, the Northern District of Georgia is a very convenient location for these cases.

C. Transfer to the Northern District of Georgia Will Promote the Just and Efficient Conduct of the Litigation

This litigation should be centralized in the Northern District of Georgia. More than twenty-five percent of the cases filed to date – the most actions of any district – are pending there. The district is centrally located and is otherwise convenient and accessible to the parties. Atlanta is located within the district and is also the location where nearly all of the judges in the district preside. Atlanta's airport is the busiest in the country with 63.1 million passengers traveling through its Hartsfield-Jackson International Airport in 2025 alone.[16] Notably, this was 12 million passengers more than any other airport in the country. Moreover, the District is easily accessible via direct flights for all the parties.

[16] https://www.oag.com.

The Northern District of Georgia also has the judicial resources and expertise to manage complex nationwide litigation. There are presently fourteen (14) District Court Judges and ten (10) Magistrate Judges in the District. There are currently four MDLs pending in the district, however, one of those MDLs (MDL 2782) shows no active cases pending on the docket. Therefore, there appears to be sufficient capacity for an additional MDL in the District.

Plaintiffs respectfully submit that Judge Thomas Thrash is appropriate for consideration for this MDL. Three of the four cases pending in the Northern District of Georgia have been assigned to Judge Thomas Thrash. Judge Thrash, who served as Chief Judge from 2014 to 2021, is thoroughly familiar with the nuances of complex multidistrict litigation by virtue of having presided over multiple previous MDLs, including product liability MDLs. Judge Thrash's MDL experience runs the gamut, including several consumer data breach litigations; product liability litigations regarding metal-on-metal hip implants; defective roof shingles; contaminated peanut butter; antitrust litigation; and consumer protection litigation regarding interest rates. Centralization in the Northern District of Georgia before Judge Thrash will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation.

III. CONCLUSION

Transfer and consolidation for pre-trial proceedings of all pending and subsequently filed Dupixent T-cell lymphoma cases will promote the just and efficient conduct of these Actions by allowing national coordination of discovery and other pretrial efforts, will prevent duplicative and potentially conflicting pre-trial rulings, will reduce the costs of litigation, and allow cases to proceed more efficiently to trial.

For all of the foregoing reasons, Plaintiffs respectfully request that the Panel issue an order transferring all actions listed in the attached Schedule of Actions, as well as all

subsequently filed related actions, for coordinated and consolidated pretrial proceedings to the Northern District of Georgia, Atlanta division, before Judge Thrash.

Dated: February 13, 2026

Respectfully submitted,

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