BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In Re: Incretin Mimetics Products Liability Litigation	§ § § § § § § §	MDL - 2452

ELI LILLY AND COMPANY AND AMYLIN PHARMACEUTICALS, LLC'S JOINT BRIEF IN SUPPORT OF PLAINTIFFS' AMENDED MOTION FOR TRANSFER TO THE SOUTHERN DISTRICT OF CALIFORNIA PURSUANT TO 28 U.S.C. § 1407

I. INTRODUCTION

Defendants Eli Lilly and Company (Lilly) and Amylin Pharmaceuticals, LLC (Amylin) hereby join in support of the Plaintiffs' Motion for Transfer of the pancreatic cancer actions at issue to the Southern District of California for consolidated or coordinated pretrial proceedings before the Honorable Anthony J. Battaglia. These actions relate to a group of incretin-based antidiabetic prescriptions medicines[1] which includes Byetta (developed and marketed jointly by Defendants Lilly and Amylin[2]), Victoza (developed and marketed by

[1] Plaintiffs refer to these medicines as part of the incretin-mimetic class of diabetes treatments. As discussed below, Section II, the four medicines involved in these actions belong to two different classes of antidiabetic medicines that are each incretin-based: GLP-1 agonists, also referred to as incretin mimetics, and DPP-4 inhibitors. As a result, "incretin mimetics" is an inaccurate label for this potential MDL and should be retitled. Lilly and Amylin respectfully suggest, *In re GLP-1/DPP-4 Products Liability Litigation*.

[2] During the relevant time period, Byetta was jointly marketed by Amylin and Lilly. This collaboration ended in November of 2011 and Lilly has not marketed or sold any Byetta in the U.S. since then. Amylin continues to market Byetta to diabetes patients.

Defendant Novo Nordisk, Inc. and Novo Nordisk A/S), and Januvia and Janumet (two related medicines developed and marketed by Defendant Merck Sharp & Dohme).

The requested transfer is warranted because the actions involve common questions of fact, and centralization into a single MDL for pancreatic cancer injuries would promote efficiency and justice.

First, the Plaintiffs' actions contain virtually identical allegations that Plaintiffs developed pancreatic cancer caused by the use of Defendants' incretin-based medicines. The actions allege common factual questions relating to whether the Defendants' products could have caused Plaintiffs' pancreatic cancers. Although individualized questions will arise with respect to each of the Defendants' separate medicines, common questions regarding Plaintiffs' pancreatic cancer causal claims apply across the group of incretin-based antidiabetic medicines at issue in these actions. Factual questions related to these common causal claims are prominent in each of these actions and weigh in favor of consolidating them into a single MDL.

Second, given the common questions related to whether the Defendants' incretin-based medicines can cause pancreatic cancer, centralization of these actions into a single MDL will eliminate duplicative expert discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel, and the judiciary.

Third, weighing all the factors, the Southern District of California is the most convenient transferee jurisdiction, and Judge Battaglia is the most appropriate transferee judge. The Southern District of California has a nexus to this nationwide litigation, as Defendant Amylin first developed Byetta at its facilities in San Diego. Amylin's company offices are in San Diego and the majority of Amylin's witnesses still reside there. Additionally, as represented

by Plaintiffs, there are more than two dozen pancreatic cancer actions pending in California state court as part of a Judicial Council Coordinated Proceeding (JCCP), *In re Byetta Cases*, JCCP No. 4574, in Los Angeles. Centralization in the Southern District of California will facilitate coordination with the pending JCCP. Further, 45 of the actions identified by Plaintiffs are already pending in the Southern District of California, and 29 of the 53 actions identified by the Plaintiffs are already before Judge Battaglia. Judge Battaglia—an experienced jurist who has developed a familiarity with the actions and the parties over the last seven months—is well-positioned to oversee the consolidation and coordination of these cases.[3]

II. BACKGROUND

The 53 actions that Plaintiffs seek to centralize for pretrial purposes claim pancreatic cancer injuries allegedly caused by a group of incretin-based antidiabetic medicines, which includes Byetta, Januvia, Janumet, and Victoza. Plaintiffs allege that the mechanism by which these medicines treated their diabetes also caused their pancreatic cancer, that Defendants knew or should have known that using their medicines increases the risk of pancreatic cancer, and that, as a result, the medicines were defectively designed, manufactured, and marketed and Defendants failed to provide appropriate warnings.

Incretins are naturally-occurring hormones released into the bloodstream from the small intestine to signal the pancreas to release insulin during and after a meal to reduce blood glucose levels. Patients with Type 2 diabetes suffer from high blood sugar levels (or

[3] Plaintiffs make numerous unsupported and untrue statements about Lilly, Amylin and Byetta. Lilly and Amylin will reserve their substantive responses to those statements for a more relevant forum.

hyperglycemia) and often do not have enough incretins. The most significant incretin for diabetes patients is the naturally-occurring antidiabetic hormone called glucagon-like peptide-1 (GLP-1). Naturally-occurring GLP-1 is quickly metabolized by an enzyme called dipeptidyl-peptidase-4 (DPP-4). Due to the rapid degradation and inactivation by the DPP-4 enzyme, injecting naturally-occurring GLP-1 into the blood stream (as one would do with insulin) is not an effective long-term treatment for a chronic illness like diabetes.[4]

Scientists, however, have created two classes of medicines to overcome this limitation. The GLP-1 agonists (also referred to as incretin mimetics) mimic naturally-occurring GLP-1 hormones but are resistant to metabolism by DPP-4 enzymes. Thus, GLP-1 agonists increase GLP-1 receptor activity in diabetic patients. DPP-4 inhibitors slow the degradation and inactivation of naturally-occurring GLP-1 by the DPP-4 enzyme, which increases the time over which naturally-occurring GLP-1 can act. Though the GLP-1 agonists and DPP-4 inhibitors have different mechanisms of action, both classes of medicines lower blood sugar levels by increasing GLP-1 receptor activity.[5]

Plaintiffs allege that Defendants' incretin-based medicines increased their levels of GLP-1 receptor activity which in turn caused their pancreatic cancers. Lilly and Amylin deny Plaintiffs' alleged causal claims as there is no evidence establishing a causal relationship between Byetta (or, for that matter, any of the other incretin-based antidiabetic medicines) and pancreatic cancer. Plaintiffs' allegation that increased levels of GLP-1 receptor activity cause

[4] *See* Erika Gebel, PhD, *Incretins and Diabetes Medications,* DIABETES FORECAST (December 2009) (available at http://forecast.diabetes.org/print/1799).

[5] *Id.*

pancreatic cancer will be a common question of fact, for all Defendants, which will be developed through expert discovery and subject to *Daubert*[6] motions.[7]

At present, Lilly and Amylin are codefendants in 42 federal court actions alleging pancreatic cancer injuries from the use of Byetta. Of these actions, 40 are currently pending in the Southern District of California and 28 are already before Judge Battaglia. Of these 28 actions, 14 involve Plaintiffs who allege pancreatic cancer injuries from taking more than one of Defendants' medicines.

III. ARGUMENT

A. Standard

Transfer of actions to one district for coordinated or consolidated pretrial proceedings is appropriate when (1) "civil actions involving one or more common questions of fact are pending in different districts," (2) "[transfer] will promote the just and efficient conduct of such actions," and (3) "[transfer] will be for the convenience of parties and witnesses."[8] In deciding whether to transfer actions, "the Panel must weigh the interests of all the plaintiffs and all the defendants, and must consider multiple litigation as a whole in the light of the purposes of the law."[9] Ultimately, centralization should "serve[] judicial economy by avoiding duplication

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[6] *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

[7] Lilly and Amylin are confident that the differences between the GLP-1 agonists (Byetta and Victoza), on the one hand, and the DPP-4 inhibitors (Janumet and Januvia), on the other hand, can be addressed through case management and pretrial procedures developed by the coordination judge with input from the parties.

[8] 28 U.S.C. § 1407.

[9] *In re Childrens' Books Litigation*, 297 F. Supp. 385, 386 (J.P.M.L. 1968).

of discovery, preventing inconsistent or repetitive rulings, and conserving the financial resources of the parties, their counsel, and the judiciary."[10]

B. Common questions of fact exist regarding the cause of Plaintiffs' pancreatic cancer injuries that will most justly and efficiently be managed through coordinated or consolidated pretrial proceedings.

Lilly and Amylin agree with Plaintiffs that centralization is appropriate because Plaintiffs allege common questions of fact that are most efficiently and justly handled through a single, centralized MDL proceeding related to claims that incretin-based antidiabetic treatments cause pancreatic cancer.

In this case, causal questions predominate.[11] As described above, all actions involve allegations that using an incretin-based antidiabetic drug causes pancreatic cancer. In each case, Plaintiffs allege that the Defendants' medicines increased the GLP-1 receptor activity in their bodies and that this increase caused their pancreatic cancers to develop. Whether incretin-based medicines can cause pancreatic cancer under any circumstance is an essential issue in each Plaintiff's action. If Plaintiffs are not able to establish a causal connection between

[10] MANUAL FOR COMPLEX LITIGATION, FOURTH, §22.33.

[11] In addition to the common issues involving all Defendants, each subset of cases (i.e., the Byetta cases, the Januvia/ Janumet cases and the Victoza cases) raises myriad common issues for the product(s) at issue. These product-specific common issues include, among other things: (i) whether the Defendant(s) adequately tested its or their drug(s), (ii) whether the Defendant(s) knew of the alleged risk of pancreatic cancer associated with its or their drug(s), and (iii) whether the Defendant(s) failed to warn of that alleged risk. Although the relevant facts and ultimate outcome of these issues may vary by product, Plaintiffs' allegations are virtually identical for each Defendant. The discovery Plaintiffs have propounded to date has been virtually identical for each Defendant. Centralization of these product-specific issues to a single MDL will allow for efficient management of discovery and ensure similar treatment for the similarly-situated Defendants.

incretin-based medicines and pancreatic cancer, then individualized questions about whether particular medicines can cause pancreatic cancer and whether particular medicines caused individual plaintiffs' injuries will never be reached. To establish such a causal connection in the absence of a coordinated MDL, every plaintiff would have to produce expert evidence to support his or her causal theory and Defendants would have to produce expert evidence to refute it in every action.

Centralization will promote the just and efficient conduct of the actions by limiting duplicative expert discovery on these core common questions of fact and ensuring consistent pretrial rulings for all parties. Centralization will avoid repetitive depositions of key common causation experts. Further, given the expected importance of expert testimony, pretrial rulings, including on *Daubert* and other grounds, will be especially important. Centralizing these actions will prevent inconsistent treatment for different Plaintiffs or Defendants and so promote justice.[12] Ultimately, by eliminating the need for duplicative discovery and pretrial motion practice, the time, money, and resources of the parties, their counsel, and the judiciary will be best conserved.

Although the Plaintiffs' actions allege common questions, they also raise a number of individualized questions related to each Defendant, each Plaintiff, and each claim. As the Panel has previously noted, however:

> Though the actions certainly present some individual issues, this is usually true of device cases and other products liability cases. Section 1407 does not require a complete identity or even a

[12] *See In re Tylenol (Acetaminophen) Marketing Sales Practices and Products Liability Litigation*, MDL No. 2436, Document No. 91, at *2 (J.P.M.L. April 1, 2013).

> majority of common factual issues as a prerequisite to centralization.[13]

Here, the common questions will significantly impact the viability of the rest of the Plaintiffs' claims. Further, as explained by the Panel, transferee judges have shown the ability to use their discretion in structuring pretrial proceedings to account for the individual differences between cases and parties and minimize the impact of the coordinated proceedings on them.[14]

Thus, given the efficiency and consistency obtained by centralizing these actions and the ability of a transferee judge to mitigate any case-specific individualized issues, it is appropriate to centralize all Plaintiffs' actions into a single MDL.

C. Transfer to the Southern District of California before Judge Battaglia will be most convenient to the parties given his familiarity with the case.

Lilly and Amylin agree that the Southern District of California will be the most convenient transferee district for the parties and that Judge Battaglia is the most appropriate transferee judge for this case. The Southern District of California is an appropriate transferee district. San Diego is a readily accessible city with a nexus to this litigation given that Amylin first developed Byetta at its San Diego facilities and its company offices are in San Diego. Many Amylin current and former employees—and most of its witnesses with knowledge relevant to the

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[13] *In re Zimmer Durom Hip Cup Products Liability*, 717 F. Supp. 2d 1376, 1378 (J.P.M.L. 2010); *see also In re Tylenol* at *1 (rejecting defendant and plaintiff arguments that centralization should be denied because plaintiffs' over-the-counter drug liability claims will turn on plaintiff-specific facts).

[14] *In re Oreck Corp. Halo Vacuum Mktg. & Sales Practices Litig.*, 842 F. Supp. 2d 1380, 1381, 2012 U.S. Dist. LEXIS 12830, 2012 WL 361687 (J.P.M.L. 2012)(citing *In re Medtronic, Inc., Implantable Defibrillators Prods. Liab. Litig.*, 408 F. Supp. 2d 1351, 1352 (J.P.M.L. 2005)).

Plaintiffs' claims—still reside in San Diego County. The vast majority of already-filed actions also have been filed in this district, and the cases in this district have progressed most significantly. In fact, on February 13, 2013 a scheduling order was issued in the cases before Judge Battaglia. Further, as this Panel recently noted, centralization of federal actions in the same state where there are a significant number of state court actions likely will facilitate coordination with the state litigation.[15] Plaintiffs have represented that there are more than two dozen related pancreatic cancer actions pending in California state court. Centralization in the Southern District of California will facilitate coordination with these pending state court actions.

Importantly, there are no other district courts in which related actions have been filed that would make them more amenable to receiving transfer of these actions. To the Defendants' knowledge, no action has been filed in any district in which any of the other Defendants maintains its company offices. No more than two actions have been filed in any one district other than the Southern District of California.[16] And no district outside of the Southern District of California has pending cases against all Defendants.

In addition, Judge Battaglia is the most appropriate transferee judge. Since October 2012, Judge Battaglia and the Honorable Magistrate Judge Mitchell D. Dembin have

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[15] *See, e.g., In re Fresenius Granuflo/Naturalyte Dialysate Products Liability Litigation*, MDL No. 2428, Document 141, *2 (J.P.M.L. March 29, 2013) (noting that "the parties informed the Panel that there are over seventy actions pending in Massachusetts state court, and centralization in the District of Massachusetts likely will facilitate coordination with this pending state litigation.").

[16] District of Arizona: 2 actions; District of Colorado: 1 action; Southern District of Kansas: 1 action; Eastern District of Missouri: 1 action; Western District of Oklahoma: 2 actions; and Pennsylvania: 1 action.

actively managed their increasing caseload of related pancreatic cancer actions and have developed a familiarity with the parties and the actions. To date, 29 of the 53 actions identified in Plaintiffs' Schedule of Actions are already pending before Judge Battaglia. Plaintiffs have represented that the additional actions pending in the Southern District of California are likely to be transferred to his Court as well. Although Judge Battaglia has an existing MDL assigned to him, the Panel has previously ruled that a judge managing one MDL is not precluded from being assigned a second.[17] Indeed, at present there are more than 50 district court judges overseeing multiple MDLs.[18]

In the event Judge Battaglia is not available to preside over a coordinated proceeding that would include *all* of the actions involving all of the incretin-based antidiabetic medicines, Lilly and Amylin ask that the actions involving Byetta be coordinated and assigned to him. Given Amylin's nexus to San Diego—a connection no other Defendant has—and given

[17] *See, e.g.*, *In re Nexium (Esomeprazole) Prods. Liab. Litig. v. AstraZeneca*, No. 2404, 2012 U.S. Dist. LEXIS 176084, at *7 (J.P.M.L. Dec. 10, 2012) (assigning MDL to the Honorable Dale S. Fischer in the Central District of California though he had been assigned an MDL a year prior in *In re CitiMortgage, Inc*., 816 F. Supp. 2d 1375 (J.P.M.L. 2011)); *In re Watson Fentanyl Patch Prods. Liab. Litig.*, 883 F. Supp. 2d 1350 (J.P.M.L. 2012) (assigning MDL to the Honorable Matthew F. Kennelly in the Northern District of Illinois though he had two pending MDLs which had been assigned in *In re Navistar 6.0 L Diesel Engine Prods. Liab. Litig.*, 777 F. Supp. 2d 1347 (J.P.M.L. 2011) and *In re Text Messaging Antitrust Litig.*, 588 F. Supp. 2d 1372 (J.P.M.L. 2008)); *In re NFL Players' Concussion Injury Litig*., 842 F. Supp. 2d 1378 (J.P.M.L. 2012) (assigning MDL to the Honorable Anita B. Brody in the Eastern District of Pennsylvania though she had a pending MDL which had been assigned in *In re Comcast Corp. Set-Top Cable TV Box Antitrust Litig.*, 626 F. Supp. 2d 1353 (J.P.M.L. 2009)).

[18] Based on an analysis of active MDL litigations found in the Panel's CM/ECF case reporting system on April 23, 2013.

that the California JCCP involves Byetta,[19] the factors favoring coordination and consolidation in the Southern District of California are strongest for Byetta cases. Of the 29 cases already assigned to Judge Battaglia, 28 involve Byetta.[20]

In the event Judge Battaglia is unavailable for any coordinated proceeding, Lilly and Amylin agree with Defendant Merck's suggestion that either the Western District of Oklahoma or the District of Colorado would be well suited to preside over the cases, for the reasons outlined by Merck.

IV. CONCLUSION

Given the common questions of fact related to whether Plaintiffs' pancreatic cancer was caused by Defendants' incretin-based antidiabetic medicines, centralization of these actions will achieve the purposes set forth in Section 1407. It will eliminate duplicative expert discovery, prevent inconsistent pretrial rulings, and so conserve the resources of the entities and individuals involved. Thus, Lilly and Amylin respectfully join Plaintiffs in requesting that the Panel transfer all actions to the Southern District of California for consolidation or coordination in front of Judge Battaglia.

[19] There is currently one case in the JCCP involving Januvia but that case has been stayed since it was transferred to the JCCP in early 2012 and it does not allege pancreatic cancer.

[20] Fifteen of the cases assigned to Judge Battaglia involve Januvia and/or Janumet and two involve Victoza.

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Respectfully submitted,

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