BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: FARXIGA (DAPAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	MDL Docket No. _____

MEMORANDUM IN SUPPORT OF MOTION FOR TRANSFER OF ACTIONS TO THE SOUTHERN DISTRICT OF NEW YORK PURSUANT TO 28 USC §1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

Pursuant to 28 U.S.C. § 1407 and Judicial Panel on Multi-District Litigation ("JPML") Rule 6.2, Plaintiff Chaim Z. Aron respectfully moves this Judicial Panel on Multi-District Litigation ("Panel") for an Order 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 either the Southern District of New York before Judge Lorna G. Schofield, the Eastern District of Pennsylvania before Judge Mitchell Goldberg, or the Southern District of Illinois before Judge Nancy J. Rosenstengel, who all have Farxiga cases assigned to them.

I. BACKGROUND

This motion for transfer involves eighteen pending cases in six district courts asserting similar claims, with thirteen of the eighteen actions pending in the Southern District of New York. In particular, cases have been filed in the Eastern District of Pennsylvania,[1]

[1] The case currently pending in the Eastern District of Pennsylvania, *Seay v Janssen et al.* is a combination Farxiga case with Invokana. It is one of a group of cases removed to the Eastern District on November 9, 2016 and is currently the subject of a remand motion. The case involves a plaintiff that first used Invokana, then used Farxiga (Xigduo XR) in the few weeks before suffering ketoacidosis, so Farxiga is likely the target or primary defendant.

Southern District of Illinois, Northern District of Mississippi, Southern District of Alabama, and the Eastern District of Louisiana. Upon information and belief, Counsel for the plaintiff herein anticipates that multiple additional complaints will be filed in the near future.

A. The Plaintiffs, Product, and Alleged Injury.

Each of these Actions arise from the same or similar operative facts and wrongful conduct alleging that, as a result of ingesting Farxiga, Plaintiffs have suffered sudden onset of life-threatening diabetic ketoacidosis (often in the setting of normal blood glucose levels), and/or acute renal failure, and/or pyelonephritis (kidney infection) and/or urosepsis and continue to suffer from the sequelae of these injuries. Farxiga (dapagliflozin) is a pharmaceutical drug used to treat Type 2 Diabetes. All of these injuries were the subject of recent FDA safety advisories.

On January 8, 2014, the FDA approved Farxiga for use in treatment of type 2 diabetics.[2] Farxiga is a part of the *gliflozin* drug class. The *gliflozin* class is referred to generally as SGLT2 (short for "Sodium Glucose Cotransporter 2") inhibitors. Xigduo XR was (*dapagliflozin* combined with metformin) designed and made by the same defendants as Farxiga, and is an extension of the Farxiga product line. Xigduo XR was approved shortly after Farxiga, on October 29, 2014.[3]

On December 4, 2015 the FDA issued a safety communication disclosing they had found 73 adverse events reported between March 2013 and May 2015 that required hospitalization due to ketoacidosis related to SGLT2 inhibitors. The FDA noted adverse event reports "include only reports submitted to FDA, so there are likely additional cases

[2] http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process
[3] http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process

about which we are unaware."[4] The same safety communication also warned of "life-threatening blood infections (urosepsis) and kidney infections (pyelonephritis). In light of the data disclosed in the December 4, 2015 safety communication, the FDA changed the label for Farxiga and Xigduo XR to include a warning "about the risks of too much acid in the blood" and urged patients taking SGLT2 inhibitors to stop taking the drug and seek immediate medical attention if they have any symptoms of ketoacidosis. The FDA also required a label change to warn of urosepsis and pyelonephritis. On June 14, 2016, the FDA issued a safety announcement which advised that the existing warning about the risk of acute kidney injury on the Farxiga and Xigduo labels would be strengthened.[5]

B. The Defendants

The Defendants in these cases are Bristol-Myers Squibb Co., AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca AB, and AstraZeneca PLC. Bristol-Myers Squibb is a Delaware corporation with its principal place of business in New York. Upon information and belief, the AstraZeneca entities are operating and existing under the laws of the State of Delaware, where they also have their principal places of business, with the exception of AstraZeneca AB, which is based out of Sweden. Plaintiffs have alleged that Bristol-Myers Squibb and AstraZeneca both were involved in the design, testing, manufacture, marketing, sales, and development of Farxiga throughout the country, including in New York.

[4] http://www.fda.gov/Drugs/DrugSafety/ucm475463.htm
[5] http://www.fda.gov/Drugs/DrugSafety/ucm505860.htm

C. The Location and Status of Federal Actions

Currently there are thirteen cases pending in the Southern District of New York,[6] and one case pending in each of the following Districts: Eastern District of Pennsylvania, Southern District of Illinois, Southern District of Alabama, Eastern District of Louisiana, and the Northern District of Mississippi. Upon information and belief, each of the eighteen filed cases have not engaged in any discovery other than minimal initial Rule 26 disclosures, so transfer would not result in prejudice, nor would it decrease efficiency.

It should be noted that while a cross-motion to include Farxiga cases with the Invokana MDL was raised, considered and ultimately denied by the Panel following the hearing in Charlotte, North Carolina, that request was opposed by both the Invokana Plaintiffs' counsel and Defendants who claimed that the litigations were sufficiently different such that a joint SGLT2 MDL was improvident. Further, at that time there were only a handful of Farxiga cases in suit. There are now substantially more such cases, and an individual MDL for Farxiga and its sister drug Xigduo XR[7] is now warranted.

II. ARGUMENT

Transfer to either the Southern District of New York, the Eastern District of Pennsylvania or the Southern District of Illinois for consolidation and coordination of pretrial proceedings is appropriate and necessary as the Actions involve common questions of fact, the centralization of these Actions will serve the convenience of the parties and witnesses, and promote the just and efficient conduct of the litigation. 28 U.S.C. § 1407.

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[6] Twelve of the Plaintiffs with cases pending in the Southern District of New York are represented by counsel Ellen Relkin, who consents to this motion.

[7] Just as the Invokana MDL also included the companion drug Invokamet, which is Invokana plus another anti-diabetic agent, metformin, Xigduo XR is Farxiga's combination product (dapagliflozin and metformin).

A. The Farxiga Cases Involve Numerous Common Question of Fact.

The first element of the transfer analysis is whether there are one or more common questions of fact. All of the cases subject to the motion to transfer involve numerous common questions of fact. All of the cases involve injuries arising out of the use of Farxiga. General causation as to whether Farxiga causes ketoacidosis and other injuries will be at issue in each of the pending cases. There are also common questions of fact with respect to the defendants' knowledge about the dangers and risks associated with Farxiga, and whether and when they disclosed this knowledge to the FDA, physicians, and consumers. Each case will involve review of adverse event reports received by the defendants and testing performed by the defendants, to determine when they became award of the problems associated with this device and what they did with that knowledge.

Not all fact questions raised by these actions are common, for example the injuries alleged in the Complaints include primarily include ketoacidosis, but also kidney injury, urinary tract infection, pyelonephritis. However, this is not a bar to centralization. In fact, the Panel has indicated previously that not all facts must be identical in order to warrant an MDL, nor must the injuries alleged be identical. *In re: Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prods. Liab. Litig.,* 53 F. Supp.3d 1379, 1381 (J.P.M.L. 2014) ("The Panel has rejected the argument that products liability actions must allege identical injuries to warrant centralization."). *See also In re: Xarelto (Rivaroxaban) Prods. Liab. Litig.,* 65 F. Supp. 3d 1402 (J.P.M.L. 2014) ("Almost all personal injury litigation involves questions of causation that are plaintiff-specific. Those differences are not an impediment to centralization where common questions of fact predominate."). In these Farxiga cases, pretrial consolidation and coordination will allow the material issues ripe for pretrial

discovery to be addressed in one coordinated action, will avoid duplicative discovery, promote judicial economy and will avoid contrary rulings.

B. Coordination or Consolidation Is Convenient For All Parties And Is An Efficient Use Of Court Resources.

Coordination or consolidation will eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary. *See In re Levaquin Prods. Liab. Litig.*, 560 F. Supp. 2d 1384 (J.P.M.L. 2008); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 398 F. Supp. 2d 1371 (J.P.M.L. 2005). At this early stage of litigation, there are already six Districts with cases pending, ten Plaintiffs firms involved, and seven different Defense firms working on behalf of Defendants, as such, the possibility of duplicative discovery and inconsistent pretrial rulings is very real.

Transfer to an MDL benefits both plaintiffs and defendants. It will reduce discovery requests, costs, and the burden on all parties. Specifically, depositions of key witnesses can be coordinated and done once. Additionally, defendants can produce documents to one central location and all plaintiffs can have access, instead of producing documents to each individual plaintiff. Plaintiffs benefit because plaintiffs' counsel can coordinate and streamline the work. *See In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173 F. Supp. 2d 1377, 1379 (J.P.M.L. 2005) ("it is most logical to assume that prudent counsel will combine their forces and apportion their workload in order to streamline the efforts of the parties and witnesses, their counsel and the judiciary, thereby effectuating and overall savings of cost and minimum of inconvenience to all concerned").

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. Both Plaintiffs and Defendants would benefit from centralization, and the economies of scale that it would bring. Transfer would also avoid that danger of inconsistent rulings and result in economy of judicial resources.

A formal MDL in this case is particularly necessary, in light of Defendants' unwillingness to informally coordinate. Thirteen of the eighteen pending actions are currently pending in the Southern District of New York. All of them are subject to (or will shortly be subject to) motions to dismiss for lack of jurisdiction or to transfer. Defendants are asking that each of the cases pending in New York be transferred to the jurisdictions where each individual plaintiff lives. If transferred to these various jurisdictions, the efficiencies Plaintiffs have attempted to establish by filing most of the actions in one forum will be eliminated, and the danger of inconsistent rulings will increase substantially.

In light of the foregoing, Movant respectfully asks the Panel to transfer these cases involving common questions of fact, for the convenience of the parties and witnesses, and to promote the just and efficient conduct of the actions, for pretrial consolidation as provided for under 28 U.S.C. § 1407.

C. Transfer to The Southern District of New York Best Serves Convenience and the Just and Efficient Conduct of These Actions.

The Panel balances a number of factors in determining the transferee forum, including: the experience, skill and caseloads of the available judges; the number of cases pending in the jurisdiction; the convenience of the parties; the location of the witnesses and evidence; and the minimization of cost and inconvenience to the parties. *See In re: Lipitor (No. II)*, 997 F. Supp. 2d at 1357; *In re: Preferential Drugs Prods. Pricing Antitrust Litig.*,

429 F. Supp. 1027, 1029 (J.P.M.L. 1977); *In re: Tri-State Crematory Litig.*, 206 F. Supp. 1376, 1378 (J.P.M.L. 2002).

As noted above, Judge Schofield in the Southern District of New York is already presiding over the vast majority of the Farxiga cases filed nationally. She has already conducted a pretrial conference to attempt to coordinate the cases pending before her. Continuing with that process would prevent any further delay in those cases. Further, Defendant Bristol-Myers Squibb has its principal place of business in New York. Undoubtedly, depositions of corporate witnesses will be taken in or near New York, and documents are likely stored there too. To the extent that the defendants have a presence outside of New York, it is strongly concentrated on the East Coast, making New York a central location.

Further, Judge Schofield has already demonstrated an intention to manage the Farxiga cases pending before her in an efficient and expeditious manner. While she has not yet had the opportunity to preside over an MDL, her many years as a litigator (both as an assistant United States Attorney and as a private attorney litigating in the field of complex litigation) and her four years on the Federal bench, make her imminently qualified.

If the Panel should decide that transfer to the Southern District of New York is not warranted, Plaintiff requests in the alternative, Transfer to either the Eastern District of Pennsylvania before Judge Mitchell Goldberg, or the Southern District of Illinois before Judge Nancy J. Rosenstengel.

III. CONCLUSION

Transfer and consolidation for pre-trial proceedings of all pending and subsequently filed Farxiga and Xigduo XR actions 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, Plaintiff respectfully requests 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 either the Southern District of New York, the Eastern District of Pennsylvania or the Southern District of Illinois.

Dated: February 3, 2017

Respectfully submitted,

s/Holly Dolejsi
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