BEFORE THE UNITED STATES JUDICIAL PANEL
ON HE MULTIDISTRICT LITIGATION

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	MDL Docket No. 2750

DEFENDANT JANSSEN PHARMACEUTICALS, INC.'S RESPONSE IN OPPOSITION TO THE SCHROEDER PLAINTIFFS' SECOND MOTION FOR TRANSFER OF ACTIONS FOR CENTRALIZATION OF PRE-TRIAL PROCEEDINGS

Defendant Janssen Pharmaceuticals, Inc. ("Janssen") submits this response in opposition to the Schroeder Plaintiffs' Second Motion for Transfer (Schroeder Pls.' Mem. (Doc. 30-1)) requesting class-wide centralization of all cases in federal court arising from injuries allegedly related to sodium glucose co-transporter 2 ("SGLT2") inhibitors.[1] Janssen supports the initial motion for transfer and consolidation of cases involving only Invokana and/or Invokamet (*see* Def.'s Resp. (Doc. 32)), but it opposes centralization on a class-wide basis. While the Schroeder Plaintiffs contend that an issue common to all of these actions is whether use of SGLT2 inhibitors results in an increased risk of diabetic ketoacidosis (DKA) and acute kidney failure, the crux of Plaintiffs' argument is instead Defendants' *failure to warn* about these potential increased risks. Schroeder Pls.' Mem. at 5 ("[D]espite their knowledge of the potential for these drugs to cause serious injuries, Defendants failed to warn. . . ."); *id.* at 6 (alleging "no Defendant took action" despite knowing SGLT2 inhibitors could cause DKA); *id.* at 7 (alleging Defendants "concealed their knowledge" of "the potential for the SGLT-2 inhibitors to cause serious injuries"). But the testing, knowledge, warnings, and labeling regarding these potential risks are specific to each manufacturer and each drug. Class-wide centralization is unwarranted because

[1] This class of drugs includes: Invokana and Invokamet, developed and marketed by Janssen; Farxiga and Xigduo XR, distributed by AstraZeneca Pharmaceuticals LP; and Jardiance, Synjardy, and Glyxambi, marketed by Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly and Company.

there are real differences among the drugs at issue—including in terms of how they were developed, labeled, and marketed. In addition, class-wide coordination would complicate case management and undermine the very purposes of coordination under 28 U.S.C. § 1407.

ARGUMENT

The Schroeder Plaintiffs seek to consolidate all pending federal cases involving any SGLT2 inhibitor, which, according to the Schroeder Plaintiffs' Schedule of Actions, currently include 61 Invokana cases, 3 Farxiga cases, 3 Jardiance cases, and 2 cases alleging injuries involving multiple SGLT2 inhibitors.[2] *See* Schroeder Pls.' Ex. C, Doc. 30-5. But any overlapping issues that may exist between and among these cases are outweighed by their differences. As the Schroeder Plaintiffs themselves recognize, the Panel is typically hesitant to centralize class-wide litigation, (*see* Schroeder Pls.' Mem. at 8 (quoting *In re: Yellow Brass Plumbing Component Prods. Liab. Litig.*, 844 F. Supp. 2d 1377, 1378 (J.P.M.L. 2012)), and the Schroeder Plaintiffs have done nothing to demonstrate that the Panel should eschew its reluctance and establish class-wide litigation in this instance, *see In re Aredia & Zometa Prods. Liab. Litig.*, 429 F. Supp. 2d 1371, 1372 (J.P.M.L. 2006) (refusing to consolidate claims against five different manufacturers because "movants have failed to persuade us that any common questions of fact between the actions against [one defendant] and the actions against the other defendants are sufficiently numerous to justify Section 1407 transfer").

I. Differences Between The Products Weigh Against Class-Wide Coordination.

While these drugs belong to the same class, they are still distinct medications. *See, e.g.*,

[2] Contrary to the Schroeder Plaintiffs' assertion, the cases involving two SGLT2 inhibitors are *not* "combination therapy" cases. Pls.' Mem. at 2. Combination therapy refers to the practice of taking two different drugs *at the same time*. SGLT2 inhibitors are only indicated for monotherapy or in combination with a non-SGLT2 inhibitor. *See* Yehuda Handelsman, *Potential Place of SGLT2 Inhibitors in Treatment Paradigms for Type 2 Diabetes Mellitus*, 21 Endocrine Practice 1054, 1062-63 (2015). Thus any "intertwined" issues that this Panel has found with combination therapy claims do not apply here. *See* Pls.' Mem. at 10.

In re Zyprexa Prods. Liab. Litig., 253 F.R.D. 69, 132-33 (E.D.N.Y. 2008), *rev'd on other grounds by UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010). And the differences among the SGLT2 inhibitors with respect to product design, testing, and development; warnings; regulatory history; and marketing will predominate over any potential common class-wide issues that the Schroeder Plaintiffs have identified.

Each of these drugs was developed at a different time, has a distinct design with a unique molecular formulation,[3] and underwent independent clinical trials that were separately reviewed and approved by the FDA. The FDA approved the drugs at different times: Invokana was approved first—on March 29, 2013; Farxiga was approved almost a year later on January 8, 2014; and Jardiance was approved almost eight months after that on August 1, 2014. And each drug is indicated for a different patient population based on varying levels of kidney function.[4]

More importantly, each drug also has a different label and a different regulatory history. The Panel typically only consolidates litigations involving multiple related pharmaceuticals on a class-wide basis when they are subject to class—not individual—labeling standards. *See, e.g.*, *In re: Fluoroquinolone Prods. Liab. Litig.*, 122 F. Supp. 3d 1378 (J.P.M.L. 2015) (noting that class

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[3] Differences between the design of the drugs are likely to be a non-issue, as several courts have found design claims to be preempted by federal law. *See* Def.'s Resp. (Doc. 32) at 3 n.5 (discussing decisions in which courts dismissed design defect claims involving Invokana with prejudice as preempted).

[4] For example, Invokana is recommended for patients with an eGFR (kidney function level) of at least 60 mL/min/1.73 m^2 (300 mg dose) or 45 mL/min/1.73 m^2 (100 mg dose). By comparison, Farxiga should not be initiated in patients with an eGFR less than 60 mL/min/1.73 m^2, and use is not recommended in patients with an eGFR consistently between 30 and less than 60 mL/min/1.73 m^2 And Jardiance should not be initiated in patients with an eGFR below 45 mL/min/1.73 m^2, and use should be discontinued if a patient's eGFR falls persistently below 45 mL/min/1.73 m^2. Because of these differences, there will likely be very few patients who have been prescribed more than one SGLT2 inhibitor. In fact, out of the 69 cases listed in the Schroeder Plaintiffs' Schedule of Actions, only two cases involve allegations where plaintiffs have taken more than one SGLT2 inhibitor.

labeling resulted in "virtually identical" warnings). Here, the warnings are distinct. *Compare* http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s015s019lbl.pdf (Invokana), *with* http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202293s009lbl.pdf (Farxiga) *and* http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s005lbl.pdf (Jardiance). Setting aside the differing lengths of the Prescribing Information for the three drugs (44 pages for Invokana and 31 and 32 pages for Farxiga and Jardiance respectively), there are distinct differences in the language contained in Sections 6 (Adverse Reactions), 7 (Drug Interactions), and 8 (Use in Specific Populations)—key aspects of the labeling that will bear on plaintiff-specific failure-to-warn allegations. And each manufacturer also has revised its label numerous times on different dates.[5]

These differences among the drugs and their labeling go to the very heart of Plaintiffs' allegations—what Defendants knew about the potential risks associated with SGLT2 inhibitors, and what warnings Defendants gave and when. The answers to these questions are different for each manufacturer and each drug. Discovery would thus necessarily involve the production of different company documents and company witnesses with different corporate knowledge. It is

[5] Janssen has revised the Invokana label five times—on May 15, 2014; March 3, 2015; December 4, 2015; March 28, 2016; and August 17, 2016. *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Set_Current_Drug&ApplNo=204042&DrugName=INVOKANA&ActiveIngred=CANAGLIFLOZIN&SponsorApplicant=JANSSEN%20PHARMS&ProductMktStatus=1&goto=Search.DrugDetails (last visited Oct. 18, 2016). AstraZeneca has updated the Farxiga label four times—on August 8, 2014; December 4, 2015; June 14, 2016; and August, 17, 2016. *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Set_Current_Drug&ApplNo=202293&DrugName=FARXIGA&ActiveIngred=DAPAGLIFLOZIN%20PROPANEDIOL&SponsorApplicant=ASTRAZENECA%20AB&ProductMktStatus=1&goto=Search.DrugDetails (last visited Oct. 18, 2016). And Eli Lilly and Boehringer Ingelheim have revised Jardiance's label three times—on December 4, 2015; February 5, 2016; and July 8, 2016. *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Set_Current_Drug&ApplNo=204629&DrugName=JARDIANCE&ActiveIngred=EMPAGLIFLOZIN&SponsorApplicant=BOEHRINGER%20INGELHEIM&ProductMktStatus=1&goto=Search.DrugDetails (last visited Oct. 18, 2016).

unclear what common discovery, if any, would overlap in actions involving the separate drugs and what efficiencies would be gained by consolidating these cases class-wide for pretrial proceedings. *See In re Watson Fentanyl Patch Prods. Liab. Litig.*, 883 F. Supp. 2d 1350, 1351 (J.P.M.L. 2012) (concluding"[c]entralization of all actions against all manufacturers will add few efficiencies to the resolution of this litigation" in light of "defendant-specific issues . . . that will overwhelm the few common issues"); *see also In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1378 (J.P.M.L. 2010) (denying consolidation where plaintiff-specific issues will "predominate, and remain likely to overwhelm any efficiencies that might be gained by centralization").

II. A Class-Wide MDL Would Undermine Judicial Efficiency.

The Schroeder Plaintiffs have not demonstrated that a class-wide centralization of the pending SGLT2 inhibitor cases will result in the "just and efficient" handling of these cases. Instead, any such centralization will complicate the litigation and impede resolution of the pending cases.

As an initial matter, according to the Schroeder Plaintiffs' Schedule of Actions, there are more Invokana cases (61) than Jardiance (3) and Farxiga (3) cases. *See* Schroeder Pls.' Ex. C, Doc. 30-5. In similar circumstances, the Panel has granted transfer of claims against a manufacturer with the majority of cases but denied transfer for the rest. *See In re Aredia & Zometa Prods. Liab. Litig.*, 429 F. Supp. 2d at 1372 (granting centralization for thirty actions and denying centralization in a small number of actions involving different medications and manufacturers). There is no basis to create class-wide centralization based on mere "anticipation" that more non-Invokana cases could be filed in the future. *See* Schroeder Pls.' Mem. at 7.

The Invokana cases are not only more numerous, they are also procedurally more advanced than the Jardiance and Farxiga cases. As Janssen previously noted, motions to dismiss have been fully briefed and decided in several Invokana cases (*see* Doc. 32 at 3 n.5), and Judge Martinotti is already working with the parties on, among other things, a short form complaint, short form answer, Plaintiff and Defendant fact sheets, and various discovery orders, (*id.* at 9). Instituting a class-wide litigation would undo the progress made in the Invokana cases and undermine judicial efficiency. Indeed, the Panel has recognized that centralization of litigations is unwise and would fail to promote judicial economy where—as here—certain actions are more advanced than others. *See, e.g.*, *In re: Dietgol Innovators, LLC ('561) Patent Litig.*, 999 F. Supp. 2d 1380, 1381 (J.P.M.L. 2014) ("The disparate progress of the actions, the heightened inconvenience that transfer may cause certain parties, and the history of dismissals in this litigation all weigh against centralization here. . . . Centralization likely will hinder the progress of the more advanced [cases].").

Not only would class-wide centralization hinder the progress being made in the Invokana cases, it would needlessly complicate the management of these cases. As the Panel repeatedly has recognized, "introduction of competing defendants into the litigation, and the need to protect trade secret and confidential information from full disclosure to the parties, would *complicate* case management" and thus undermine the very purpose of coordination under 28 U.S.C. § 1407. *In re: Tropicana Orange Juice Mktg. & Sales Practices Litig.*, 867 F. Supp. 2d 1341, 1342 (J.P.M.L. 2012) (emphasis added); *see also In re Watson Fentanyl Patch Prods. Liab. Litig.*, 883 F. Supp. 2d at 1351 ("[C]entralization could complicate these matters, as defendants may need to erect complicated confidentiality barriers, since they are business competitors."). Here, the drugs are all relatively new to the market—indeed, Janssen just received FDA approval for Invokamet

XR within the last month—and are independently patented. It would be detrimental to each manufacturer to give its competitors access to their documents and company witnesses for the purposes of centralization.

The Schroeder Plaintiffs point to the two cases that allege use of two different manufacturers' SGLT2 inhibitors as a basis for consolidation, (Pls.' Mem. at 12), but these cases alone do not justify the creation of an class-wide centralized litigation. Instead, the Panel can sever the Invokana claims of these plaintiffs to an Invokana MDL for pretrial proceedings. *See, e.g.*, *In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005) (severing cases that involved two different medications where "claims involving a prescription drug other than Vioxx . . . do not share sufficient questions of fact" to warrant inclusion in MDL proceedings).

The two decisions that the Schroeder Plaintiffs cite in support of class-wide centralization do not compel centralization here. In each case, all or nearly all of the defendants agreed to the coordination. *In re: Incretin Mimetics Products Liability Litigation*, 968 F. Supp. 2d 1345, 1346 (J.P.M.L. 2013) (all defendants agreed to consolidation); *In re: AndroGel Prods. Liability Litigation*, 24 F. Supp. 3d 1378, 1378–79 (J.P.M.L. 2014) (five defendants with majority of cases supported establishment of industry-wide multidistrict litigation). The Schroeder Plaintiffs have not demonstrated that class-wide centralization is warranted here.

III. If The Panel Forms A Class-Wide MDL, It Should Transfer The Cases To The District of New Jersey (Before Judge Martinotti) Or, In The Alternative, The Northern District Of Illinois (Before Judge St. Eve).

Should the Panel decide to centralize cases on a class-wide basis, Janssen requests the same choices of transferee courts as articulated in its response to the initial transfer motion: Judge Martinotti in the District of New Jersey or, in the alternative, Judge St. Eve in the Northern District of Illinois. *See* Doc. 32 at 7–12.

CONCLUSION

For the foregoing reasons, Janssen opposes the Schroeder Plaintiffs' motion for class-wide centralization. Janssen, however, supports consolidation of the Invokana and Invokamet cases and the transfer of these cases to the District of New Jersey before Judge Martinotti or, in the alternative, to the Northern District of Illinois before Judge St. Eve.

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Respectfully submitted,

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