BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: Xarelto Products Liability Litigation	)	MDL No. 2592

BAYER'S MEMORANDUM IN OPPOSITION TO MOTION TO TRANSFER ACTIONS PURSUANT TO 28 U.S.C. § 1407

Defendants Bayer Corporation, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") respectfully submit this memorandum in opposition to the motion filed by certain plaintiffs (hereinafter, "Movants") to establish a multidistrict litigation proceeding in the U.S. District Court for the Southern District of Illinois.[1]

INTRODUCTION

Xarelto® is a prescription medicine approved by the U.S. Food and Drug Administration for the treatment and prevention of blood clots. It represents a significant medical advance over previous medicines for these conditions. Before the introduction of Xarelto and other medicines within the group of so-called "new oral anticoagulants" (NOACs) beginning in 2010, patients needing blood-thinning treatment were primarily consigned to a product called warfarin. Warfarin, originally developed as a rodenticide, entails significant drawbacks—for example, its effect can vary greatly depending on a patient's diet and use of other medications, and its effect must be monitored through frequent blood tests. NOACs, by contrast, are more predictable for doctors and more convenient for patients because they present limited food- and drug-interaction complications and do not require routine monitoring.

[1] Some cases name German-based Bayer entities—Bayer HealthCare AG, Bayer Pharma AG, and Bayer AG—as defendants, but to date none of the German entities has been served with a complaint. If and when those German entities are served, they will appear through counsel and assert their rights as appropriate.

In the lawsuits that are the subject of Movants' motion, plaintiffs complain that they suffered physical injuries as a result of their prescribed use of Xarelto. Most plaintiffs allege that inadequate warnings or misrepresentations in the Xarelto labeling about the absence of a reversal agent or the risk of bleeding caused their injuries. The first of these lawsuits was filed several months ago, in June 2014.

Ultimately, plaintiffs' claims will fail on the merits. Plaintiffs will be unable to show that Xarelto is unreasonably dangerous or that its warnings and instructions to the physicians who prescribed Xarelto were not fully adequate. Significantly, since the FDA initially approved Xarelto in July 2011, its warnings and prescribing instructions have clearly and consistently warned that "Xarelto increases the risk of bleeding and can cause serious and fatal bleeding." And Xarelto's labeling and prescribing instructions have always disclosed that a "specific antidote . . . is not available," even though its short half-life and other available clinical measures make a reversal agent or "antidote" unnecessary in the vast majority of instances. In the last three years, there has been no substantive change to Xarelto's warnings about bleeding and the lack of a specific reversal agent.

The question for the Panel, of course, is not whether plaintiffs' claims have merit but rather whether the existing cases should be transferred to a single district and consolidated for pretrial proceedings. In short, the answer to that question is "no." Movants contend that the Panel "routinely" consolidates pharmaceutical product-liability cases, and they point, in particular, to *In re Pradaxa (dabigatran etexilate) Prods. Liab. Litig.*, MDL No. 2385, as a "bench mark of sorts." As explained below, however, the circumstances surrounding the *Pradaxa* litigation (and the ensuing MDL) are very different from those here. Movants cannot use *Pradaxa* as a proxy for consolidation here, and they have not met their burden to show why

consolidation *of these cases* is appropriate. Consolidation is not warranted here—these cases will turn on individualized facts that will predominate over any common issues. Rather than formally consolidating these disparate cases, the Panel should (as it has done before in similar circumstances) allow the parties and their counsel the opportunity to coordinate among themselves any overlapping discovery.

In the alternative, if the Panel ultimately concludes that formal consolidation is appropriate, the cases should not be transferred to Movants' preferred venue, the Southern District of Illinois. That jurisdiction has no meaningful connection to the events that underlie this litigation, save for the fact that several plaintiffs have opted to file lawsuits there. Instead, if there is to be a consolidated proceeding, it should be established in the District of New Jersey, where both defendants have their U.S. headquarters—and, therefore, where the vast majority of witnesses and documents that will be relevant to this litigation are located. Not only is the District of New Jersey a logical choice based on the facts and allegations in Movants' cases, but the docket conditions in that court—which averages only *one-sixth* the number of civil cases per judgeship as the Southern District of Illinois—are favorable to "the just and efficient conduct" of the proceedings and "the convenience of parties and witnesses." 28 U.S.C. § 1407(a).

FACTUAL BACKGROUND

Bayer HealthCare AG and Janssen Pharmaceuticals, Inc. jointly developed Xarelto, which was initially approved by FDA for sale in the United States in July 2011. By contractual agreement, Janssen holds an exclusive license to market Xarelto in the United States. Bayer Pharmaceuticals Inc. maintains some limited U.S. marketing rights, but Janssen otherwise has sole responsibility for Xarelto's sale, marketing, and labeling in this country.

Xarelto is one of three FDA-approved NOACs. Boehringer Ingelheim's product, Pradaxa®, became the first NOAC approved for sale in the United States in October 2010.

Bristol Myers Squibb and Pfizer Inc. jointly developed a product called Eliquis® that followed Pradaxa and Xarelto into the market in 2012. There are, of course, some similarities between the three products. Each represents a significant medical improvement over warfarin, for example, and none has a known reversal agent. But there are also important differences—especially, as relevant here given Movants' persistent efforts to equate them, between Xarelto and Pradaxa. For instance, Xarelto is a "factor Xa inhibitor," while Pradaxa is a "direct thrombin inhibitor," which means that, as a chemical matter, the medicines work very differently to impede clot formation. And Xarelto is indicated for treatments that Pradaxa is not, including for the prevention of deep vein thrombosis following hip- or knee-replacement surgery.

Another key difference between Xarelto and Pradaxa—one that Movants' motion obscures—is in the products' respective regulatory histories. Although both products have always warned about a risk of increased bleeding,[2] the products' labeling has differed with respect to the absence of a reversal agent. When FDA initially approved Xarelto, the "Overdosage" section of its labeling stated that "[a] specific antidote for [Xarelto] is not available." Several months later, in November 2011, that language was added to the label's "Warnings and Precautions" section.[3] Significantly, all of the plaintiffs in the cases that are subject to Movants' motion started using Xarelto *after* this labeling amendment, and there has been no intervening substantive change to that warning. By contrast, although Pradaxa's initial

[2] *See* Xarelto July 2011 Label § 5.2 ("Xarelto increases the risk of bleeding and can cause serious and fatal bleeding."); Pradaxa Oct. 2010 Label § 5.1 ("Pradaxa increases the risk of bleeding and can cause significant and, sometimes fatal bleeding.").

[3] Notably, FDA also approved in November 2011 an additional Xarelto indication (for nonvalvular atrial fibrillation, or "NVAF") under a different New Drug Application, No. 202439. *See* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/202439s000ltr.pdf. The "Warnings and Precautions" section of the labeling associated with the NVAF indication has always warned that "[a] specific antidote for [Xarelto] is not available."

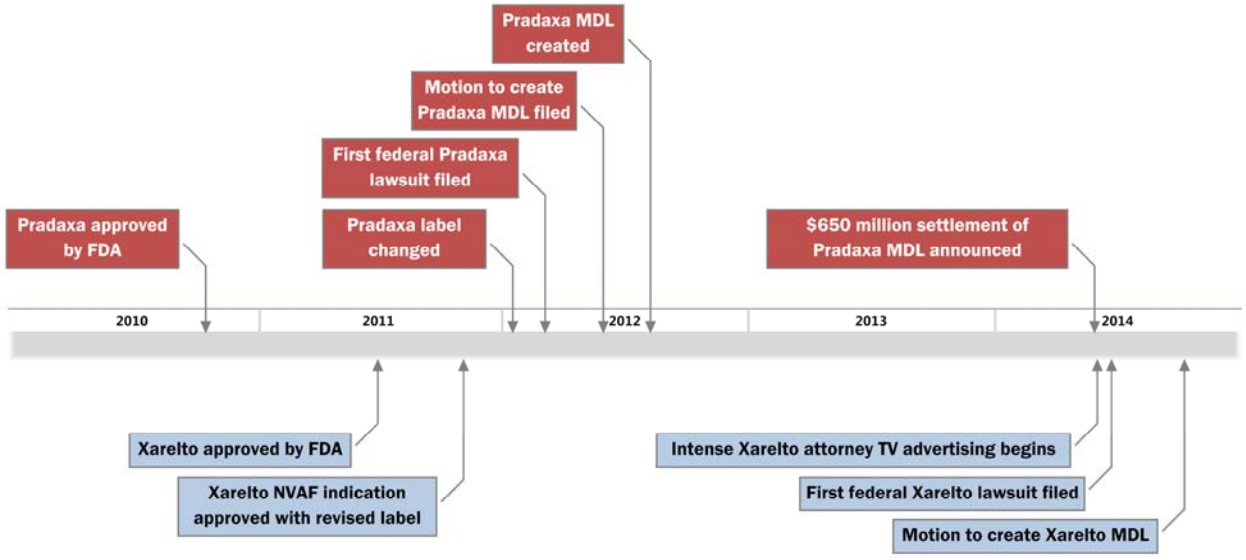
labeling likewise included a statement in the "Overdosage" section that "there is no antidote," the label's "Warnings and Precautions" section did not contain any similar language until January 2012, after FDA had announced (in December 2011) that it was evaluating bleeding events associated with Pradaxa.

All of this matters because Movants' request for consolidation reads as if consolidation of the Xarelto cases should follow *ipso facto* from the *Pradaxa* MDL. That is incorrect, as a review of the history shows. The Pradaxa lawsuits—and the ensuing MDL—followed a specific triggering event; in particular, the initial suits were filed almost immediately after the January 2012 Pradaxa label change, on behalf of plaintiffs who had used the drug *before* that change.[4] The Panel consolidated the Pradaxa cases in the Southern District of Illinois before the Honorable David Herndon. *See In re Pradaxa (dabigatran etexilate) Prods. Liab. Litig.*, 883 F. Supp. 2d 1355 (J.P.M.L. 2012). In May 2014, on the eve of the plaintiffs' expert disclosure deadline as the first trials were approaching, counsel for Movants here—as co-lead of the *Pradaxa* Plaintiffs' Executive Committee—negotiated a $650 million settlement with Boehringer Ingelheim covering the majority of the claims in the *Pradaxa* MDL.

That lucrative settlement—*not* a label change, new scientific study, or any other substantive development—is what triggered these cases. In June 2014, before the ink on the Pradaxa settlement was even dry and before a single Xarelto case had been filed in federal court, Movants' counsel and other personal-injury lawyers began running advertisements in what would quickly become an intense attorney-advertising campaign soliciting Xarelto plaintiffs. By July 2014, the lawyers had increased their Xarelto-related television-advertising spending

[4] To be clear, labeling amendments can arise for any number of reasons. The point here is not that any labeling change should create litigation; the point is simply that Pradaxa's January 2012 labeling change seems to have done just that.

14,900%, to $1.2 million. In August, they increased their spending another 92%, to $2.3 million, and in September, they spent another $3.9 million, making Xarelto the "top ad target" in trial lawyers' mass-tort marketing.[5] So, between June and September 2014, even in the absence of any regulatory or scientific development, plaintiffs' lawyers—led by Movants' counsel here—spent more than $7.4 million on a television-advertising campaign against Xarelto. Unsurprisingly, during the same time as that mass ad campaign, Xarelto lawsuits followed, as the following graphic shows:



The point is simply this: whereas lawsuits involving Pradaxa followed from a substantive labeling change, lawsuits involving Xarelto resulted *only* from plaintiffs' lawyers' aggressive marketing tactics in the wake of a massive payday. If there were any doubt about the connection

[5] The Silverstein Group, "Xarelto Debuts As Top Ad Target," August 28, 2014, *available at* http://www.silversteingroup.net/mass-tort-ad-watch-blog/xarelto-debuts-as-top-ad-target; *see also The Clot Thickens: Lawyers Boost Spending to Solicit Xarelto Lawsuits*, Wall St. J. Pharmalot, Aug. 29, 2014, *available at* http://blogs.wsj.com/pharmalot/2014/08/29/the-clot-thickens-lawyers-boost-spending-to-solicit-xarelto-lawsuits/; The Silverstein Group, Mass Tort Advertising Report, September 2014, *available at* http://us7.campaign-archive2.com/?u=35ed1e6f2b2f1244337e3f989&id=f7e7b27aac; The Silverstein Group, Mass Tort Advertising Report, October 2014, *available at* http://us7.campaign-archive2.com/?u=35ed1e6f2b2f1244337e3f989&id=42437d8462.

between the Pradaxa settlement and the Xarelto cases, it is resolved by the fact that Movants' counsel have, in some instances, copied Pradaxa allegations into Xarelto complaints—at times with allegations that, while relevant to the Pradaxa cases, don't even fit Xarelto's history.[6]

On the heels of that advertising campaign, plaintiffs have filed 30 cases in 14 federal district courts.[7] All six of the plaintiffs who moved for consolidation—those in *Lemp, Leach, Haney, Pennell, McMunn* and *Mulroney*—filed their cases in the Southern District of Illinois. Those cases were originally transferred to the Honorable Staci Yandle, but have since been reassigned to Judge David Herndon.[8]

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[6] *Compare, e.g., McCoy v. Boehringer Ingelheim Pharm., Inc.*, No. 3:12-cv-00806 (S.D. Ill.), ECF No. 2 ¶ 27 ("Defendants' original labeling and prescribing information for Pradaxa . . . failed to disclose in the 'Warnings' section that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa . . . ."), *with Mulroney v. Janssen Research & Dev. LLC*, No. 3:14-cv-01073 (S.D. Ill.), ECF No. 5 ¶ 101 ("Defendants' original and, in some respects, current labeling and prescribing information for Xarelto . . . failed to disclose in the 'Warnings' Section that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto . . . ."). The plaintiff in *Mulroney* (like other plaintiffs) contends that she used Xarelto for NVAF. As explained *supra* n.3, the "Warnings and Precautions" section of the labeling associated with the NVAF indication has always warned that "[a] specific antidote for [Xarelto] is not available."

[7] None of these cases is a class action. Separately, 20 cases are pending in Pennsylvania state court—the earliest of which was filed on February 21, 2014—and discovery recently commenced in those actions.

[8] After Movants requested consolidation, Chief Judge Michael J. Reagan reassigned all Xarelto cases pending in the Southern District of Illinois from Judge Yandle to Judge Herndon. *See Lemp v. Janssen Research & Dev. LLC*, No. 3:14-cv-00987 (S.D. Ill. Oct. 24, 2014), ECF No. 28. Movants noted in their opening brief that Judge Yandle had been "assigned to seven out of the eight Xarelto® cases currently on file in the Southern District of Illinois, which is more than any jurist in the federal judiciary." Mot. at 14. That was so because Judges Herndon and Reagan had transferred their Xarelto cases to Judge Yandle consistent with the "law of [the Seventh] Circuit . . . that related cases filed within the same District Court should be handled by a single District Judge" and the Southern District of Illinois "protocol" that related cases are "transferred to the District Judge with the first-filed/earliest-filed case"—here, Judge Yandle. *Haney v. Janssen Research & Dev. LLC*, No. 3:14-cv-00988 (S.D. Ill. Sept. 12, 2014) (Reagan, J.), ECF No. 13. The October 24 order provides no explanation for the re-reassignment to Judge Herndon. Earlier today, Judge Herndon entered a case management order setting a status conference and litigation hold for these cases. *See Lemp*, No. 3:14-cv-00987 (S.D. Ill. Oct. 31, 2014), ECF No. 33.

ARGUMENT

The Panel should decline to consolidate these cases because Movants have failed to carry their "burden of demonstrating the need for centralization" under section 1407. *In re Best Buy Co., Cal. Song-Beverly Credit Card Act Litig.*, 804 F. Supp. 2d 1376, 1379 (J.P.M.L. 2011). Because these actions will involve highly individualized issues, consolidation would not create significant litigation efficiencies or enhance convenience for the parties, their counsel, or the courts. In the alternative, should the Panel conclude that consolidation is appropriate, it should transfer the cases to the District of New Jersey—the site of both defendants' U.S. corporate headquarters and thus the home of many key documents and witnesses—rather than the Southern District of Illinois, which has no connection to the litigation other than the fact that several plaintiffs have unilaterally opted to file complaints there.

I. Consolidation Would Not Promote The "Just And Efficient" Conduct Of The Pending Cases Or Serve The "Convenience of Parties And Witnesses."

Movants devote only two pages of their brief to advocating for centralization, and even then, their argument rests principally on conclusory assertions, some of which have no place in the consolidation analysis—*e.g.*, that "many common questions of fact and law exist"; that the Panel "routinely" grants motions to transfer in pharmaceutical product-liability cases; and (most notably) that "the Pradaxa litigation [is] a bench mark of sorts" and, accordingly, that "it is very likely that the number of Xarelto cases will grow exponentially and into the thousands." Mot. at 7–8. Those assertions are largely untethered from the requirements of Section 1407—in particular, the requirements that consolidation should "promote the just and efficient conduct of such actions" and serve "the convenience of parties and witnesses." 28 U.S.C. § 1407(a).[9]

[9] It widely recognized that the "most important prerequisite to MDL transfer and consolidation is a showing that the just and efficient conduct of the actions will be served thereby." 15 CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE & PROCEDURE § 3863 (4th ed. 2014); *see also id.*

Because Movants have failed to establish that "centralization is necessary" at this time, the Panel should deny their motion. *See In re Adderall XR (Amphetamine/Dextroamphetamine) Mktg., Sales Practices & Antitrust Litig.*, 968 F. Supp. 2d 1343, 1344–45 (J.P.M.L. 2013).

A. These Cases Turn on Highly Individualized Facts.

The Panel has denied consolidation where case-specific facts are "likely to predominate" in a particular litigation, *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, __ F. Supp. 2d __, MDL No. 2559, 2014 WL 4049821, at *2 (J.P.M.L. Aug. 12, 2014), or where there are "differences in the health risks alleged," *In re Oxyelite Pro & Jack3d Prods. Liab. Litig.*, __ F. Supp. 2d __, MDL No. 2523, 2014 WL 1338475, at *1 (J.P.M.L. Apr. 2, 2014). *See also In re Prescription Drug Co-Pay Subsidy Antitrust Litig.*, 883 F. Supp. 2d 1334, 1335 (J.P.M.L. 2012) (denying consolidation because "[i]ndividualized discovery and legal issues [were] likely to be numerous and substantial").

Those considerations counsel against consolidation here. The plaintiffs in these cases allege (1) that they used Xarelto for different purposes (including some for off-label uses) and (2) that they suffered different injuries from using Xarelto. With respect to product use, some plaintiffs claim that they took Xarelto for nonvalvular atrial fibrillation (*e.g.*, *Armstrong*, *Bolton*), others for pulmonary embolism (*e.g.*, *Braswell*, *Cox*), and still others for hip- and knee-replacement surgery (*e.g.*, *Griggs*, *Grossman*). With respect to claimed harms, although many plaintiffs allege a bleeding injury of some kind, the specific types of bleeds that they allege vary significantly—from brain hemorrhaging (*e.g.*, *Brien*) to gastrointestinal bleeding (*e.g.*,

§ 3863 ("Read broadly, as is consistent with the open-ended character of the statutory language, of course, this third requirement really subsumes the other two.").

Dalrymple) to uterine bleeding (*e.g.*, *Cox*).[10] And some plaintiffs allege non-bleeding injuries. *See McMunn* (pulmonary embolism); *Goodwin* (myocardial infarction). *See also generally* Exhibit 1.

In the face of these differences, Movants are left simply to assert that there will be some common factual questions, but that alone is not a sufficient basis for consolidation. *See, e.g.*, *In re Mirena*, 2014 WL 4049821, at *2 (denying consolidation of nine cases "[a]lthough the actions share factual questions"); *In re Qualitest Birth Control Prods. Liab. Litig.*, __ F. Supp. 2d __, MDL No. 2552, 2014 WL 4050055, at *1 (J.P.M.L. Aug. 12, 2014) (denying consolidation in spite of common "factual questions arising out of the design, manufacturing, and packaging of the Qualitest birth control products").[11] Similarly, Movants' assertion that prescription-drug litigations are "routinely" consolidated, Mot. at 7, paints with too broad a brush. To be sure, the Panel has consolidated pharmaceutical cases when the statutory conditions are satisfied, but just as surely, the Panel has frequently *rejected* MDL proposals in cases involving prescription drugs. *See, e.g.*, *In re Oxycontin Prods. Liab. Litig.*, 395 F. Supp. 2d 1358, 1359 (J.P.M.L. 2005) (denying motion to transfer with respect to 25 cases in 17 federal districts); *In re Reglan/Metoclopramide Prods. Liab. Litig.*, 622 F. Supp. 2d 1380, 1381 (J.P.M.L. 2009) (denying motion to transfer with respect to 11 actions in 10 federal districts notwithstanding "share[d] factual issues as to whether the drug metoclopramide causes neurological injuries").

[10] Some plaintiffs have not provided any details about their bleeding event (*e.g.*, *Griggs*, *Haney*, *Jeffcoat*).

[11] *See also In re Oxycontin Prods. Liab. Litig.*, 395 F. Supp. 2d 1358, 1359 (J.P.M.L. 2005); *In re Eli Lilly & Co. (Cephalexin Monohydrate) Patent Litig.*, 446 F. Supp. 242, 244 (J.P.M.L. 1978) (concluding that "movants have not met their burden of convincing us that those common factual questions are sufficiently complex or that the accompanying discovery will be so time consuming as to justify transfer under Section 1407").

Consolidation is not appropriate here, as Movants suggest, just because these are pharmaceutical cases, or just because Xarelto and Pradaxa are members of the same general group of medicines. The question for the Panel is whether Section 1407(a)'s "just and efficient" and "convenience" criteria are satisfied. They are not. In light of the "differences in the health risks alleged," *In re Oxyelite*, 2014 WL 1338475, at *1—and other differences that could arise out of plaintiffs using Xarelto for different purposes, at different times—consolidation will not be nearly as efficient or convenient as Movants contend.

B. In the Circumstances Here, Informal Coordination Is Preferable to Formal Consolidation.

The Panel has emphasized that where it is possible, informal coordination is "preferable to formal centralization." *In re Adderall Mktg.*, 968 F. Supp. 2d at 1345.[12] That kind of coordination is certainly possible here—these cases are at a very early stage, many of them involve common plaintiffs' counsel, and Bayer's counsel is ready and willing to work cooperatively with the plaintiffs' counsel (as they have done in the past in other litigations) to coordinate discovery and other pretrial matters as appropriate. *See, e.g.*, *In re Oxyelite*, 2014 WL 1338475, at *2 (denying centralization where there was "a limited number of actions and involved counsel, with two groups of plaintiffs' counsel already coordinating most of the personal injury actions"); *In re Mirena*, 2014 WL 4049821, at *1 (denying consolidation in favor of informal coordination due to "few involved counsel" in the "limited number of actions" that were "in their infancy"). Rather than order formal consolidation in what is, at best, a marginal

[12] For example, "[n]otices of deposition can be filed in all related actions; the parties can stipulate that any discovery relevant to more than one action can be used in all those actions; or the involved courts may direct the parties to coordinate their pretrial activities." *In re Adderall Mktg.*, 968 F. Supp. 2d at 1345 (citation and internal quotation marks omitted).

circumstance, the Panel should allow the parties to work together to coordinate their efforts to achieve any achievable efficiencies.

* * *

Movants have not made a compelling case that formal consolidation would promote Section 1407's goals of enhancing "efficien[cy]" and "convenience." And consolidation would be particularly inappropriate—un-"just"—given the history of this litigation and the tenor of the motion, both of which suggest an effort among certain plaintiffs' counsel to roll their profits from the *Pradaxa* MDL over into another investment. The cases targeting Xarelto have been driven *not* by any medical, scientific, or regulatory developments, but rather by a deluge of attorney advertising. A Panel order consolidating these cases would only encourage additional filings and thereby help fulfill Movants' irrelevant speculation, Mot. at 8, that "there will be thousands of these cases filed throughout the country" in the coming months.[13]

II. In The Alternative, If The Panel Concludes That Consolidation Is Appropriate, The Cases Should Be Transferred To The District Of New Jersey, Not The Southern District Of Illinois.

A. The Southern District of Illinois Is Not a Proper Venue.

If the Panel is inclined to grant the motion to transfer, Bayer submits these cases should be sent to the District of New Jersey—where both defendants' U.S. corporate offices, and thus many of the key witnesses and documents, are located—not to the Southern District of Illinois.

Movants have asked the Panel to consolidate the cases in the Southern District of Illinois—and, more specifically, to send an MDL to either Judge David Herndon or Judge Staci Yandle. Movants' venue choice, like their consolidation request more generally, would neither

[13] *Cf., e.g., In re Intuitive Surgical, Inc., Da Vinci Robotic Surgical Sys. Prods. Liab. Litig.*, 883 F. Supp. 2d 1339, 1340 (J.P.M.L.2012) (denying centralization, noting that "[w]hile proponents maintain that this litigation may encompass 'hundreds' of cases or 'over a thousand' cases, we are presented with, at most, five actions").

"promote the just and efficient conduct" of these cases nor serve the "convenience of parties and witnesses." 28 U.S.C. § 1407(a). The Southern District of Illinois has no meaningful connection to this litigation—other than the fact that plaintiffs' counsel in several cases have opted to file complaints there. Moreover, according to statistics compiled by the Office of the United States Courts, the Southern District of Illinois is home to an average of 3,228 civil cases per judgeship—making it the *second busiest federal district court in the entire country*, behind only the Eastern District of Pennsylvania. *See U.S. District Court—Judicial Caseload Profile* (June 2014) (excerpts attached as Exhibit 2). The statistics specifically concerning MDL proceedings are equally daunting; the Southern District of Illinois's two active MDLs together comprise nearly 10,000 actions. *See MDL Statistics Report—Distribution of Pending MDL Dockets by District* (Oct. 15, 2014) (attached as Exhibit 3). In short, not only is the Southern District of Illinois a relative stranger to the facts underlying Movants' cases, but there is no indication that the court has the capacity necessary to efficiently administer a substantial new MDL proceeding.

Moreover, although Movants' preferred judges—Judges Herndon and Yandle—are both capable jurists, neither is presently well-situated to handle what Movants promise will be a substantial MDL. Judge Herndon is already currently presiding over not one but two large MDLs: in addition to his oversight of the global settlement of the *Pradaxa* MDL, he is also presently handling *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2100, which still comprises more than 1,200 currently active pending cases against Bayer, and is in the midst of intense discovery proceedings ahead of a May 2015 trial. *See In re Yasmin/Yaz*, CMO 65 (attached as Exhibit 4). Even for the most accomplished judge,

such a caseload is surely taxing.[14] An assignment to Judge Yandle, who was confirmed to the federal bench in June 2014, may present geographic complications, in that she sits in Benton, Illinois, not East St. Louis. Movants' arguments about the conveniences of East St. Louis, *see* Mot. at 15–16, do not apply to Benton, which is nearly 100 miles from East St. Louis and more than 110 miles from the Lambert-St. Louis International Airport. Because no major airline flies to the Benton Municipal Airport, travel to and from Benton would be difficult.

B. The District of New Jersey Would Be a Superior Venue.

If the Panel chooses to consolidate, the cases should be sent to the District of New Jersey, which, unlike the Southern District of Illinois, would serve the statutory goals of "efficien[cy]" and "convenience." 28 U.S.C. § 1407(a). The District of New Jersey holds several significant advantages.

First, to the extent there is a "center of gravity" for these cases, it is in New Jersey. Xarelto is prescribed to patients throughout the country, and there is no reason to believe that the various injuries that Movants allege would occur in one region more often than any other; accordingly, there is no geographic focal point for the plaintiffs and their witnesses (*e.g.*, prescribing doctors, family members, etc.). There is, however, a focal point on the defendants' side of the "*v.*"—namely, New Jersey. Bayer's U.S. headquarters are in Whippany, New Jersey, and Janssen is located in Titusville, New Jersey. Consequently, most of the potential U.S.-based corporate witnesses and documents likely are located in New Jersey. In short, the discovery that

[14] The Panel often assigns MDLs involving medicines within the same general group to different presiding judges. For instance, among nonsteroidal anti-inflammatory drugs ("NSAIDs"), the Panel assigned the *Vioxx* MDL, No. 1657, to Judge Eldon Fallon (E.D. La.) and the *Bextra & Celebrex* MDL, No. 1699, to Judge Charles Breyer (N.D. Cal.). Among antidepressant selective serotonin reuptake inhibitors ("SSRIs"), the Panel assigned the *Zyprexa* MDL, No. 1596, to Judge Jack Weinstein (E.D.N.Y.) and the *Zoloft* MDL, No. 2342, to Judge Cynthia Rufe (E.D. Pa.). And among Type-2 diabetes drugs, the Panel assigned the *Avandia* MDL, No. 1871, to Judge Rufe, and the *Actos* MDL, No. 2299, to Judge Rebecca Doherty (W.D. La.).

would be relevant to any common questions of fact will, in large measure, be focused on witnesses and documents located in New Jersey.

For these very reasons, the Panel has repeatedly—and sensibly—transferred cases to the district where the defendant's corporate headquarters are based. *See, e.g.*, *In re Nickelodeon Consumer Privacy Litig.*, 949 F. Supp. 2d 1377, 1377–78 (J.P.M.L. 2013) (concluding that the District of New Jersey was "a convenient and accessible forum," in part because it was "relatively close to potential witnesses and evidence located in New Jersey and New York City"); *In re: Fresenius Granuflo/Naturalyte Dialysate Prods. Liab. Litig.*, 935 F. Supp. 2d 1362, 1363 (J.P.M.L. 2013) (concluding that the District of Massachusetts had "a nexus to this nationwide litigation given that Fresenius is headquartered [there] and relevant witnesses and documentary evidence common to all the actions are likely to be found there"); *In re Lead Contaminated Fruit Juice Prods. Mktg. & Sales Practices Litig.*, 777 F. Supp. 2d 1353, 1355 (J.P.M.L. 2011) (same); *In re Kugel Mesh Hernia Patch Prods. Liab. Litig.*, 493 F. Supp. 2d 1371, 1373 (J.P.M.L. 2007) (same).

Indeed, the Panel ranks the locus of a defendant's corporate headquarters (and the attendant accessibility of corporate witnesses and documents) so highly that it frequently assigns MDLs on that basis, even when (as here) there is no case then pending in the transferee district. *E.g.*, *In re Nutramax Cosamin Mktg. & Sales Practices Litig.*, 988 F. Supp. 2d 1371, 1371–72 & n.2 (J.P.M.L. 2013) ("[The District of Maryland] provides a geographically central forum for this nationwide litigation, and is convenient and accessible for the parties and witnesses. Nutramax is headquartered in the district, and thus relevant documents and potential witnesses are likely to be found there. . . . Although no constituent action is currently pending in the District of Maryland, that is not an impediment to its selection as the transferee district."); *In re Darvocet,*

Darvon & Propoxyphene Prods. Liab. Litig., 780 F. Supp. 2d 1379, 1381–82 (J.P.M.L. 2011) (same; assigning MDL to the Eastern District of Kentucky, even though "no constituent action [was] currently pending" there).[15]

Second, in addition to these case-based efficiencies, the District of New Jersey offers significant travel-related conveniences. The District's courthouses in Newark, Trenton, and Camden, as well as the defendants' offices in Whippany (in the greater Newark area) and Titusville (in the greater Trenton area), are easily accessible by parties and counsel. *See In re Trasylol Prods. Liab. Litig.*, 545 F. Supp. 2d 1357, 1358 (J.P.M.L. 2008) (selecting venue, in part, because it "offer[ed] an accessible metropolitan location"); *In re Long-Distance Tel. Serv. Fed. Excise Tax Refund Litig.*, 469 F. Supp. 2d 1348, 1350 (J.P.M.L. 2006) (explaining that forum was appropriate because the "vicinity provides an easily accessible location" for the parties, witnesses, and discovery).

In terms of travel, all of the good things that Movants have said about the convenience of the Southern District of Illinois (*e.g.*, St. Louis's airport and accommodations) apply doubly to the District of New Jersey. New Jersey's Newark Liberty International Airport, for instance, is a hub for United Airlines, handled 17.5 million passengers in 2013, and currently serves 73 different cities on 955 direct flights every day. *See Federal Aviation Administration, Commercial Service Airports Based on Calendar Year 2013 Enplanements* (Sept. 29, 2014), *available at* https://www.faa.gov/airports/planning_capacity/passenger_allcargo_stats/passenger/

[15] *See also, e.g.*, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig. (No. II)*, 988 F. Supp. 2d 1369, 1370 & n.3 (J.P.M.L. 2013) (same; assigning MDL to the District of Maryland); *In re BP P.L.C. Sec. Litig.*, 734 F. Supp. 2d 1376, 1379 (J.P.M.L. 2010) (same; assigning MDL to the Southern District of Texas); *In re Sw. Life Ins. Co. Sales Practices Litig.*, 268 F. Supp. 2d 1377, 1378 (J.P.M.L. 2003) (same; assigning MDL to the Northern District of Texas).

media/cy13-commercial-service-enplanements.pdf (attached as Exhibit 5).[16] Likewise, Philadelphia International Airport, located just across the Delaware River from Camden, New Jersey, is a hub for U.S. Airways, handled 14.7 million passengers in 2013, and serves 87 different cities on 569 direct flights each day. *See id.* St. Louis's airport, by contrast, is not a hub for *any* major U.S. airline, handled only about 6.4 million passengers last year, and serves only 53 cities through 446 direct flights each day. *See id.*

For these and other similar reasons, the Panel has consistently observed that "[t]he [D]istrict [of New Jersey] is a convenient and accessible forum." *In re Nickelodeon*, 949 F. Supp. 2d at 1377–78; *accord, e.g.*, *In re Ins. Brokerage Antitrust Litig.*, 360 F. Supp. 2d 1371, 1373 (J.P.M.L. 2005) (concluding that the District of New Jersey "offers an accessible metropolitan location that is geographically convenient for many of this docket's litigants and counsel").[17] In any event, it is by every objective measure more "convenient" and "accessible" than the Southern District of Illinois.

Finally, and significantly, the District of New Jersey has the docket capacity—as well as judges with pertinent expertise—to handle these cases. The Panel sensibly considers the "relative docket conditions" of potential transferee districts when selecting a venue for MDL

[16] *See, e.g.*, MULTIDISTRICT LITIGATION MANUAL § 6:7 ("The Panel has recognized that transfer and consolidation impose travel burdens on the litigants and their attorneys. Proximity may be evaluated in terms of ease of access by air travel. A location with a large airport offering frequent air service to the other centers of activity in the case may be much more convenient than a location physically closer to the witnesses or documents but which is much more difficult to get to.").

[17] Movants tout several attributes of the Southern District of Illinois' clerk's office. Mot. at 9–10. While the services they feature—for example, a "state-of-the-art webpage"—are commendable, they do not distinguish the Southern District of Illinois from any other district court that might handle an MDL. *See, e.g.*, *In re Ins. Brokerage Antitrust Litig.*, 360 F. Supp. 2d at 1373 ("[T]he [D]istrict [of New Jersey] is equipped with the resources that this complex antitrust docket is likely to require."); *In re Comp. of Managerial, Prof'l & Technical Employees Antitrust Litig.*, 206 F. Supp. 2d 1374, 1375–76 (J.P.M.L. 2002) (same).

proceedings, favoring districts with lighter civil caseloads. *In re Webvention LLC ('294) Patent Litig.*, 831 F. Supp. 2d 1366, 1367 (J.P.M.L. 2011); *see also In re Wright Med. Tech., Inc., Conserve Hip Implant Prods. Liab. Litig.*, 844 F. Supp. 2d 1371, 1373 (J.P.M.L. 2012) ("favorable docket conditions"); *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litig.*, 787 F. Supp. 2d 1358, 1360 (J.P.M.L. 2011) ("caseload conditions conducive to handling [the] litigation"). As of June 30, 2014, the District of New Jersey was averaging 545 pending civil cases per judgeship, which ranks it only 27th among federal district courts. *See* Exhibit 2. By contrast, in the Southern District of Illinois, there were 12,910 pending cases, with an average of 3,228 pending civil cases per judgeship, making the Southern District of Illinois the *second busiest court in the country*—and *six times* busier than the District of New Jersey. *See id.* The MDL statistics tell a similar story: although the District of New Jersey is home to 17 pending MDLs, those proceedings comprise a total of only 1,003 pending cases, compared to the 9,430 constituent cases that remain pending in the Southern District of Illinois's MDLs. *See* Exhibit 3. Put simply, as the Panel has recognized on many earlier occasions, the District of New Jersey "has the resources and capacity to efficiently handle this litigation." *In re Nickelodeon*, 949 F. Supp. 2d at 1377–78; *accord, e.g., In re Comp. of Managerial, Prof'l & Technical Employees Antitrust Litig.*, 206 F. Supp. 2d 1374, 1375–76 (J.P.M.L. 2002) ("[T]he District of New Jersey [is an] accessible, urban district[] equipped with the resources that this complex docket is likely to require."). That is as true now as before—and particularly true in comparison with the (relatively overtaxed) Southern District of Illinois.

The judges in District of New Jersey have extensive experience handling MDL proceedings, an important consideration in selecting the appropriate forum. *See, e.g., In re Google Inc. Cookie Placement Consumer Privacy Litig.*, 867 F. Supp. 2d 1356, 1357 (J.P.M.L. 2012) (as-

signing MDL to "a jurist experienced in complex multidistrict litigation"); *In re Celexa & Lexapro Prods. Liab. Litig.*, 416 F. Supp. 2d 1361, 1363 (J.P.M.L. 2006) (same). Indeed, 12 judges in the District are currently presiding over MDLs. To be sure, several of the judges' dockets may be too crowded to take on an additional multidistrict assignment. For instance, Judge Joel Pisano is handling *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, MDL No. 2243, which comprises 517 constituent actions, and Judge Susan Wigenton is handling *In re Zimmer Durom Hip Cup Prods. Liab. Litig.*, MDL No. 2158, with 309 actions. Together, those two proceedings account for more than 80% of the MDL cases pending in the District of New Jersey. *See* Exhibit 3. Judges Kevin McNulty, Esther Salas, and Katharine Hayden likewise appear to be very busy; each has an active MDL and, in addition, a three-year civil-case backlog (34, 27, and 32 cases, respectively) that is significantly larger than the Third Circuit average. *See* Admin. Office of the U.S. Courts, *Civil Justice Reform Act of 1990 Report* (September 30, 2013) (excerpts attached as Exhibit 6).

By contrast, several of the District of New Jersey's judges with MDL experience seem to have manageable caseloads. *See, e.g., In re Nebivolol ('040) Patent Litig.*, 867 F. Supp. 2d 1354, 1356 (J.P.M.L. 2012) (emphasizing that transferee judge "enjoy[ed] favorable caseload conditions" and was "an experienced transferee judge"). Chief Judge Jerome Simandle and Judge Freda Wolfson, for example, both preside over very limited MDLs and manage dockets with small three-year civil-case backlogs.[18] *See* Exhibits 3 & 6. Moreover, at last count, neither had any motions or bench trials pending for more than six months. *See id.* Judges Stanley Chesler and William Martini are similarly situated; both currently preside over multiple MDLs comprising very few active cases, and both manage those dockets and their remaining cases very effi-

[18] Chief Judge Simandle's *In re Caterpillar Engine Prods. Liab. Litig.* MDL, No. 2540, comprises only 16 pending cases, and Judge Wolfson's *Plavix* MDL, No. 2418, only 31 active cases.

ciently.[19] *See id.* Finally, although Judge Robert Kugler, a 12-year district judge (and before that, a 10-year magistrate judge), has not previously handled an MDL, his motions and bench-trial statistics—zero of either pending for more than six months—indicate that he would manage an MDL proceeding efficiently. *See id.*

* * *

On balance, should the Panel conclude that consolidation is appropriate, the District of New Jersey is the most appropriate venue for an MDL proceeding—far superior to Movants' preferred forum in the Southern District of Illinois. Unlike the Southern District of Illinois, the District of New Jersey is convenient to the parties and witnesses, especially the witnesses relevant to the alleged common questions of fact; the District of New Jersey's civil docket is not so large as to impede efficient resolution of these cases; and its judges have the appropriate experience and capacity to handle multidistrict litigation.

CONCLUSION

For the reasons stated above, the Panel should deny Movants' Section 1407 motion to transfer. In the alternative, the Panel should consolidate these cases in the District of New Jersey, not in the Southern District of Illinois as Movants have requested.

[19] Judge Chesler's two active MDLs, *In re Merck & Co., Inc., Sec., Derivative & "ERISA" Litig.*, MDL No. 1658, and *In re Nickelodeon Consumer Privacy Litig.*, MDL No. 2443, comprise a total of only eight active cases, and he has fewer than average motions and bench trials pending for longer than six months. Judge Martini's three MDLs comprise a total of only 28 active cases; at last count, he does not have any bench trials pending for longer than six months.

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By: /s/ F.M. (Tripp) Haston, III

F.M. (Tripp) Haston, III
Bradley Arant Boult Cummings LLP
One Federal Place
1819 Fifth Avenue North
Birmingham, Alabama 35203
Telephone: (205) 521-8303
Facsimile: (205) 488-6303
thaston@babc.com

Counsel for Bayer Corporation, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals Inc.