BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: PROTON-PUMP INHIBITOR PRODUCTS LIABILITY LITIGATION	:	**MDL DOCKET NO.: 2757**
***Spratt v. AstraZeneca Pharmaceuticals LP*, No. 2:16-cv-05523 (D.N.J.)**	:	FILED ELECTRONICALLY

BRIEF OF PFIZER INC. IN OPPOSITION TO MOTION FOR TRANSFER OF ACTIONS TO THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF LOUISIANA PURSUANT TO 28 U.S.C. § 1407 AND JPML 7.2 FOR COORDINATED AND CONSOLIDATED PRETRIAL PROCEEDINGS

ORAL ARGUMENT REQUESTED

Defendant Pfizer Inc. ("Pfizer") respectfully submits this Response in opposition to transfer and centralization of these actions pursuant to 28 U.S.C. § 1407. Pfizer requests that the Judicial Panel on Multidistrict Litigation ("JPML" or "Panel") deny the Motion for Transfer ("Motion") because the cases sought to be transferred lack the characteristics necessary to warrant the creation of a Multidistrict Litigation ("MDL") proceeding. As set forth below, and in the opposition to the motion to transfer submitted by defendant AstraZeneca, which Pfizer endorses and incorporates herein, the proton pump inhibitor ("PPI") cases at issue in the motion to transfer involve so many varying parties and issues that justice and efficiency will not be served by transfer and centralized management. Moreover, even if an MDL proceeding involving ***prescription*** PPIs were appropriate, it should not extend to include the one case involving claims against Pfizer, based on its manufacture of an over-the-counter ("OTC") PPI, because such claims will turn on very different facts and legal standards from claims involving prescription PPIs.

FACTUAL BACKGROUND

The cases proposed for transfer involve allegations of injury allegedly sustained as a result of the use of a wide variety of prescription PPI drugs, which are manufactured, marketed and sold by different companies, in various forms and dosages, and are prescribed for a host of different medical issues, including relief of symptoms of acid reflux or gastroesophageal reflux disease, treatment of peptic or stomach ulcer and treatment of damage to the lower esophagus caused by acid reflux. Plaintiffs in these cases allege that these various, different products caused them a broad range of kidney-related injuries, including acute interstitial nephritis, acute kidney injury, acute renal failure, chronic kidney disease, chronic interstitial nephritis, interstitial nephritis, end stage renal disease, death, and unspecified "kidney failure or injury."

In their transfer motion, certain plaintiffs in these actions seek consolidated treatment of all PPI claims, regardless of whether they involve prescription or OTC formulations. Specifically, the transfer motion applies to claims based on the use of several different ***prescription*** PPIs, including Prilosec and Nexium, which are manufactured and sold by co-defendant AstraZeneca; Dexilant® and Prevacid®, which are manufactured and sold by co-defendant Takeda; and Zegerid®, which is manufactured and sold by Santarus Inc. (which is not named as a defendant). In addition, the transfer motion encompasses claims based on the sale of various OTC PPI formulations, including Prilosec OTC® and Nexium 24HR®, which are manufactured and sold by defendants The Procter & Gamble Co. and Pfizer, respectively. Pfizer sells only OTC PPI formulations, and is named in only one of the actions subject to the motion. *See Spratt v. AstraZeneca Pharmaceuticals, L.P.*, No. 2:16-cv-05523 (D.N.J.).

At this point, the transfer motion implicates roughly two-dozen corporate defendants based on injuries sustained as a result of taking at least six different drugs manufactured by at least five of those defendants. In addition, if an MDL proceeding is established, it could

potentially involve claims against more than 41 ***additional*** companies that have manufactured and/or sold 26 additional, different PPIs over the course of three decades.[1]

ARGUMENT

Movants seek to create an MDL proceeding captioned "In re: Proton-Pump Inhibitor Products Liability Litigation" that would coordinate claims arising from the use of numerous different PPIs. The problem with this proposal is that PPIs are a large category of drugs, which are manufactured by different companies, subject to different representations and warnings, prescribed to treat different conditions and that are alleged to have caused different types of injuries. Thus, there is no prevailing common factual thread among the cases that would allow for centralized pre-trial management. Further, even if some centralized treatment of PPI claims were appropriate, it should not include claims regarding OTC medications, which are sold at different doses, subject to different regulatory requirements and turn on entirely different facts from those involving prescription drugs. Finally, if the Panel decides to establish an MDL proceeding, it should be overseen by the Honorable Dale S. Fischer of the United States District Court for the Central District of California.

First, as set forth in more detail in the opposition to the motion to transfer submitted by defendant AstraZeneca, which Pfizer endorses, the creation of any MDL proceeding is inappropriate. In order to justify MDL transfer, the moving party must establish that the cases proposed for transfer involve common questions of fact and that justice and efficiency will be served by transfer and centralization. *See* 28 U.S.C. § 1407. Such a showing is not possible here because the cases at issue involve so many varying products, defendants and alleged injuries.

[1] The likelihood that additional claims will be filed involving additional products and defendants is increased by the fact that plaintiffs' attorneys in this litigation engage in lawyer advertising that solicits claims arising from the use of any PPI. *See* Sandy Liebhard, *Nexium, Prilosec, Prevacid Lawsuit TV Commercial*, BERNSTEIN LIEBHARD LLP (May 24, 2016), www.nexiumlawsuit.com/nexium-prilosec-prevacid-lawsuit-tv-commercial.

This Panel is "'typically hesitant to centralize litigation against multiple, competing defendants which marketed, manufactured and sold similar products.'" *In re Watson Fentanyl Patch Prods. Liab. Litig.*, 883 F. Supp. 2d 1350, 1351 (J.P.M.L. 2012) (citation omitted) (denying the request to centralize all actions involving a product "irrespective of manufacturer"); *In re Prescription Drug Co-Pay Subsidy Antitrust Litig*., 883 F. Supp. 2d 1334, 1335 (J.P.M.L. 2012) (denying transfer because "[p]lacing multiple different defendants, many of whom are competitors, into the same action will inject additional and unnecessary complexity into this already complex litigation"). As the Panel noted in *In re Watson*, centralized management of such cases is inappropriate because claims "against each manufacturer will involve unique product- and defendant-specific issues (such as the different product designs, manufacturing processes, regulatory histories, company documents and witnesses) that will overwhelm the few common issues." 883 F. Supp. 2d at 1351. Similarly, in *In re Honey Production Marketing & Sales Practice Litigation*, 883 F. Supp. 2d 1333, 1333 (J.P.M.L 2012), the Panel denied transfer of eight actions involving different product manufacturers, noting that while there were "some common factual questions" at issue in the actions, MDL treatment was inappropriate because the "actions involve different defendants, marketing different . . . products, and involve different state regulations subject to different legal challenges by the defendants." *Id*.

The same is true here. As explained in AstraZeneca's briefing, the multitude of defendants, products and alleged injuries at issue in these cases raise many individualized issues that significantly outweigh any common factual questions and make these cases inappropriate for centralization by the Panel.

Second, even if the Panel were to find that centralization of some PPI claims in an MDL proceeding is appropriate, that proceeding should be limited to prescription PPI claims, which

involve manifestly different allegations from cases involving OTC medications. This Panel has previously recognized that it is not appropriate to coordinate claims involving both prescription and OTC drugs. *See In re Aredia & Zometa Prods. Liab. Litig*., 429 F. Supp. 2d 1371, 1372-73 (J.P.M.L. 2006). In *In re Aredia & Zometa*, the Panel granted a motion to transfer actions concerning Aredia and Zometa, two prescription cancer medications manufactured by Novartis that were alleged to have caused osteonecrosis of the jaw. The Panel expressly refused, however, to include in that proceeding claims involving non-prescription medications manufactured by other companies that were alleged to have caused the same injury. *Id.* Differentiating between prescription and OTC medications for litigation purposes is logical because prescription and OTC drugs are governed by very different regulatory regimes and their manufacturers have differing obligations to the Food and Drug Administration. Thus, the facts and law at issue in OTC cases will vary significantly from those in cases involving prescription drugs.

As set forth above, only one suit has been filed against Pfizer based on its manufacture of an OTC PPI. It would be inefficient to allow this one case, and all of the individualized issues related to OTC development and promotion implicated by it, to complicate an MDL proceeding that is otherwise focused on prescription PPIs. Accordingly, even if the Panel is inclined to find that establishment of an MDL proceeding is appropriate with respect to PPIs, that proceeding should be limited to suits involving prescription medications.

Third, if the Panel orders centralization, Pfizer adopts the request by AstraZeneca and the Takeda defendants that the cases be transferred to The Honorable Dale S. Fischer of the U.S. District Court for the Central District of California. Judge Fischer is presiding over *In re Nexium (Esomeprazole) Products Liability Litigation* (MDL No. 2404), 908 F. Supp. 2d 1362 (J.P.M.L.

2012), which includes product liability claims involving proton pump inhibitors manufactured and sold by AstraZeneca and Takeda Pharmaceuticals USA, Inc. and Takeda Pharmaceuticals USA, Inc. As noted in Astra Zeneca's opposition to the instant motion, Judge Fischer is uniquely suited to oversee any consolidated proceeding involving PPI claims because she is familiar with some of the defendants involved, PPIs, their intended uses, risk-benefit profiles, pharmacology and metabolism in the body, and some of the scientific and regulatory issues at play in these cases.

CONCLUSION

For the reasons set forth above, Pfizer respectfully requests that the JPML deny the pending Motion for Transfer. In the alternative, if the JPML determines that these actions should be centralized, it should only transfer the actions involving prescription PPI medications.

Dated: November 22, 2016

Respectfully submitted,

s/ John H. Beisner
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PROOF OF SERVICE

In compliance with Rule 4.1(a) of the Rules of Procedure for the United States Judicial Panel on Multidistrict Litigation, I hereby certify that a copy of the foregoing was electronically filed with the Clerk of the JPML by using the CM/ECF and was served on all counsel or parties in the following case electronically on November 22, 2016:

Spratt v. AstraZeneca Pharmaceuticals LP **U.S. District Court for the District of New Jersey, Case No. 2:16-cv-05523**	
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