BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: NEXIUM (ESOMEPRAZOLE) PRODUCTS LIABILITY LITIGATION	:	**MDL DOCKET NO.: 2404**
	:	
	:	FILED ELECTRONICALLY

ASTRAZENECA'S RESPONSE TO THE PLAINTIFFS' FACTUAL AVERMENTS IN THEIR MOTION FOR TRANSFER OF ACTIONS TO THE CENTRAL DISTRICT OF CALIFORNIA PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP ("AstraZeneca") hereby file this Response in Opposition to the Motion of Plaintiffs for Transfer of Actions to the Central District of California Pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial Proceedings and respectfully requests that the Panel deny transfer of the actions involving proton pump inhibitors to the Central District of California. In support of said response, AstraZeneca states as follows:

1. AstraZeneca admits that the actions listed on Plaintiffs' Schedule of Actions, and attached as Exhibits to Plaintiffs' Motion, are civil actions currently pending in federal district courts.

2. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca also admits that Nexium® is a prescription medication and that the conditions for which it is indicated are set forth in the

product label. AstraZeneca denies the remaining allegations set forth in Paragraph 2 as stated.

3. AstraZeneca denies the allegations set forth in Paragraph 3 as stated.

4. AstraZeneca admits that on May 25, 2010, the FDA issued a Safety Announcement regarding proton pump inhibitors, but denies the remaining allegations set forth in Paragraph 4 as stated.

5. AstraZeneca denies the allegations set forth in Paragraph 5 as stated.

6. AstraZeneca admits the allegations set forth in Paragraph 6 as stated.

7. AstraZeneca denies the allegations set forth in Paragraph 7 as stated.

8. AstraZeneca denies the allegations set forth in Paragraph 8 as stated.

9. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the first sentence of Paragraph 9 and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 9 as stated.

10. AstraZeneca admits that AstraZeneca Pharmaceuticals LP and AstraZeneca LP are limited partnerships organized under the laws of, with their principal places of business in, Delaware. AstraZeneca also admits that it is unaware of any personal injury, products liability actions involving allegations related to proton pump inhibitor use currently pending in the Delaware District Court, but denies the remaining allegations set forth in Paragraph 10 as stated.

11. AstraZeneca denies the allegations set forth in Paragraph 11 as stated.

12. AstraZeneca denies the allegations set forth in Paragraph 12 as stated.

13. AstraZeneca denies the allegations set forth in Paragraph 13 as stated.

14. AstraZeneca denies the allegations set forth in Paragraph 14 as stated.

15. AstraZeneca denies the allegations set forth in Paragraph 15 as stated.

16. AstraZeneca admits that there are currently eight lawsuits filed against AstraZeneca pending before the Hon. Dale S. Fischer in the Central District of California involving allegations of proton pump inhibitor use and personal injury and that the Central District of California has experience handling multidistrict litigation. AstraZeneca denies that the Central District of California is geographically convenient for the majority of the parties and their counsel.

Respectfully submitted,

ICE MILLER LLP

*/s/Amy K. Fisher*_____

Amy K. Fisher, Indiana Attorney No. 23079-49A
Audra J Ferguson-Allen, Indiana Attorney No. 27835-41
Attorneys for Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP
ICE MILLER LLP
One American Square
Suite 2900
Indianapolis, IN 46282-0200
Tel: (317) 236-2100
Fax: (317) 592-5443
Email: Amy.Fisher@icemiller.com
Audra.Ferguson-Allen@icemiller.com

BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE: NEXIUM® (ESOMEPRAZOLE) PRODUCTS LIABILITY LITIGATION	:	**MDL DOCKET NO.: 2404**
	:	
	:	FILED ELECTRONICALLY

ASTRAZENECA'S RESPONSE IN OPPOSITION TO MOTION FOR TRANSFER OF ACTIONS TO THE CENTRAL DISTRICT OF CALIFORNIA PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

ORAL ARGUMENT REQUESTED

Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP ("AstraZeneca") submit this Response **opposing** transfer and centralization of these actions pursuant to 28 U.S.C. § 1407. AstraZeneca requests that the Judicial Panel on Multidistrict Litigation ("JPML" or "Panel") deny the Motion for Transfer ("Motion") because the cases sought to be transferred ("the cases")[1] lack the characteristics necessary to warrant Multidistrict Litigation ("MDL").

What is not readily apparent from the Motion, and of which Movants have not advised the Panel, is that the cases do not involve one common defendant or proton pump inhibitor ("PPI"), but involve numerous potential named and unnamed defendants and products. Moreover, Movants fail to identify the significant and robust procedural history of the cases; the advanced procedural posture of several of the cases; the lack of common injury; the non-

[1] Movants' Schedule of Actions fails to list all of the pending actions. While AstraZeneca disputes that *any* of these actions possess the commonality required for transfer under 28 U.S.C. § 1407, AstraZeneca has endeavored to list the additional actions on its Notice of Potentially Related Actions filed on September 12, 2012 in accordance with Panel Rule 6.2(d). Dkt. 33.

California residency of the vast majority of Plaintiffs; and, generally, the complete information regarding the pending cases, all of which weigh against any economies gained by an MDL:

Motion for Transfer	Complete Factual Context
The significant history of these cases: • "Between July 2011 and the present, hundred [sic] of plaintiffs filed fifteen lawsuits in state courts in California and Tennessee alleging that exposure to Nexium® caused serious damage to the bones." (Motion p. 3)	**The litigation originated in Texas, not California or Tennessee, and the history of that matter (involving Movants' counsel) demonstrates that the litigation and discovery has already significantly progressed:** • On May 25, 2011, thirty-five plaintiffs, represented by attorney Jason Gibson ("Gibson"), brought the *Stempfer* action in Texas state court, and on July 11, 2011, amended the petition to include an additional sixty-two plaintiffs. *Stempfer v. AstraZeneca LP et. al*., Case No. 2011-31419 (Tex. July 11, 2011). (Ex. A, *Stempfer* Amended Petition). • Fact sheets, ESI Agreement, and Protective Order were negotiated and entered by the court. • AstraZeneca produced nearly two million pages of documents in response to the *Stempfer* plaintiffs' discovery requests. • On the eve of AstraZeneca producing the two million pages, and almost a year after the original action was filed, on May 16, 2012, Gibson dismissed the action and associated himself with Girardi & Keese ("Girardi") for purposes of refiling the actions elsewhere. • On May 24, 2012, Movants filed twelve actions in the Los Angeles County Superior Court, which included all but two of the ninety-seven *Stempfer* plaintiffs. • Gibson has now appeared in the transferred actions of *Arevalo* (S.D. Tex.), *Avelar* (W.D. Tex.), and *Belcher* (E.D. Tex.).
The products at issue: • On May 25, 2010, FDA issued a "safety announcement stating it was revising the labeling and prescribing information for *Nexium*® due to increased risk of fractures of the spine, hip	**There are numerous PPIs and PPI manufacturers. While the Motion implies Nexium® is the only medication at issue, that has not been established in the vast majority of the cases:** • On May 25, 2010, the FDA alert stated that FDA "is revising the prescription and over-the-counter (OTC) labels for a *class of drugs called proton pump inhibitors* . . . ." (*See* Ex. B, FDA Alert) (emphasis added). • Omeprazole was first approved by FDA in 1989. Since then,

Motion for Transfer	Complete Factual Context
and wrist associated with the drug." (Motion p. 3, emphasis added).	numerous brand name and generic PPIs have been marketed and sold by at least twenty-two manufacturers. (*See e.g.* Ex. C, Listing of PPI Products). Four such manufacturers are named defendants in the cases in addition to AstraZeneca. Moreover, in addition to Nexium®, plaintiffs allege use of Prilosec®, Dexilant®, Zegerid®, Prevacid®, Protonix®, and Aciphex®.[2]
The posture of the cases: • The cases are "all in the preliminary stages of litigation." (Motion p. 2)	**Several cases are advanced and nearing the close of discovery or discovery is proceeding apace:** • In *Biggers* (M.D. Tenn.), discovery has been ongoing, plaintiffs' expert disclosures are due in December 2012, and fact discovery closes in January 2012. In *Johnson* (N.D. Ala.), the general causation/fact discovery deadline is February 2013. Fact discovery closes in Movants' *Kuhn* (E.D. Wis.) and *Moore* (W.D. Wis.) matters in May 2013 and January 2014, respectively. • In Movants' *Arevalo* (S.D. Tex.) matter, the court ordered the fifteen plaintiffs to produce fact sheets by September 7, 2012. • Scheduling orders have been entered in *M. Johnson* (N.D. Ala.), *Biggers* (M.D. Tenn.), *Rose* (W.D. Tenn.), *Moore* (W.D. Wis.) and *Kuhn* (E.D. Wis.).
Overlapping discovery and duplicative efforts • "Coordinating the actions before one judge at this early stage will allow the parties and the court to address this overlapping discovery . . . and avoid the potentially very costly duplication of efforts . . . ." (Motion p. 6)	**The parties are already coordinating:** • The parties have already conducted global meet and confers for a vast majority of the cases and are endeavoring to use the same Protective Orders, ESI Agreements and Fact Sheets entered by the courts in cases involving different counsel, parties. • Fact Sheets, ESI Agreements, and Protective Orders have already been negotiated with Movants' counsel vis-à-vis *Stempfer* and with plaintiffs' counsel in *Biggers* (M.D. Tenn.). AstraZeneca has produced nearly two million pages of documents in *Stempfer* and 700,000 pages in *Biggers*. These pleadings, as well as AstraZeneca's production sources, are already being negotiated with counsel in *M. Johnson* (N.D. Ala.), *Beatty* (N.D. Cal.), and *Debartolo* (N.D. Ill.) as well as with Movants' counsel (to the extent additional negotiation is warranted, recognizing that these pleadings were already negotiated with, and significant document production made to,

[2] Plaintiff *Lilak* (D. Colo.) alleges that he ingested Nexium®, Dexilant®, Prilosec®, Zegerid®, Prevacid®, Protonix®, and Aciphex®. Plaintiff *Goodman* (D. Nev.) alleges that he ingested Zegerid®, Prevacid®, Nexium®, and Aciphex®.

Motion for Transfer	Complete Factual Context
	Movants' counsel in *Stempfer*). • Even if consolidation occurs at the federal court level, there will be state court cases proceeding separately as counsel for Movants has refused to remove to federal court his 201 plaintiffs pending in Los Angeles County.
A common allegation: • "Each [action] alleges that Nexium® can and did cause bone damage, osteoporosis, and other injuries and that Defendants failed to adequately warn of such risks." (Motion p. 5)	**The alleged injuries do not constitute a "common issue of fact:"** • The cases allege a broad range of injuries, including osteoporosis, osteopenia, hypomagnesemia[3], bone "ache," and hip, wrist, vertebral, and even "pinky finger" fractures. • The only "commonality" is that plaintiffs allege that they ingested a PPI and it caused *some type* of injury.
Information regarding Nexium®: • "Nexium® has been linked to several severe medical disorders including, but not limited to, osteoporosis and/or broken bones." (Motion p. 2)	**Nexium® is approved by FDA and any alleged causation with regard to bone fractures has not been established:** • There are no studies which establish a cause and effect relationship between Nexium® and osteoporosis or broken bones. Recent studies doubt any such causation. FDA notes that the relationship is only "possible" and caution that based on the available data, it is not clear that PPIs are the cause of the increased risk of fracture. (*See* Ex. B, FDA Alert).
The nexus to California: • "Eight of the Nexium® cases, with nearly a thousand plaintiffs, are pending before the Hon. Dale S. Fischer in the Central District of California." (Motion p. 8) • "All but one of the complaints include defendants who are	**There are currently only fifty-five California resident plaintiffs. Defendants and potential defendants are primarily located outside of California:** • The plaintiffs reside in forty-four different states. California is the home state for only fifty-five (4.8%) plaintiffs. • Other states are home to a significantly larger percentage of plaintiffs. For example, 255 (22.4%) plaintiffs reside in Texas. • Not one, but *several* of the complaints do not involve California defendants, *e.g. Hornsby* (S.D. Cal.), *Biggers* (M.D. Tenn.),

[3] Hypomagnesemia is a condition involving low levels of magnesium in the blood.

Motion for Transfer	Complete Factual Context
California residents." (Motion p. 8) • Plaintiffs state that McKesson, Takeda California, Inc. and Rebel Distributors have their principal places of business in California. (Motion p. 8)	*Johnson* (N.D. Ala.), *Debartolo* (N.D. Ill.), *Lilak* (D. Colo.), *Goodman* (D. Nev.), and *Arevalo* (S.D. Tex.).[4] • Takeda California is an improperly named entity as noted by the publicly available removal notice and affidavit filed in the *Beatty* action. *See* Ex. D, Takeda Affidavits; *see also Beatty et. al. v. AstraZeneca Pharmaceuticals L.P. et. al.*, No. 3:12-cv-03507, Defendant AstraZeneca Pharmaceuticals LP and AstraZeneca LP's Notice of Removal, Dkt. 1, ¶¶ 20-30 (N.D. Cal. July 5, 2012). Takeda Pharmaceuticals U.S.A. Inc. has its principal place of business in Illinois. • Rebel Distributors has been dismissed and is not a party to any of the cases.[5] • Defendants and potential defendants are located in the following additional states: Illinois, Ohio, Pennsylvania, New Jersey, Delaware, and Florida.

The significant case-specific issues begin with product identification: whether each plaintiff ingested one of the numerous other PPIs manufactured by companies not parties to this litigation will be a significant issue requiring a unique inquiry for each individual case. Although all of the plaintiffs, save *Goodman, Lilak,* and one *Beatty* plaintiff, allege they only ingested Nexium®, it is not clear that once medical records are obtained, such allegations will be borne out. What is clear is that for 98% of the plaintiffs, product identification has not been established. Even the small percentage of medical and pharmacy records obtained thus far indicate usage of several different PPIs manufactured by different companies. Identifying and joining the proper defendant(s) is a case-specific inquiry and each defendant will have its own

[4] Movants amended the *Arevalo* complaint to dismiss McKesson. *See Arevalo et. al. v. McKesson Corp. et. al.*, No. 4:12-cv-02099, Dkt.37, Plaintiffs' First Amended Complaint (S.D. Tex. Sept. 7, 2012).

[5] Plaintiff's First Amended Complaint dismissed Rebel. *See Lois Hornsby, et. al., v. AstraZeneca Pharmaceuticals LP and AstraZeneca LP*, No. 3:12-cv-01307, Dkt. 8, First Amended Complaint for Damages (S.D. Cal. Aug. 27, 2012).

unique dispositive motions to raise on product identification issues. This will negate any efficiencies to be gained from an MDL.

The pending cases involve such diverse issues as:

- Multiple PPI medications on the market for over two decades and thus, significant product identification issues
- No common defendant, but rather numerous potential defendants with multiple different products and formulations[6]
- No typical plaintiff and a broad spectrum of alleged injuries
- Myriad potential causes for each alleged injury and vastly different underlying medical conditions and histories
- Unique case issues; for example, in *Goodman*, bankruptcy issues necessitating a pending motion to dismiss for lack of standing and judicial estoppel
- Individualized knowledge of each company for the diverse time frames alleged in the cases regarding notice, warnings, labeling, disclosures, and design issues
- Plaintiff-specific issues including medical history, use of concomitant medications, dosage, period of use, frequency and compliance with regimen, differential diagnosis, treatment, nature and extent of alleged damages, and knowledge and information from plaintiff's physicians
- Individualized questions of fact and causation issues, necessitating different experts for each case
- Allegations involving forty-four state law causes of action and violations of specific state statutes which must be analyzed on a state-by-state basis
- Varying procedural postures for many of the cases

The individual district courts are in a better position to handle each unique case on a discrete basis, whereas individualized issues will *overwhelm* the efficiencies, if any, to be gained from centralization. *See In re G.D. Searle & Co. "Copper 7" IUD Prods. Liab. Litig.*, 483 F. Supp. 1343, 1345 (J.P.M.L. 1980) (recognizing that the various federal district courts had well-supervised the uncentralized actions).

[6] As set forth in more detail below, there are numerous products and formulations, including, but not limited to, Dexilant®, Zegerid®, Prevacid®, Protonix®, Aciphex®, Prilosec OTC®, Prevacid 24HR®, omeprazole, lansoprazole, and pantoprazole sodium. Ex. C, Listing of PPI products; Ex. E, excerpts of Orange Book.

STATEMENT OF FACTS

Nexium®, approved by FDA in 2001, is a branded prescription medication consisting of esomeprazole magnesium. Nexium® is a product within the class of products known as proton pump inhibitors or PPIs, which "work by reducing the amount of acid in the stomach." Ex. B, FDA Alert. In addition to Nexium®, there are at least twenty-one other brand name and generic medications within the PPI class. For a list of the potential brand name and generic medications at issue, s*ee* Ex. C, Listing of PPI Products. Some of the brand name prescription PPIs mentioned in the FDA Alert include Dexilant®, Zegerid®, Prevacid®, Protonix®, Aciphex®, and Vimovo®. Ex. B, FDA Alert. In addition to the prescription PPIs, there are at least three over-the-counter ("OTC") products included in the FDA Alert, manufactured by at least three different defendants, such as Prilosec OTC®, Zegerid OTC®, and Prevacid 24HR®. *Id.*

On May 25, 2010, FDA issued a Safety Announcement regarding prescription and over-the-counter (OTC) labels for the *class of drugs* called proton pump inhibitors. Ex. B, FDA Alert (emphasis added). Contrary to Movants' implication, the FDA Safety Announcement **did not** single out the product, Nexium®. *Id.* Moreover, as noted in the attached chart, there are numerous manufacturers and medications at issue. Ex. C, Listing of PPI Products.

On May 25, 2011, thirty-five plaintiffs represented by Gibson brought an action in Texas state court against AstraZeneca (amended on July 11, 2011 to include an additional sixty-two plaintiffs. *Stempfer* Amended Petition, Ex. A). Plaintiffs dismissed that action twelve months later on May 16, 2012 (*Stempfer* Notice of Non-Suit, Ex. F) to re-file it elsewhere, despite the fact that the litigation had significantly progressed and AstraZeneca had produced nearly two million pages of documents in response to the plaintiffs' discovery requests. Gibson associated with Girardi and, on May 24, 2012, Girardi filed twelve actions in the Los Angeles County

Superior Court involving a total of 1302 plaintiffs, with only sixty-six[7] California residents. All but two of the ninety-seven *Stempfer* plaintiffs are re-named in the California actions. On June 1, 2012, AstraZeneca removed the actions to federal court[8] and subsequently filed 12(b)(6) motions to dismiss and motions to sever and transfer, which the *Velasco* court sua sponte granted on July 10, 2012. Thereafter, the remaining Central District of California cases were deemed related before Judge Dale Fischer. Judge Fischer remanded four non-CAFA cases; however, plaintiffs have admitted that jurisdiction is proper for the remaining eight CAFA cases, and AstraZeneca's motions to sever and transfer are fully briefed.

The cases pending outside of California exist in many different procedural postures. For example, in *Biggers* (M.D. Tenn.), AstraZeneca has already produced nearly 700,000 pages of documents. Plaintiffs must serve expert reports in December 2012 and fact discovery closes in January 2013.[9] Similarly, in *M. Johnson* (N.D. Ala.), general causation and fact discovery will close in February 2013. Fact discovery closes in Movants' *Kuhn* (E.D. Wisc.) and *Moore* (W.D. Wisc.) matters in May 2013 and January 2014, respectively. In numerous other matters, including *Lilak* (D. Colo.), *Goodman* (D. Nev.), *Rose et. al.* (W.D. Tenn.), *Nyblod et. al.* (W.D. Wash.), *Johnson* (S.D. W. Va.), *Arevalo* (S.D. Tex.), *Avelar* (W.D. Tex.), *Belcher* (E.D. Tex.), *Abina* (C.D. Cal.), *Arae* (C.D. Cal.), *Carrasco* (C.D. Cal.), *Cudney* (C.D. Cal.), *A. Johnson* (C.D. Cal.), *Mason* (C.D. Cal.), *Nickerson* (C.D. Cal.), and *Solomon* (C.D. Cal.), motions to dismiss are

[7] Eleven of the California plaintiffs were subsequently remanded back to California state court.
[8] Eight actions were removed as a "Mass Action" pursuant to 29 U.S.C. § 1332(D)(11), the Class Action Fairness Act ("CAFA").
[9] Citing the pending JPML ruling, the Honorable Judge Haynes administratively closed the case without seeking input from the parties. *See James R. Biggers, Jr. and Pamela Biggers v. AstraZeneca LP and AstraZeneca Pharmaceuticals LP*, No. 1:11-cv-0062, Dkt. 25, Order (M.D. Tenn. Sept. 10, 2012). AstraZeneca is seeking to re-open the case and will ask the *Biggers* (M.D. Tenn.) plaintiffs to join in that motion.

fully briefed. Additionally, the courts in *M. Johnson* (N.D. Ala.), *Biggers* (M.D. Tenn.), *Rose* (W.D. Tenn.), *Moore* (W.D. Wis.) and *Kuhn* (E.D. Wis.) have entered scheduling orders, discovery is currently underway in *Arevalo* (S.D. Tex.), and the parties in *Beatty* (N.D. Cal.) and *Debartolo* (N.D. Ill.)[10] are in the process of finalizing Protective Orders, ESI Agreements and Fact Sheets and commencing discovery.

LEGAL ARGUMENT

The cases lack the threshold requirements necessary for transfer. Product identification has ***not*** been established, despite Movants' posturing of these cases as involving only ingestion of and injury by Nexium®. Rather, these cases will involve at least twenty-two different companies that manufactured and/or distributed different types of PPIs over two decades. Additionally, the injuries alleged run the gamut from hypomagnesemia to osteoporosis to a broad spectrum of fractures (hip, vertebral, foot, and even "pinky finger"). With so many different products, parties, alleged injuries and issues, the Movants are simply unable to demonstrate that sufficient common questions of fact exist such that consolidation is appropriate.

Before the Panel will order transfer, the moving party must establish three elements. 28 U.S.C. § 1407. First, the moving party must establish the existence of common questions of fact. *See* 15 Charles A. Wright *et al*., FEDERAL PRACTICE AND PROCEDURE: JURISDICTION AND RELATED MATTERS § 3862, at 380 (2007). However, commonality of questions of fact is seldom "sufficient, by itself, to justify granting the motion to transfer." *Id.* Second, the moving party must establish that consolidation will "serve the convenience of the parties and witnesses." *Id.* at 407. Third, the moving party must establish "that the just and efficient conduct of the actions

[10] Counsel for the plaintiff in *Debartolo* represented at a status conference on September 13, 2012 that plaintiff does not support the motion for transfer. As such, the court ordered that the parties proceed with discovery and a Scheduling Order.

will be served" by transfer and centralization. *Id.* at 413. "[I]t has been argued that the crucial issues in determining whether to grant pretrial consolidation is not whether there are common questions or whether the parties will be inconvenienced, but whether the economies of transfer outweigh the resulting inconvenience to the parties." *Id.* at 414-15 (internal quotations omitted).

I. The Motion to Transfer, Consolidation and/or Coordination Should be Denied.

A. Transfer Should be Denied Due to the Lack of Commonality or Shared Factual Issues Among the Various Named and Unnamed Defendants.

The lack of product identification, the existence of multiple products and defendants, and the differences in factual issues among those defendants should be considered when determining whether transfer is appropriate. *In re Asbestos and Asbestos Insulation Material Prods. Liab. Litig.*, 431 F. Supp. 906, 910 (J.P.M.L. 1977) (noting that a factor supporting denial of transfer was the existence of individual questions in determining liability of each defendant). The FDA Alert changed the prescribing information for all PPI products due to a *possible* increased risk of fracture while also cautioning that, based on the available data, it is not clear that PPIs are the cause of the increased risk of fracture. Ex. B, FDA Alert. As stated above, Nexium® is just one PPI in a class of many. There are numerous other products and manufacturers within the PPI class. Ex. C, Listing of PPI Products. Moreover, the complaints themselves allege injury by multiple products and manufacturers: one of the *Beatty* plaintiffs alleges ingestion of Prevacid® manufactured by Takeda; *Goodman* alleges injury by Nexium®, Zegerid®, Prevacid®, and Aciphex®, manufactured by AstraZeneca, Takeda, Santarus, Janssen Pharmaceuticals, and Johnson and Johnson; and *Lilak* alleges injury by Nexium®, Dexilant®, Prilosec®, Zegerid®, Prevacid®, Protonix®, and Aciphex®. This Panel has denied other MDL petitions under similar circumstances. *See e.g. In re Table Saw Prods. Liab. Litig.*, 641 F. Supp. 2d 1384 (J.P.M.L. 2009) (denying coordination of cases involving multiple defendants with different products).

When the Panel has been faced with cases involving different defendants, the analysis has involved the additional step of determining whether the various defendants "share sufficient questions of fact with claims" against the parties. *In re Celexa and Lexapro Prods. Liab. Litig.*, 416 F. Supp. 2d 1361, 1363 (J.P.M.L. 2006) (excluding claims against pharmaceutical manufacturer Wyeth Pharmaceuticals from transfer order as they did not "share sufficient questions of fact with claims" against manufacturer Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc.). In addition, when the defendants are not uniformly named in the same actions, this Panel has denied transfer. *See In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010) ("Most, if not all, defendants are named in only a minority of actions; and several defendants are named in but a handful of actions.").

Product identification is a case-specific inquiry requiring an individualized analysis of plaintiffs' medical and pharmacy records which may well change the defendant line-up from case to case. The medical records obtained to date clearly demonstrate that several plaintiffs ingested a multitude of different PPIs over various time periods. While, plaintiffs allege that AstraZeneca's "strategy beginning in the 1990's has been to aggressively market and sell Nexium® . . . ." (Motion p. 3.), Nexium® was not even approved by FDA until 2001. Thus, even in those cases in which AstraZeneca is the only named manufacturer, it is without question that other products and manufacturers are involved in these actions.[11] An implication that these cases involve only one product/defendant is wholly inaccurate. Centralization of cases in which plaintiffs have failed to name all the manufacturers does not promote economy and, in fact, will create costly side issues that are better handled on a case-by-case basis.

[11] Several plaintiffs have alleged ingestion of Nexium before FDA approval. *See e.g.* Beatty Amend. Compl. p. 4, ¶ 14 (Plaintiff Schultz alleges that she began taking Nexium in 2000).

Moreover, even after product identification issues have been addressed in each case (which could result in motion practice dispositive of entire cases), case-specific issues individual to the relevant company will need to be addressed: e.g., the development, design and labeling history of each product, each company's communications with FDA for each product, each company's warnings for each product, when each product received market approval from FDA, and how each company marketed and promoted each product. In addition to the numerous PPI manufacturers, there are other *types* of defendants both named and unnamed. For example, in some cases, plaintiffs have named McKesson as the only distributor of Nexium®. However, AstraZeneca alone utilizes at least thirty-three different distributors for Nexium® (Ex. G, Affidavit of John B. Callahan, Jr.). In others, plaintiffs have named "Doe" doctors. *See e.g., Abina* (C.D. Cal.). Thus, if plaintiffs intend to include distributors and physicians in these actions, the correct distributor and physician(s) for each plaintiff will also need to be determined. Clearly there will not be one "common" defendant for all cases. While these issues can be (and are) handled efficiently on a case-by-case basis at the district court level, they will not easily be accomplished through consolidated discovery. Rather, any discovery will focus solely on the individual plaintiff to ensure that the correct entities are named.

Additionally, plaintiffs' allegations do not create a common issue of fact or law.[12] Instead, discovery with regard to these issues, central to plaintiffs' claims, will vary from company to company as well as for each individual physician, hospital and medical facility. *See In re Pharmacy Benefit Plan Adm'rs Pricing Litig*., 206 F. Supp. 2d 1362, 1363 (J.P.M.L. 2002) (transfer denied based upon a finding that "while these five actions clearly share common legal

[12] Nor are the allegations the same, thus creating different legal issues. For example, the Girardi cases assert California statutory violations. *See e.g. Abina* (C.D. Cal.).

questions and, perhaps, a few factual questions, unique questions of fact predominate over any common questions of fact"). These cases do not involve one defendant, or even one type of defendant or product. Instead they involve potentially several products sold by multiple companies with potentially divergent regulatory, design, and marketing histories which were distributed by numerous other companies. Moreover, the majority of previously centralized medical device and pharmaceutical product liability cases did not involve the panoply of manufacturers and defendants potentially involved here. *See In re Inter-Op Hip Prosthesis Prod. Liab. Litig.*, MDL Dkt 1401 (one manufacturer, Sulzer); *In re St. Jude Medical, Inc. Silzone Heart Valves Prod. Liab. Litig.*, MDL Dkt. 1396 (one product, Silzone heart valves, and defendant, St. Jude); *In re Telectronics Pacing Sys. Inc., Accufix Atrial "J" Leads Prod. Liab. Litig.*, MDL Dkt. 1057 (one manufacturer and product); *In re Copley Pharms., Inc. "Albuterol" Prods. Liab. Litig.*, MDL Dkt. 1013 (involving one manufacturer and drug).[13]

B. Significant Individual Factual Issues Support Denial of the Motion to Transfer.

Another factor weighing against transfer is the breadth and dominance of individualized plaintiff issues. The plaintiffs are not homogeneous due to a wide range of issues including age, gender, underlying condition necessitating alleged ingestion of PPIs, use of concomitant medications, medical history, and nature and extent of alleged damages. This Panel has long recognized that where there are significant individual factual questions on liability, transfer should be denied. *See In re Rely Tampon Prods. Liab. Litig.*, 533 F. Supp. 1346, 1347 (J.P.M.L. 1982) (denying transfer where Panel was not persuaded "that these common questions of fact will predominate over individual questions of fact present in each action"); *In re Sears, Roebuck*

[13] Although the Panel granted transfer in *In re Silicone Gel Breast Implants Prod. Liab. Litig.*, MDL Dkt 926, all defendants favored MDL transfer signifying their belief that there was a common issue which would benefit the parties by consolidation.

and Co. Bankruptcy Debtor Redemption Agreements Litig., No. 1389, 2001 WL 34834426, at *1 (J.P.M.L. Jan. 31, 2001) (noting that "individual, not common questions of fact rise to the forefront"); *In re Shoulder Pain Pump Chondrolysis Prods. Liab. Litig.*, 571 F. Supp. 2d 1367, 1368 (J.P.M.L. 2008) (noting that the cases involved "multiple individualized issues (including ones of liability and causation)").

Causation is a threshold element and should be considered when determining whether an MDL is appropriate. In this instance, even if there was a common issue with regard to whether one defendant's product could be *capable* of causing the types of injuries alleged by plaintiffs (which is denied), whether each defendant's product *rather than something else* caused each plaintiff's injury will require a plaintiff-by-plaintiff specific inquiry wholly inappropriate for MDL treatment. Although "specific causation" is not a completely uncommon issue in a consolidated proceeding, the level of individualization of injury in this matter would make the transferee court's responsibility untenable. Even assuming that all of the plaintiffs here alleged a "bone fracture" (which is not the case as the injuries range from nonspecific findings of reduced bone mineral density to magnesium electrolyte disturbance), "fracture" is not the type of uniform or signature injury which leads to efficiency through MDL treatment. Significantly, plaintiffs do not allege any common fracture site – instead the alleged fractures range from neck bones to toes and everything in between. Setting aside the multiple fracture sites, plaintiffs also have not alleged (much less proven) that the various fractures result from fragility (weak bones) and low-impact trauma, rather than as a result of significant trauma, *e.g.* car accident or fall, a leading natural cause of fractures. Moreover, even if the fractures were all incurred on low-impact, the incidence of such non-specific injury is commonplace and statistically correlated to such naturally occurring phenomenon as the aging process, poor diet, gender (due to the drop in

estrogen at menopause) and numerous, common chronic medical conditions and the treatments for those conditions. For nearly every plaintiff, individualized issues will be present making the determination of specific causation a uniquely case-by-case determination unsuitable for centralized supervision. *See In re Abbott Labs., Inc., Similac Prods. Liab. Litig.*, No. 2:10-cv-03242, 2011 WL 346943 (J.P.M.L. Feb. 4, 2011) (denying the motion to transfer and noting that individual facts, such as the particular product each plaintiff purchased, the injuries the product caused, and the representations made to each plaintiff, would predominate over common facts).

As determined by this Panel in similar cases, the "individual, not common, questions of fact rise to the forefront" of these cases, and transfer should be denied. *See also In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010) ("[I]ndividual issues of causation and liability continue to appear to predominate, and remain likely to overwhelm any efficiencies that might be gained by centralization."); *In re Repetitive Stress Injury Prods. Liab. Litig.*, 1992 WL 403023, at *1 (J.P.M.L. Nov. 27, 1992) (denying consolidation even though 159 actions were pending because the "degree of common questions of fact among these actions [did not] rise to the level that transfer under Section 1407 would best serve the overall convenience of the parties and witnesses and promote the just and efficient outcome in the litigation.").

C. Judicial Economy and Convenience Would Not Be Furthered By Consolidation.

Although centralization may "eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel, and the judiciary," *In re Merrill Lynch & Co. Auction Rate Secs. Litig.*, 626 F. Supp. 2d 1331, 1332 (J.P.M.L. 2009), these same benefits can be achieved in other ways. *See In re Shoulder Pain Pump Chondrolysis Prods. Liab. Litig.*, 571 F. Supp. 2d, at 1368 (noting that "parties can avail themselves of alternatives to Section 1407 transfer to minimize whatever possibilities there might be of

duplicative discovery and/or inconsistent pretrial rulings"); *In re Abbott Labs. Inc., Similac Prods. Liab. Litig.*, 2011 WL 346943 ("We consider voluntary coordination among the parties and the involved courts of these relatively few actions to be a preferable alternative to centralization at this time."). Such coordination is already occurring.

Plaintiffs' Motion is another attempt to coordinate these cases solely for the convenience of their counsel. Movants' counsel first attempted to bring several of the claims in Texas, then dismissed those actions and refiled them, along with hundreds of other non-California plaintiffs, in California state court. Those actions and the instant motion are forum shopping at its worst. Even Movants' own statement that coordination would conserve resources is contradicted by the fact that they refuse to move their 201 state court plaintiffs to federal court via CAFA.

Centralization would not appreciably enhance the convenience of the parties and/or judicial economy. Coordination has already been achieved through global meet and confers and negotiation of template scheduling orders. Moreover, search terms, production format, ESI Agreement, Protective Order, and a Fact Sheet have already been negotiated with Movants' counsel Gibson. Custodians have been disclosed and over two million pages of documents produced. Coordination can be achieved without centralization through common depositions, and, as has already occurred, common documents can be shared among the parties where appropriate, pursuant to the Protective Orders. Additionally, the JPML has noted that parties could, in addition to informal efforts, "seek orders from the involved courts directing the parties to coordinate their pretrial efforts." *In re Children's Personal Care Prods. Liab. Litig.*, 655 F. Supp. 2d 1365, 1366 (J.P.M.L. 2009). Ultimately, any preservation of judicial economy or enhanced convenience that might flow from MDL transfer would be undermined by the need to address the many significant differences among the plaintiffs and potential manufacturers. *See*

id. (holding that, in light of the fact that "[m]ore than ten different baby products with differing formulations are involved in these actions," the movants "failed to persuade us that, given these circumstances, transfer under Section 1407 would serve the convenience of the parties and witnesses or further the just and efficient conduct of this litigation").

In sum, the individual facts in these actions will predominate over any common facts, and any potential necessity for any common discovery and/or pretrial coordination can be accomplished informally. Thus, this Panel should deny the Motion to Transfer and instead encourage the parties to pursue alternatives to minimize any potential duplicative discovery.

II. If this Panel Determines that Transfer is Appropriate, then AstraZeneca Requests that the Cases be Transferred to the Southern District of Texas.

Although AstraZeneca opposes centralization, if the JPML determines that these actions should be consolidated, then AstraZeneca requests that the cases be transferred to the Southern District of Texas with Judge Lynn Hughes presiding. Judge Hughes is an experienced jurist who has been on the federal bench since 1985. Prior to joining the federal bench, he served as a judge in the Civil District Court, State of Texas, Houston. His extensive amount of judicial experience should serve him well in handling an MDL that promises to pose complex legal issues.[14]

The vast majority of the plaintiffs reside in Texas. In fact, over twenty-two percent, or 255, of the plaintiffs reside in Texas. By far, more plaintiffs hail from Texas than any other state (Alabama is second with only seventy-eight). In addition to the large number of plaintiffs residing in Texas, the surrounding states, such as Oklahoma, Arkansas, Louisiana, Mississippi, and Alabama, combined, constitute another twenty percent of the plaintiffs. As such, Texas will

[14] Moreover, Judge Hughes is already familiar with this litigation having already held a status conference and having demonstrated his willingness to move these cases forward.

be the most convenient forum for the plaintiffs and will be the location of much discovery, *e.g.* product identification, plaintiffs' depositions, and treater depositions.

The Southern District of Texas is also appropriate as a transferee forum because it is centrally located. The plaintiffs reside in forty-four different states and the cases are pending in jurisdictions from California to Tennessee. *See* Ex., H, geographical map. Depositions of the plaintiffs, treaters, family members, and fact witnesses will take place throughout the country. As the JPML has recognized, one factor to be considered in choosing a venue for nationwide litigation is whether the court is in a geographically central district. *See In re TJX Companies, Inc. Fair and Accurate Credit Transactions Act (FACTA) Litig.*, 505 F. Supp. 2d 1379, 1380 (J.P.M.L. 2007) ("Given the geographic dispersal of actions, no district stands out as the geographic focal point for this nationwide docket. Thus, we have sought a transferee district that is centrally located [District of Kansas] . . . ."); *In re Teflon Prods. Liab. Litig.*, 416 F. Supp. 2d 1364, 1365 (J.P.M.L. 2006) (transferring to the cases to a "geographically central location" when the related cases were pending across the country); *In Re Ameriquest Mortg. Co. Lending Practices Litig.*, 408 F. Supp. 2d 1354, 1355 (J.P.M.L. 2005) (transferring cases to a "geographically central district [that] will be a convenient location for a litigation already nationwide in scope"); *In re Inter-Op Hip Prosthesis Prod. Liab. Litig.*, 149 F. Supp. 2d 931, 933 (J.P.M.L. 2001) (where related cases were filed across the country, centralization in the Northern District of Ohio was appropriate given "the geographic dispersal of current and anticipated constituent actions"). As a central location, Houston's George Bush International Airport and Hobby Airport together offer service on almost every major domestic airline. Thus, while plaintiffs' counsel may have a preference to litigate near their homes, Houston is a convenient and accessible forum for ***all*** parties, witnesses and counsel concerned.

Most of the defendants and potential defendants are located throughout the country. Specifically, Defendant AstraZeneca is located in Delaware; Defendants KBI, Janssen, and Johnson & Johnson and potential Defendants Eisai, Inc., Par Pharmaceutical Co., Merck & Co., Inc., Watson Pharmaceuticals, Inc., Kremers Urban Pharmaceuticals Inc., Wyeth LLC, Sun Pharmaceutical Industries Inc., Dr. Reddy's Laboratories Inc., and Sandoz Inc. are located in New Jersey; Defendant McKesson is located in California; potential Defendant Apotex Corp. is located in Florida; and Defendant Takeda Pharmaceuticals and potential Defendant TAP Pharmaceuticals are located in Illinois. The JPML has repeatedly looked for a central location where relevant discovery will likely be conducted in determining an appropriate transferee forum. *See In Re: Air Crash Near Medan, Indonesia, On September 5, 2005*, 2008 U.S. Dist. LEXIS 30430, at *2 (J.P.M.L. April 10, 2008) (ruling that transferee forum was appropriate because it was located midway between defendants' relevant headquarters).

In contrast, the Central District of California cannot be considered a convenient or centralized location. In fact, the only convenience would be to plaintiffs' counsel in California. To the contrary, it would be terribly inconvenient for ninety-five percent of the plaintiffs who reside outside of California or for defendants' counsel who are located on the other side of the country; for example, AstraZeneca's national counsel is located in Indianapolis, Indiana and Takeda's national counsel is in Baltimore, Maryland. Moreover, the Panel has "long held that the convenience of counsel is not by itself a factor to be considered under Section 1407 in the Panel's decision whether to order transfer or in the selection of a transferee forum for a group of actions. Only if the inconvenience of counsel would impinge on the convenience of the parties or witnesses would the convenience of counsel become a factor to be considered by the Panel." *In re DirectBuy, Inc. Marketing and Sales Practices Litig.*, 682 F. Supp. 2d 1349 (J.P.M.L. 2010)

(internal quotations omitted). Plaintiffs' counsel have not demonstrated that transfer outside of California would impinge on the parties or witnesses. In fact, plaintiffs' counsel Gibson,[15] who has already appeared in these actions and is intimately familiar with the facts, is located in Texas.

Consequently, AstraZeneca posits that, if the JPML grants the pending Motions to Transfer, Judge Hughes' court in the Southern District of Texas would be a more appropriate transferee court.

CONCLUSION

AstraZeneca respectfully requests that the JPML deny the pending Motion for Transfer or, in the alternative, if the JPML determines that these actions should be consolidated, to transfer the cases to the Southern District of Texas with Judge Lynn Hughes presiding.

Respectfully submitted,

ICE MILLER LLP

*/s/Amy K. Fisher*_____

Amy K. Fisher, Indiana Atty No. 23079-49A
Audra J Ferguson-Allen, Indiana Atty No. 27835-41
ICE MILLER LLP
One American Square
Suite 2900
Indianapolis, IN 46282-0200
Tel: (317) 236-2100
Fax: (317) 592-5443
Email: Amy.Fisher@icemiller.com
Audra.Ferguson-Allen@icemiller.com
Attorneys for Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP

Dated: September 19, 2012

[15] As mentioned previously, Mr. Gibson filed the *Stempfer* action in Texas. Prior to the dismissal by Mr. Gibson, the action was pending in Texas for nearly a year. Gibson has also entered his appearance in the *Arevalo*, *Avelar*, and *Belcher* cases pending in Texas.