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SUPREME COURT OF MISSOURI

STATE ex rel. BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER ESSURE INC., and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	**Case No. SC96189**
Relators,	)	**Missouri Court of Appeals, Eastern District No. ED105183**
vs.	)	**Circuit Court of St. Louis City Cause No. 1622-CC01049-01**
THE HONORABLE JOAN L. MORIARTY,	)	**Division No. 31**
Respondent.	)	

BRIEF OF RELATORS BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER ESSURE INC., AND BAYER HEALTHCARE PHARMACEUTICALS INC.

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ORAL ARGUMENT REQUESTED

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Jurisdictional Statement

Upon application of Relators Bayer Corporation, Bayer HealthCare LLC, Bayer Essure Inc., and Bayer HealthCare Pharmaceuticals Inc. ("Bayer"), this Court issued a Preliminary Writ of Prohibition on July 7, 2017. This Court has jurisdiction to hear this Writ pursuant to Article V § 4.1 of the Missouri Constitution. Bayer seeks a Permanent Order of Prohibition to prevent the Honorable Joan L. Moriarty from enforcing her order of December 20, 2016, denying Bayer's Motions to Dismiss, Sever, and Transfer. The record before Respondent demonstrated that Bayer was not subject to personal jurisdiction with respect to the claims of the non-Missouri Plaintiffs in this action, that the claims of all Plaintiffs were preempted by federal law, and that the claims are not properly joined and not in the proper venue.

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Introduction

The Court should make permanent the writ of prohibition it issued in July, directing Respondent to show cause "why a writ of prohibition should not issue prohibiting you from doing anything other than vacate the December 20, 2016 order (denying Defendants' motion to dismiss, motion to sever, and motion to transfer venue)." **A467**. This case involves 92 Plaintiffs, only seven of whom allege any connection to Missouri. The other 85 Plaintiffs allege no connection to the State. They nonetheless wish to pursue their claims in Missouri because they know that other courts around the country have dismissed identical claims on the pleadings. *See infra* at pp.3-4. The Court should grant the writ for two reasons.

First, under binding precedent from this Court and the United States Supreme Court, there is no personal jurisdiction with respect to the claims of the 85 non-Missouri Plaintiffs. *See State ex rel. Norfolk S. Ry. v. Dolan*, 512 S.W.3d 41 (Mo. banc 2017); *BNSF Ry. v. Tyrrell*, 137 S. Ct. 1549, 1559 (2017); *Bristol-Myers Squibb Co. v. Super. Ct. of Cal., San Francisco Cty.*, 137 S. Ct. 1773 (2017). Contrary to Respondent's ruling, and as this Court's recent decision in *Norfolk Southern Railway* makes clear, Bayer did not "consent" to personal jurisdiction merely because some of the Bayer Defendants have registered agents in Missouri. *See Norfolk S. Ry.*, 512 S.W.3d at 52. Nor is Bayer subject to general jurisdiction in Missouri, because no Defendant is incorporated in Missouri or has its principal place of business in Missouri; merely doing business in Missouri and having a registered agent in the state are not sufficient to establish general jurisdiction. *Id.* at 47-48; *see also BNSF*, 137 S. Ct. at 1559. Finally, Bayer is not subject to specific

jurisdiction in Missouri with respect to the non-Missouri Plaintiffs' claims because those claims do not arise from Bayer's Missouri contacts, and the non-Missouri Plaintiffs cannot piggyback on the claims of the Missouri Plaintiffs. *See Norfolk S. Ry.*, 512 S.W.3d at 49; *Bristol-Myers*, 137 S. Ct. at 1781. Respondent's ruling also erred in refusing to sever the claims and transfer them to the proper venue.

Second, and equally importantly, Respondent erred in failing to dismiss all claims as preempted. Under federal law, state law claims against medical devices, like Essure, which have received pre-market approval from the federal Food and Drug Administration, are expressly preempted where, as here, they impose requirements "different from, or in addition to" federal requirements, see 21 U.S.C. § 360k(a). As several courts across multiple jurisdictions have held, Plaintiffs' claims are preempted. *See, e.g.*, *Williams v. Bayer Corp.*, No. 15BA-CV02526 (Mo. Cir. Ct. Boone Cty. July 18, 2016) (dismissing all claims with prejudice) (**A324**) (appeal docketed); *Olmstead v. Bayer Corp.*, No. 3:17-cv-387, 2017 WL 3498696 (N.D.N.Y. Aug. 15, 2017) (same); *Burrell v. Bayer Corp.*, No. 1:17-cv-00031, 2017 WL 1955333 (W.D.N.C. May 10, 2017) (same) (appeal docketed); *Norman v. Bayer Corp.*, No. 3:16-cv-00253, 2016 WL 4007547 (D. Conn. July 26, 2016) (same) (appeal docketed); *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085 (N.D. Cal. 2016) (dismissing all claims as preempted); *Medali v. Bayer HealthCare LLC*, No. RG15771555, slip op. (Cal. Super. Ct. Feb. 16, 2016) (same) (**A90-91**); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804 (E.D. Pa. 2016) (dismissing 10 of 12 claims); *McLaughlin v. Bayer Corp.*, Nos. 14-7315 *et al.*, 2017 WL 697047, at *19 (E.D. Pa. Feb. 21, 2017) (further narrowing claims in

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amended complaint); Transcript, *Noris v. Bayer Essure, Inc.*, No. BC589882 (Cal. Super. Ct. Apr. 26, 2016) (dismissing claims) (**A94-124**); *Lance v. Bayer Essure Inc.*, RG16809860 (Cal. Super. Ct. Aug. 2, 2016) (dismissing multiple claims) (**A487-508**); *Journey v. Bayer Corp.*, JCCP No. 4887 (Cal. Super. Ct. Apr. 12, 2017) (**A509-21**) (further narrowing claims in amended complaint).

Respondent's ruling to the contrary is the *only* written decision in the country to disagree. Because Respondent's rulings were based on several legal errors, this Court should grant the writ of prohibition.

Statement of Facts

Plaintiffs filed their Petition in the Circuit Court on April 13, 2016. **A1**. In it, they allege that they suffered various injuries as a result of using Essure, a Class III medical device approved by the U.S. Food and Drug Administration as a form of permanent female contraception. Bayer manufactures and distributes Essure. None of the Bayer Defendants is incorporated in Missouri or has its principal place of business in Missouri. Only seven of the Plaintiffs are from Missouri, and the other 85 (the "non-Missouri Plaintiffs") allege no connection with this State. The Petition nonetheless asserts that Bayer is subject to "both general and specific personal jurisdiction" in Missouri because Bayer did business in Missouri, derived revenue in Missouri by marketing Essure to women in Missouri, and allegedly "committed torts in whole or in part against Plaintiffs in Missouri." **A3**.

On June 20, 2016, Bayer moved to dismiss the Petition. *See* **A47**. Bayer argued that it was not subject to personal jurisdiction in Missouri with respect to the non-

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Missouri Plaintiffs' claims. **A61-66**. It also argued that all Plaintiffs' claims were preempted by federal law, *see Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).[1] **A67**; *see also* **A296-322**. Alternatively, Bayer moved to sever individual non-Missouri Plaintiffs' claims and transfer those individual Plaintiffs to appropriate venues. *See* **A332-41**.

On December 20, 2016, Respondent denied Bayer's Motion to Dismiss and Motion to Sever and Transfer. *See* **A394**. With respect to personal jurisdiction, Respondent held that Bayer "is present or has consented to jurisdiction" in Missouri because some of the Defendants appointed registered agents for service of process. **A397**. With respect to preemption, Respondent ruled that Plaintiffs' claims were not preempted, **A399-400**, relying on *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996) (which is inapplicable as discussed below), applying a presumption against preemption (which is incorrect as a matter of law), and noting that Defendants did not cite any Missouri cases on preemption (which is both factually inaccurate and legally irrelevant). *Id.* at 494. Finally, Respondent denied Bayer's Motion to Sever and Transfer, finding that all Plaintiffs' claims arose from the same alleged conduct and that all properly joined Plaintiffs could bring suit in the same venue as the City of St. Louis Plaintiff. **A402-04**.

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[1] Bayer further argued that the non-Missouri Plaintiffs' claims should be dismissed under the doctrine of *forum non conveniens*, and that all Plaintiffs' claims should be dismissed as inadequately pleaded. **A66-67**, **A80-83**. Respondent held to the contrary. **A397-99**, **A401**. While Bayer disagrees with those rulings and preserves the issues for appeal, Bayer does not challenge those rulings in this Petition for a Writ of Prohibition.

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Bayer then filed a Petition for Writ of Prohibition, Suggestions in Support, and Exhibits with the Missouri Court of Appeals, Eastern District. **A406**. That court summarily denied the petition. **A436**.

Bayer next filed its Petition for Writ of Prohibition in this Court. **A437**. While the Petition for Writ of Prohibition was pending, this Court and the United States Supreme Court decided several cases bearing directly on the issues of personal jurisdiction, including *Norfolk S. Ry.*, 512 S.W.3d 41, *BNSF*, 137 S. Ct. 1549, and *Bristol-Myers*, 137 S. Ct. 1773. Following the U.S. Supreme Court's decision in *Bristol-Myers*, Bayer filed supplemental suggestions in support of the Writ of Prohibition. **A522**.

On July 7, 2017, this Court issued a writ of prohibition on a preliminary basis, ordering Respondent to show cause "why a writ of prohibition should not issue prohibiting you from doing anything other than vacate the December 20, 2016, order" denying Bayer's Motion to Dismiss and Motion to Sever and Transfer. **A467**. Respondent, represented by counsel for the Plaintiffs, filed her answer on July 24, 2017. **A469**.

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POINTS RELIED ON

I. BAYER IS ENTITLED TO A PERMANENT ORDER PROHIBITING RESPONDENT FROM ENFORCING HER ORDER DENYING BAYER'S MOTION TO DISMISS AS TO NON-MISSOURI PLAINTIFFS' CLAIMS BECAUSE BAYER IS NOT SUBJECT TO PERSONAL JURISDICTION WITH RESPECT TO THE CLAIMS OF THESE NON-MISSOURI PLAINTIFFS AND RESPONDENT ABUSED HER DISCRETION AND USURPED JUDICIAL AUTHORITY IN HOLDING OTHERWISE.

- *State ex rel. Norfolk S. Ry. v. Dolan*, 512 S.W.3d 41 (Mo. banc 2017)
- *BNSF Ry. v. Tyrrell*, 137 S. Ct. 1549 (2017)
- *Bristol-Myers Squibb Co. v. Super. Ct.t of Cal., San Francisco Cty.*, 137 S. Ct. 1773 (2017)
- *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014)

II. BAYER IS ENTITLED TO A PERMANENT ORDER PROHIBITING RESPONDENT FROM ENFORCING HER ORDER DENYING BAYER'S MOTION TO DISMISS AS TO ALL PLAINTIFFS' CLAIMS BECAUSE ALL PLAINTIFFS' CLAIMS ARE PREEMPTED UNDER FEDERAL LAW AND RESPONDENT ABUSED HER DISCRETION AND USURPED JUDICIAL AUTHORITY IN HOLDING OTHERWISE.

- 21 U.S.C. § 360k(a)
- 21 U.S.C. § 337(a)

- *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)
- *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)
- *Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938 (2016)
- *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010)

Summary of Argument

"A writ of prohibition is available: (1) to prevent a usurpation of judicial power when the trial court lacks authority or jurisdiction; (2) to remedy an excess of authority, jurisdiction or abuse of discretion where the lower court lacks the power to act as intended; or (3) where a party may suffer irreparable harm if relief is not granted." *State ex rel. Houska v. Dickhaner*, 323 S.W.3d 29, 32 (Mo. banc 2010). Respondent abused her discretion and usurped judicial authority by refusing to dismiss non-Missouri Plaintiffs' claims for lack of personal jurisdiction and refusing to dismiss all claims as preempted.

I. Recent decisions, including decisions of this Court and the U.S. Supreme Court, make clear beyond all doubt that Missouri courts lack personal jurisdiction over these claims. First, contrary to Respondent's ruling, non-Missouri corporations such as Bayer do not consent to personal jurisdiction by maintaining a registered agent in Missouri. *See Norfolk S. Ry.*, 512 S.W.3d at 52. Second, neither maintaining a registered agent in Missouri nor conducting substantial business and deriving revenue from business in Missouri are sufficient to establish general jurisdiction in Missouri. *See id.* at 47-48; *see also BNSF*, 137 S. Ct. at 1559; *Daimler*, 134 S. Ct. at 760, 761 & n.19. Third, regardless

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of whether the non-Missouri Plaintiffs' claims are properly joined under Missouri law, Bayer is not subject to personal jurisdiction with respect to those Plaintiffs' claims because they do not arise out of or relate to Bayer's Missouri contacts. *See Norfolk S. Ry.*, 512 S.W.3d at 49; *Bristol-Myers*, 137 S. Ct. at 1781. Non-Missouri Plaintiffs cannot piggyback on the personal jurisdiction that exists with respect to the claims of Missouri Plaintiffs. *See Bristol-Myers*, 137 S. Ct. at 1781; *see also Jordan v. Bayer Corp.*, No. 4:17-CV-865, 2017 WL 3006993 (E.D. Mo. July 14, 2017) (dismissing non-Missouri plaintiffs in an Essure case for lack of personal jurisdiction following *Bristol-Myers*); *Siegfried v. Boehringer Ingelheim Pharm., Inc.*, No. 4:16 CV 1942, 2017 WL 2778107 (E.D. Mo. June 27, 2017) (dismissing non-Missouri plaintiffs under *BNSF* and *Bristol-Myers Squibb*). Accordingly, there is no basis for personal jurisdiction, and Respondent erred in refusing to dismiss the non-Missouri Plaintiffs' claims. In addition, Respondent erred in refusing to sever the claims and transfer them to the proper venue.

II. Furthermore, Respondent abused her discretion in ruling that federal preemption principles do not bar Plaintiffs' claims. Plaintiffs' claims are (1) expressly preempted, because they seek to impose requirements on Bayer "different from, or in addition to" requirements imposed by federal law, *see* 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 322-23, or (2) impliedly preempted, because they exist solely by virtue of the Food, Drug, and Cosmetics Act and do not depend on independent state-law duties, *Buckman*, 531 U.S. at 349 n.4; *see also* 21 U.S.C. § 337(a) ("[A]ll . . . proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). In holding otherwise, Respondent relied on the wrong U.S. Supreme

Court case, applied an inapplicable "presumption against preemption," failed to apply well-established preemption principles, and predicated her ruling on the incorrect and irrelevant premise that Bayer failed to cite Missouri state-court precedent holding common-law claims preempted by federal law. These errors warrant a permanent writ of prohibition.

Argument

I. BAYER IS ENTITLED TO A PERMANENT ORDER PROHIBITING RESPONDENT FROM ENFORCING HER ORDER DENYING BAYER'S MOTION TO DISMISS AS TO NON-MISSOURI PLAINTIFFS' CLAIMS BECAUSE BAYER IS NOT SUBJECT TO PERSONAL JURISDICTION WITH RESPECT TO THE CLAIMS OF THESE NON-MISSOURI PLAINTIFFS AND RESPONDENT ABUSED HER DISCRETION AND USURPED JUDICIAL AUTHORITY IN HOLDING OTHERWISE.

A. Introduction

Respondent abused her discretion and usurped judicial authority in determining that the court had personal jurisdiction over Bayer with respect to the claims of 85 out-of-state Plaintiffs, who have alleged no connection between their claims and the State of Missouri. This decision is contrary to Due Process, to this Court's decision in *Norfolk Southern Railway*, and to the U.S. Supreme Court's decisions in *Daimler*, *BNFS*, and *Bristol-Myers*. This Court should make permanent its writ as to the claims of the 85 non-Missouri Plaintiffs.

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B. Relator Has Met The Standard For Issuance Of A Permanent Writ Of Prohibition.

"A writ of prohibition is available: (1) to prevent a usurpation of judicial power when the trial court lacks authority or jurisdiction; (2) to remedy an excess of authority, jurisdiction or abuse of discretion where the lower court lacks the power to act as intended; or (3) where a party may suffer irreparable harm if relief is not granted." *Houska*, 323 S.W.3d at 32. Prohibition is intended to "prevent exercise of extrajurisdictional power," and "may be appropriate" if a court's "abuse of . . . discretion is so great as to be an act in excess of jurisdiction [and] create[s] injury which cannot be remedied on appeal." *State ex rel. K-Mart Corp. v. Holliger*, 986 S.W.2d 165, 169 (Mo. banc 1999). In particular, "[p]rohibition may be appropriate to prevent unnecessary, inconvenient, and expensive litigation." *Houska*, 323 S.W.3d at 32; *see also Mo. State Bd. of Registration for Healing Arts v. Brown*, 121 S.W.3d 234, 236 (Mo. banc 2003) ("prohibition is appropriate whenever … there is no adequate remedy by appeal for the party seeking the writ, and the 'aggrieved party may suffer considerable hardship and expense as a consequence of the erroneous decision [of the lower court].'") (second alteration in original).

Significantly, it is well established that a writ of prohibition is an appropriate remedy to correct a trial court's improper exercise of personal jurisdiction. *See*, *e.g.*, *State ex rel. William Rani Assocs., Inc. v. Hartenbach*, 742 S.W.2d 134, 137 (Mo. banc 1987) ("Prohibition is the proper remedy to prevent further action of the trial court where personal jurisdiction of the defendant is lacking.") (citing *State ex rel. Boll v. Weinstein*,

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295 S.W.2d 62 (Mo. 1956). The Writ of Prohibition should be made permanent because Respondent's refusal to dismiss the claims of non-Missouri Plaintiffs for lack of personal jurisdiction was an abuse of discretion and usurped judicial authority.

C. Respondent Erred By Holding That Bayer Consented To Personal Jurisdiction By Appointing A Registered Agent In Accordance With Missouri Law.

Respondent held that Bayer "consented to jurisdiction through the appointment of a registered agent in the state" because "[a] corporation has long been considered 'present' within the state when its agent is served with process in the state." **A397**. That reasoning is inconsistent with *Daimler*, was squarely rejected by this Court in *Norfolk Southern Railway*, and should similarly be rejected here.

In *Norfolk Southern Railway*, this Court ruled that under Missouri law a corporation does not consent to personal jurisdiction merely by appointing a registered agent for service of process in accordance with Missouri's foreign corporation registration statutes. "The plain language of Missouri's registration statutes does not mention consent to personal jurisdiction for unrelated claims, nor does it purport to provide an independent basis for jurisdiction over foreign corporations that register in Missouri." *Norfolk S. Ry.*, 512 S.W.3d at 52. Instead, the statute merely authorizes service on a registered agent of process "required or authorized to be served on the foreign corporation," Mo Ann. Stat. § 351.594.1, but no statute "provide[s] that suit may be brought in Missouri against non-resident corporations for suits unrelated to the corporation's activities in this state." *Norfolk S. Ry.*, 512 S.W.3d at 52. In short, "the

registration statute does not provide an independent basis for broadening Missouri's personal jurisdiction to include suits unrelated to the corporation's forum activities when the usual bases for general jurisdiction are not present." *Id.* Accordingly, contrary to Respondent's ruling, Bayer did not consent to jurisdiction by appointing a registered agent.[2]

Indeed, a contrary ruling would create a backdoor to evade the limits of general jurisdiction the U.S. Supreme Court explained in *Daimler*. As Bayer set forth in its Petition for a Writ of Prohibition, Respondent improperly relied on pre-*Daimler* opinions of this Court, which did not in fact hold that appointment of a registered agent by itself is sufficient to establish consent to personal jurisdiction in all cases. *See State ex rel. K-Mart Corp. v. Holliger*, 986 S.W.2d 165, 168 (Mo. banc 1999) (reserving the question whether "designation of an agent for service of process, without more, is always sufficient to confer jurisdiction"). *Daimler* makes clear that it *cannot* be sufficient: The general rule is that a corporation may not be subject to general jurisdiction in a state in which it is neither incorporated nor has its principal place of business except in an "exceptional case." *Daimler*, 134 S. Ct. at 761 n.19. And, because it is not "exceptional"

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[2] Moreover, Bayer Essure Inc. *is not* registered to do business in Missouri, which Plaintiffs implicitly concede in their Response to the Motion to Dismiss. **A263** ("Bayer Corporation, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals Inc. consented to general jurisdiction in Missouri Courts . . . ."). At a minimum, therefore, Respondent's finding that Bayer Essure Inc. consented to jurisdiction is plainly incorrect.

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for large corporations to maintain registered agents in many states, numerous courts have held in the wake of *Daimler* that appointment of a registered agent does not establish consent to personal jurisdiction. *See*, *e.g.*, *Brown v. Lockheed Martin Corp.*, 814 F.3d 619, 640 (2d Cir. 2016); *Addelson v. Sanofi*, S.A., No. 4:16-cv-1277, 2016 WL 6216124, at *4 (E.D. Mo. Oct. 25, 2016); *Smith v. Union Carbide Corp.*, No. 1422-CC00457, 2015 WL 191118, at *3 (Mo. Cir. Ct. St. Louis City Jan. 12, 2015).

D. There Is No Basis For Holding That Bayer Is Subject To General Jurisdiction In Missouri.

Moreover, no Bayer Defendant is subject to general jurisdiction in Missouri. "With respect to a corporation, the place of incorporation and principal place of business are 'paradig[m] . . . bases for general jurisdiction.'" *Daimler*, 134 S. Ct. at 760, 761 & n.19 (ellipsis and first alteration in original); *see also BNSF*, 137 S. Ct. at 1559. It is undisputed that no Bayer Defendant is incorporated or has its principal place of business in Missouri.

The Supreme Court has also recognized that in certain "exceptional case[s]," a party's connection to a jurisdiction will be "so substantial," its contacts "so continuous and systematic," "as to render the corporation at home in that State." *Daimler*, 134 S. Ct. at 761 n. 19. But Plaintiffs do not allege that Bayer possesses such substantial ties to Missouri as to make this an "exceptional case" in which Bayer is "essentially at home" in Missouri.

Again, *Norfolk Southern Railway* is controlling. As explained above, this Court held that a non-resident corporation does not become subject to general jurisdiction in

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Missouri either by appointing a registered agent or conducting substantial business in Missouri. *Norfolk S. Ry.*, 512 S.W.3d at 47. Indeed, a corporation that is not incorporated in Missouri and does not have its principal place of business in Missouri is subject to general jurisdiction in Missouri only if Missouri is "a 'surrogate for place of incorporation or home office' such that the corporation is 'essentially at home' in [Missouri]." *Id.* at 48 (quoting *Daimler*, 134 S. Ct. at 756 n.8). "[F]inding a corporation at home wherever it does business would destroy the distinction between general and specific jurisdiction, for '[a] corporation that operates in many places can scarcely be deemed at home in all of them.'" *Id.* (quoting *Daimler*, 134 S. Ct. at 756 n.8). Thus, "when 'a corporation is neither incorporated nor maintains its principal place of business in a state, mere contacts, no matter how "systematic and continuous," are extraordinarily unlikely to add up to an "exceptional case."'" *Id.* (quoting *Brown*, 814 F.3d at 629).

A few months after *Norfolk Southern Railway*, the U.S. Supreme Court issued a similar holding in *BNSF*. There, the Court reiterated its observation in *Daimler* that "'the general jurisdiction inquiry does not focus solely on the magnitude of the defendant's in-state contacts'" but "'calls for an appraisal of a corporation's activities in their entirety.'" *BNSF*, 137 S. Ct. at 1559 (quoting *Daimler*, 134 S. Ct. at 762 n.20). Thus, "in-state business . . . does not suffice to permit the assertion of general jurisdiction over claims . . . that are unrelated to any activity occurring in [the forum state]." *Id.*

Respondent did not even address general jurisdiction, having erroneously found that Bayer consented to jurisdiction. But it is plain under this Court's ruling in *Norfolk Southern Railway* that general jurisdiction is absent: Plaintiffs have alleged no facts to

suggest that any Bayer Defendant has such extensive Missouri contacts as to make Missouri in essence its home or "surrogate" place of incorporation or principal place of business, *see Norfolk S. Ry.*, 512 S.W.3d at 48, and their in-state business is not sufficient, *id.*; *see BNSF*, 137 S. Ct. at 1559. Indeed, in Response to Bayer's Motion to Dismiss, Plaintiffs made no argument that any Bayer Defendant would be subject to general jurisdiction in Missouri other than the contention that Bayer maintains a registered agent in the State. There is no basis for finding that Bayer is subject to general jurisdiction in Missouri.

E. Bayer Is Not Subject To Specific Jurisdiction In Missouri With Respect To The Non-Missouri Plaintiffs' Claims.

Finally, Bayer is not subject to specific jurisdiction with respect to the claims of the non-Missouri Plaintiffs. "Specific jurisdiction requires consideration of the 'relationship among the defendant, the forum, and the litigation,'" *Norfolk S. Ry.*, 512 S.W.3d at 48 (quoting *Andra v. Left Gate Prop. Holding, Inc.*, 453 S.W.3d 216, 226 (Mo. banc 2015)), and "encompasses cases in which the suit arises out of or relates to the defendant's contacts with the forum," *Daimler*, 134 S. Ct. at 748-49.

Again, Respondent did not even consider specific jurisdiction, instead relying on the clearly erroneous ruling that Bayer consented to jurisdiction. In their opposition to Bayer's motion to dismiss, Plaintiffs argued that Bayer was subject to specific jurisdiction with respect to the non-Missouri Plaintiffs' claims because "Bayer does not challenge personal jurisdiction as to the Missouri Plaintiffs' claims" and "the non-Missouri Plaintiffs alleged[] [that they] were implanted with the same product the

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Defendants marketed and sold in Missouri and were injured by the same conduct allegedly injuring the Missouri Plaintiffs." **A264**. The U.S. Supreme Court subsequently rejected an identical argument in *Bristol-Myers*. *See* **A522**. There, nonresident plaintiffs argued that Bristol-Myers' nationwide marketing—including marketing in California—and its sales and other business in California gave rise to specific jurisdiction with respect to their claims. The Supreme Court rejected that argument, holding that "[t]he mere fact that other plaintiffs were prescribed, obtained, and ingested [the drug] in California—and allegedly sustained the same injuries as did the nonresidents—does not allow the State to assert specific jurisdiction over the *nonresidents'* claims." *Bristol-Myers*, 137 S. Ct. at 1781 (emphasis added).

Rather, "settled principles regarding specific jurisdiction" require each plaintiff to identify "an 'affiliation between the forum and the underlying controversy, principally [an] activity or an occurrence that takes place in the forum state.'" *Id*. (alteration in original). Because "[t]he relevant plaintiffs [were] not California residents" and "all the conduct giving rise to the nonresidents' claims occurred elsewhere," specific personal jurisdiction over their claims did not exist in California courts. *Id.* at 1782. In short, a state court cannot exercise specific jurisdiction over the claims of out-of-state plaintiffs against an out-of-state defendant when "the conduct giving rise to the nonresidents' claims occurred elsewhere." This is true regardless of whether there is specific jurisdiction over other plaintiffs' claims joined in the same case: "What is needed—and what is missing here—is a connection between the forum and specific claims at issue." *Bristol-Myers*, 137 S. Ct. at 1781.

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In the wake of *Bristol-Myers*, numerous courts—including one addressing a nearly identical case about Essure—have dismissed non-Missouri plaintiffs' claims for lack of personal jurisdiction when those plaintiffs have sought to piggyback on the specific jurisdiction that exists with respect to Missouri plaintiffs' claims. *See Jordan*, No. 4:17-CV-865, 2017 WL 3006993; *see also Siegfried*, No. 4:16 CV 1942, 2017 WL 2778107. Under *Norfolk Southern Railway*, it is not sufficient to allege that the non-Missouri Plaintiffs' claims are based on the same "type" of conduct as the Missouri Plaintiffs' claims. 512 S.W.3d at 49. It would "turn specific jurisdiction on its head" to hold that an activity (such as sales, marketing, or clinical trials) that Bayer conducts in many states—including Missouri—gives rise to specific jurisdiction in Missouri over the claims of non-Missouri plaintiffs that have no particular connection to those Missouri activities. *Id.* If that were the law, "[t]here would never be a need to discuss general jurisdiction, for every state would have specific jurisdiction over every national business corporation." *Id.*

Thus, there is no personal jurisdiction with respect to the non-Missouri Plaintiffs' claims, even though Bayer and its predecessor (Conceptus) conducted clinical trials and marketing activities in Missouri—and numerous other States. The non-Missouri Plaintiffs' claims do not arise out of Bayer's Missouri contacts. These Plaintiffs did not allegedly participate in the clinical trials in Missouri or even see marketing materials in Missouri. Therefore, Respondent erred in failing to dismiss these Plaintiffs' claims.

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F. Respondent Erred In Refusing To Grant Bayer's Motion To Sever And Transfer.

In the alternative, Respondent abused her discretion in two additional ways. First, she failed to sever individual Plaintiffs' claims and drop these 85 non-Missouri Plaintiffs' claims from this case. *See* Mo. Ann. Stat. §§ 507.040, 507.050; Mo. S. Ct. R. 52.05, 52.06. The individual Plaintiffs' claims do not meet the standard for joinder because they do not arise out of the same "transaction, occurrence, or series of transactions or occurrences." Mo. Ann. Stat. § 507.040; Mo. S. Ct. R. 52.05. Rather, each Plaintiff's claim involves a different series of transactions and occurrences involving different physicians prescribing Essure at different times in light of each Plaintiff's different medical history, reliance on different alleged misrepresentations, and different alleged injuries. A growing body of case law—including in Missouri—holds that severance in such circumstances is warranted. *See*, *e.g.*, *Brown v. Walgreens Co.*, No. 1022-CC00765, slip op. at 4 (Mo. Cir. Ct. St. Louis City Nov. 15, 2010); *Ballard v. Wyeth*, No. 042-07388A, slip op. at 4 (Mo. Cir. Ct. St. Louis City Aug. 24, 2005); *Alday v. Organon USA, Inc.*, Nos. 09-cv-1415 & 08-md-1964, 2009 WL 3531802, at *1 (E.D. Mo. Oct. 27, 2009); *Boschert v. Pfizer, Inc.*, No. 08-cv-1714, 2009 WL 1383183 (E.D. Mo. May 14, 2009); *see also Stinnette v. Medtronic Inc.*, No. H-09-03854, 2010 WL 767558, at *2 (S.D. Tex. Mar. 3, 2010) ("A multitude of cases around the country have held that

plaintiffs were not properly joined when the only common link among them was a defective drug or medical device.").

In addition, Respondent abused her discretion by finding venue in the City of St. Louis proper as to the 85 non-Missouri Plaintiffs and the six Missouri Plaintiffs who do not allege they were injured in the City of St. Louis. Under Missouri law, "in all actions in which there is any count alleging a tort and in which the plaintiff was first injured in the state of Missouri, venue shall be in the county were the plaintiff was first injured by the wrongful acts or negligent conduct alleged in the action." Mo. Ann. Stat. § 508.010(4). In tort cases in which a non-Missouri plaintiff was injured outside the state of Missouri, "venue shall be in any county where a defendant corporation's registered agent is located." Mo. Ann. Stat. § 508.010(5)(1). "A plaintiff is considered first injured where the trauma or exposure occurred rather than where symptoms are first manifested." *Id.* § 508.010(14). Here, only one Plaintiff alleges that she was injured in the City of St. Louis. Because each individual plaintiff "must satisfy venue requirements," the other 91 plaintiffs are necessarily in the wrong venue, even if they are properly joined. *State ex rel. Kinsey v. Wilkins*, 394 S.W.3d 446, 453 (Mo. App. E.D. 2013) (citing *State ex rel. Turnbough v. Gaertner*, 589 S.W.2d 290, 292 (Mo. banc 1979), and *State ex rel. Jinkerson v. Koehr*, 826 S.W.2d 346, 348 (Mo banc. 1992)).

Respondent's severance and venue rulings compound the abuse of discretion in the refusal to dismiss the 85 non-Missouri Plaintiffs' claims for lack of personal jurisdiction. As a result of all of these rulings, numerous Plaintiffs whose claims have no business being tried together in the City of St. Louis will consume time and resources

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improperly litigating their claims in that forum. A writ of prohibition is appropriate to prevent both the violation of Bayer's due process rights and a needless waste of judicial resources in Missouri.

II. BAYER IS ENTITLED TO A PERMANENT ORDER PROHIBITING RESPONDENT FROM ENFORCING HER ORDER DENYING BAYER'S MOTION TO DISMISS AS TO ALL PLAINTIFFS' CLAIMS BECAUSE ALL PLAINTIFFS' CLAIMS ARE EXPRESSLY OR IMPLIEDLY PREEMPTED UNDER FEDERAL LAW AND RESPONDENT ABUSED HER DISCRETION AND USURPED JUDICIAL AUTHORITY IN HOLDING OTHERWISE.

A. Introduction

Respondent abused her discretion and usurped judicial authority by failing to adhere to well established legal principles in determining that Plaintiffs' claims are not preempted.

B. Relator Has Met The Standard For Issuance Of A Permanent Writ Of Prohibition

"A writ of prohibition is available: (1) to prevent a usurpation of judicial power when the trial court lacks authority or jurisdiction; (2) to remedy an excess of authority, jurisdiction or abuse of discretion where the lower court lacks the power to act as intended; or (3) where a party may suffer irreparable harm if relief is not granted." *Dickhaner*, 323 S.W.3d at 32. Prohibition is intended to "prevent exercise of extrajurisdictional power," and "may be appropriate" if a court's "abuse of . . . discretion

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is so great as to be an act in excess of jurisdiction [and] create[s] injury which cannot be remedied on appeal." *Holliger*, 986 S.W.2d at 169. In particular, "[p]rohibition may be appropriate to prevent unnecessary, inconvenient, and expensive litigation." *Dickhaner*, 323 S.W.3d at 32; *see also Brown*, 121 S.W.3d at 236 ("prohibition is appropriate whenever … there is no adequate remedy by appeal for the party seeking the writ, and the 'aggrieved party may suffer considerable hardship and expense as a consequence of the erroneous decision [of the lower court].'") (second alteration in original).

A writ of prohibition is "the proper remedy" to correct a trial court's incorrect determination that federal law does not preempt state-law causes of action. *See, e.g.*, *State ex rel. Jones Chems., Inc. v. Seier*, 871 S.W.2d 611, 614 (Mo. Ct. App. 1994). The Writ of Prohibition should be made permanent here because Respondent abused her discretion and usurped judicial authority in concluding that Plaintiffs' claims are not preempted.

C. Respondent Erred In Holding That Plaintiffs' Claims Are Not Preempted.

Respondent clearly abused her discretion in concluding that Plaintiffs' common-law claims are not preempted by federal law. The Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetics Act ("FDCA") include an express preemption provision that applies to devices like Essure, which have received pre-market approval ("PMA") from the FDA. This provision prohibits states from imposing requirements that are "different from, or in addition to" those already imposed by the U.S. Food and Drug Administration. 21 U.S.C. § 360k(a). The U.S. Supreme Court has

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recognized that state-law claims that are inconsistent with FDA requirements, *i.e.*, that are not "parallel," are expressly preempted by the MDA. *See Riegel*, 552 U.S. 312 at 330 ; *see also* 21 U.S.C. § 360k(a). Moreover, only FDA may enforce FDCA requirements. *See Buckman*, 531 U.S. 341, 349 n.4 ; 21 U.S.C. § 337(a). Accordingly, as the Eighth Circuit has explained in a widely adopted formulation, for a state common-law claim to survive preemption, it must fit within a "narrow gap": "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010).

None of the claims that Plaintiffs raise here fall within this "narrow gap." Plaintiffs' claims boil down to five basic theories: (1) Essure is defectively designed; (2) Bayer made misrepresentations concerning Essure; (3) Bayer inadequately warned of the risks of Essure; (4) Essure devices were defectively manufactured; and (5) Bayer negligently trained physicians in the Essure procedure. Many of these claims—including the challenges to Essure's design and labeling language—are frontal attacks on FDA's requirements for the device, and are clearly expressly preempted. The remainder, including claims that Bayer failed to report adverse events or follow FDA manufacturing standards, are impliedly preempted because they are simply an attempt to privately enforce the FDCA.

Applying these principles, courts across the country have dismissed nearly identical claims. *Williams*, No. 15BA-CV02526 (dismissing all claims with prejudice)

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(**A324**) (appeal docketed); *Olmstead*, No. 3:17-cv-387 (same); *Burrell*, No. 1:17-cv-00031, 2017 WL 1955333 (same) (appeal docketed); *Norman*, No. 3:16-cv-00253, 2016 WL 4007547 (same) (appeal docketed); *De La Paz*, 159 F. Supp. 3d 1085 (dismissing all claims as preempted); *Medali*, No. RG15771555, slip op. (same) (**A90-91**); *McLaughlin*, 172 F. Supp. 3d 804 (dismissing 10 of 12 claims); *McLaughlin*, Nos. 14-7315 *et al.*, 2017 WL 697047 (further narrowing claims in amended complaint); *Noris*, No. BC589882 (dismissing claims) (**A94-124**); *Lance*, RG16809860 (dismissing multiple claims) (**A487-508**); *Journey*, JCCP No. 4887 (**A509-21**).

Respondent failed to apply this well-settled and binding legal framework. Instead, Respondent committed a series of plain errors that require this Court's immediate attention through a writ of prohibition.

First, Respondent applied the wrong U.S. Supreme Court precedent. Respondent erroneously relied on *Lohr* instead of *Riegel*. **A400**. In *Lohr*, the Supreme Court held that the MDA did not preempt state-law tort claims against devices approved through FDA's § 510(k) substantial equivalence process. 518 U.S. at 492-94. But more recently, in *Riegel*, the Supreme Court squarely held that *Lohr* does not apply to medical devices such as Essure that are approved through FDA's far more rigorous pre-market approval process. That process imposes federal "requirements" upon devices, and the MDA accordingly preempts any inconsistent state-law requirements—including state-law tort claims brought against PMA devices. *Riegel*, 552 U.S. at 322-23. As explained above, Essure is a pre-market approved medical device; *Riegel*, and not *Lohr*, is therefore the governing precedent.

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Second, Respondent applied "a basic presumption against preemption" when no such presumption applies to this case. **A400** (citing *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 449 (2005)). The MDA expressly preempts inconsistent state-law requirements. As the U.S. Supreme Court has explained, when a "statute contains an express pre-emption clause, *we do not invoke any presumption against preemption* but instead focus on the plain working of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016) (emphasis added). *Riegel* applied no such presumption in interpreting the preemption provision at issue here; only a single *dissenting* Justice did so. *See* 552 U.S. at 334 (Ginsburg, J., dissenting) (departing with majority and arguing that the presumption against preemption should apply). Indeed, another court addressing the same argument in a highly similar Essure case held that the "argument that there is a strong presumption against preemption and that this presumption applies to the MDA's express preemption clause is frivolous." *Olmstead*, 2017 WL 3498696, at *3 n.2. Respondent fundamentally erred in presuming that Plaintiffs' claims are not preempted.

Third, Respondent permitted clearly preempted claims to go forward. For example, under *Riegel*, it is axiomatic that a frontal attack on the FDA-approved design of a PMA medical device is preempted. *See Riegel*, 552 U.S. at 330; *accord*, *e.g.*, *Norman*, 2016 WL 4007547 at *3 n.3 (dismissing nearly identical claims brought by the same plaintiffs' counsel and holding: "FDA has approved the design of the Essure. Therefore any finding that defendants were liable for that design would necessarily impose requirements 'in addition to, or different from' those imposed by the FDA. The

claim is therefore preempted."); *De La Paz*, 159 F. Supp. 3d at 1095 ("[D]esign defect claims cannot survive preemption, in as much as [plaintiff] cannot allege that Bayer departed from the design for Essure approved by the FDA"). Indeed, Plaintiffs did not even defend their design defect claim in their response to Bayer's motion to dismiss. *See* **A250**.

Yet Respondent erroneously allowed such claims to proceed. Respondent acknowledged that Plaintiffs' complaint directly challenged the FDA-approved design for Essure: "Plaintiffs allege that Essure was defectively designed and that its design was unreasonably dangerous." **A399**. Respondent further recognized that "Defendants argue that this design defect claim is preempted, because the FDA specifically approved the design of Essure and found that the design is safe and effective." **A399**. However, Respondent allowed this clearly preempted claim to proceed even though Plaintiffs did not allege that the design of Essure departed in any manner from the design that FDA approved, let alone in a way that caused injury to Plaintiffs.[3]

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[3] Respondent also failed to address Bayer's arguments regarding implied preemption under *Buckman*. Plaintiffs' failure-to-warn-FDA and manufacturing claims, to the extent they allege that Bayer failed to comply with FDA regulations, are efforts to enforce FDA requirements, an exclusive duty of FDA. As the Eighth Circuit held, such claims are "foreclosed by § 337(a) as construed in *Buckman*" because they "are simply . . . attempt[s] by private parties to enforce the MDA." *In re Medtronic*, 623 F.3d at 1205-06. Thus, these claims are impliedly preempted.

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Respondent similarly erred in failing to dismiss the other claims, which are equally meritless. Bayer cited the numerous court decisions that dismissed identical claims, *see supra* at pp.3-4, and Respondent ignored all of them. Because all of Plaintiffs' claims are preempted under persuasive precedent, Respondent should have granted Defendants' motion to dismiss.

Fourth, rather than analyze Plaintiffs' claims under established preemption principles, Respondent stated: "Tellingly, Defendants have cited to no Missouri state court case dismissing a claim on preemption grounds." **A400**. This observation is both legally irrelevant and factually untrue. It is legally irrelevant because under the Supremacy Clause, U.S. Const. art. VI, § 2, U.S. Supreme Court decisions on issues of federal law (including preemption) are binding on state courts. *See James v. City of Boise*, 136 S. Ct. 685, 686 (2016) ("The Idaho Supreme Court, *like any other state or federal court*, is bound by this Court's interpretation of federal law.") (emphasis added); *Kraus v. Bd. of Educ. of City of Jennings*, 492 S.W.2d 783, 784-85 (Mo. 1973) ("State court judges in Missouri are bound by the 'supreme law of the land," as declared by the Supreme Court of the United States."); *Doe v. Roman Catholic Diocese of St. Louis*, 311 S.W.3d 818, 823 (Mo. Ct. App. 2010) ("Decisions of the United States Supreme Court on matters of federal law . . . bind all state courts.") (citing *Chesapeake & Ohio Ry. Co. v. Martin*, 283 U.S. 209, 221 (1931)). Bayer repeatedly cited *Riegel* and *Buckman*, and a host of federal courts of appeals and district court cases interpreting federal law. The U.S. Supreme Court's decisions are binding, and the lower federal courts' interpretations of federal law are persuasive. Indeed, the Missouri Supreme Court has recognized that,

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given the interest in uniformity on issues of federal law, lower federal court decisions are entitled to "significant consideration." *Buemi v. Kerckhoff*, 359 S.W.3d 16, 23 (Mo. banc 2011).

Respondent's observation is also factually untrue because Bayer cited two Missouri state court decisions holding that state common-law claims were preempted by the MDA. *See* **A57** (citing *McDonald v. Lester E. Cox Med. Ctrs.*, No. 1231 CV 02646, 2014 WL 58773, at *3 (Mo. Cir. Ct. Jan. 2, 2014)); **A303**, **A312**, **A313**, **A318**, **A320** (citing *Williams*). *Williams*, in particular, involved claims concerning the Essure device similar to those plaintiffs raise here, and the Boone County Circuit Court dismissed all of them. **A303**, **A324**. Respondent also ignored numerous federal and state court decisions regarding Essure claims that Bayer cited in its briefs and that concluded that claims virtually identical to Plaintiffs' are preempted by federal law. *See supra* at pp.3-4. In fact, the district court in *Norman* determined that all claims in a complaint filed by plaintiffs' counsel—which is almost word for word the same as Plaintiffs' complaint here—were preempted. *See Norman*, 2016 WL 4007547, at *3-6.

For these reasons, Respondent's order regarding preemption is a clear abuse of judicial discretion. It relies on the wrong set of cases, applies the wrong doctrine, fails to address dispositive arguments, and adopts positions contrary to the federal Constitution. In addition, if uncorrected, Bayer will be required to defend against—and conduct burdensome discovery regarding—claims that are not viable under federal law. The Missouri courts will likewise have to adjudicate these claims and any discovery disputes

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that might arise, wasting their own resources. A writ of prohibition is therefore appropriate and necessary.

CONCLUSION

Thus, this Court should make permanent the writ of prohibition and direct Respondent to refrain from taking any further action in this matter except (i) to grant the motion to dismiss the non-Missouri Plaintiffs' claims because Respondent lacks personal jurisdiction over them and (ii) to grant Bayer's motion to dismiss all Plaintiffs' claims because they are preempted by federal law. In the alternative, as to any remaining claims or Plaintiffs, this Court should issue a writ of prohibition that directs Respondent to refrain from taking any further action in this matter except to grant Bayer's Motion to Sever and Transfer the cases of the non-Missouri Plaintiffs to the Circuit Court for Cole County, and to transfer the cases of the Missouri Plaintiffs to the venues in which they were first injured.

DATED: August 24, 2017

Respectfully submitted,

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RELATORS BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER ESSURE INC., AND BAYER HEALTHCARE PHARMACEUTICALS INC.'S CERTIFICATION

Signature of this filing certifies the foregoing Brief complies with the limitations contained in Rule 84.06(b). This brief contains approximately 8,304 words.

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The undersigned certifies that true and accurate copies of this Brief and Appendix were served this 24th day of August, 2017 as indicated below:

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