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SUPREME COURT, U.S.

No. 21-___

IN THE

Supreme Court of the United States

LEACH, *et al.*,

Petitioners,

v.

MENTOR WORLDWIDE LLC,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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September 20, 2021

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QUESTION PRESENTED

The question presented is whether preemption under the Medical Device Amendments to the Food, Drug, and Cosmetic Act supports Rule 12(b)(6) dismissal of state common law claims alleging failure to warn by virtue of inaccurate post-approval, post-sale public reporting of adverse events, and claims alleging defective manufacture of medical devices.

PARTIES TO THE PROCEEDING

Petitioners here were included in an appellate case listed below but chose to go a different direction pursuant to this Court's Rule 10(a)(b)(c).

Sewell, et al. v. Mentor Worldwide LLC, et al., 9th Circuit 19-56393; Dist. of Cent. California 19-cv 01126.

Petitioners herein chose to pursue a different direction as pro se filings of: Petition for Rehearing, Petition for Rehearing En Banc and Motion for Reconsideration to file a Stay for purposes of Writ of Certiorari.

STATEMENT OF RELATED CASES

The following proceedings are directly related to this petition:

United States District Court for the Central District of California Judgments:

> *Sewell v. Mentor Worldwide LLC*, SA CV 19-01126-AB (PLAx). Judgment entered October 29, 2019.

United States Court of Appeals for the Ninth Circuit Judgments:

> *Sewell v. Mentor Worldwide LLC*, 19-56393. Judgment entered February 5, 2021.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners respectfully petition for a writ of certiorari to review the judgments of the United States Court of Appeals for the Ninth Circuit and Petitioner's Due Process Rights Violations, Federal Rules of the Appellate Process Violations and Obstruction of Justice.

OPINIONS BELOW

The opinions of the Ninth Circuit Court of Appeals are reported at:

> *Sewell v. Mentor Worldwide LLC*, 847 F. App'x 380 (9th Cir. Feb. 5, 2021), App. 60.

The Orders of the United States District Court for the Central District of California are officially reported or otherwise available at:

> *Sewell v. Mentor Worldwide LLC* (8:19-cv-01126 Document 9 Filed 06/10/19 Page ID #:596(C.D. Cal. June 2019)
>
> *Sewell v. Mentor Worldwide LLC*, 2019 WL 4038219 (C.D. Cal. Aug. 2019)

The Orders of the United States Court of Appeals for the Ninth Circuit are officially reported or otherwise available at:

> *Sewell et al v. Mentor Worldwide, L.L.C.*, Case No., 19-56393 (C.D. Cal. Nov. 27, 2019).

JURISDICTION

The judgment of the Ninth Circuit Court of Appeals was entered on February 5, 2021. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1254(1). Additionally, Petitioners herein have filings pursuing pro se motions. A Petition For Rehearing and

a Petition For Rehearing En Banc were filed by Petitioners. Both were denied, despite meeting the 3 of 3 Federal Rules of the Appellate Procedure (here in F.R.A.P.) required by the rules of the Court to file these Petitions. After the denials, the appellate judges denied future filings on April 21, 2021 despite the fact Petitioners had further F.R.A.P rules to pursue within their Due Process Rights. On April 28, 2021, Petitioners filed timely their Motion For Reconsideration and Motion To Stay The Mandate for purposes of filing a Petition For Writ of Certiorari, which the Court never responded back even though this filing was filed timely and Petitioners had further F.R.A.P. Rules to utilize. (Fed. R. App. P. 41(b) and (d), (1), (2), (a).

On April 21, 2021, The Court had denied Petitioners herein their Due Process Rights to use F.R.A.P Rule 41 even though Petitioners filed timely stating they "must show cause that the Certiorari Petition would present a substantial question and there is a good cause for a Stay". (Fed. R App P 41(d)(2)(A); (5th Cir. R. 41.1); (6th Cir. R. 41(a); (10th Cir. R.41.1); (11th Cir. R. 41-1(a); (D.C. Cir. R. 41(a)(2). (Dkt. 94, -100).

In addition to The Court not responding back after April 28, 2021, regarding Petitioners' request for a Stay, this obstructed Petitioners' use of Supreme Court Rules 22 23 and 33.2. See 28 U.S.C. 2101(f).

This Petition is timely under this Court's Order from April 21st, 2021, regarding filing deadlines in the COVID-19 pandemic, extending the time for filing the Petition to 150 days from the date of the judgment below.

STATUTORY PROVISIONS

21 U.S.C. § 360k

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if –

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement –

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

STATEMENT

I. INTRODUCTION

Through its rulings in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), this Court established that state law claims arising from requirements that are "parallel" under state and federal law are neither expressly nor impliedly preempted.

The court below misapplied *Buckman* and *Riegel* in finding that claims alleging failure to warn through inaccurate public reporting of adverse events are preempted. The Ninth Circuit's misapplication of this Court's precedent reflects a conflict between circuits and an acknowledged state of confusion across the federal judiciary.

The court below further misapplied *Buckman* and *Riegel* in declaring defective manufacture claims to be preempted, and by granting, without leave to amend, a 12(b)(6) motion based upon preemption, an affirmative defense. The Ninth Circuit's ruling manifests a nationwide wave of federal court rulings extending *Buckman* and *Riegel* far beyond the Court's intention, establishing what now appears to be overbroad immunity from suit for medical device manufacturers who defectively manufacture their products, an immunity never intended by Congress.

II. FACTUAL BACKGROUND

A. FDA Approval of Silicone Gel-Filled Breast Implants

Silicone gel-filled breast implants first entered the American market in 1963. For more than a decade, the devices were largely subject to regulation by the states.

In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). The MDA divides medical devices into three classes, based upon patient risk and need for regulatory scrutiny. Class I devices require the least, and most general, oversight. 21 U.S.C. § 360c(a)(1)(A). Class II devices are reviewed according to more stringent "special controls," such as performance standards. 21 U.S.C. § 360c(a)(1)(B). Finally, Class III devices receive the most oversight and require rigorous premarket review and approval. 21 U.S.C. § 360c(a)(1)(C)(ii).

Initially, breast implants were categorized as Class II devices, reviewed only through the premarket notification process. In 1988, due to growing safety concerns, the FDA re-classified breast implants as Class III devices.

Class III devices support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury. Because the FDA deems general and special controls alone to be insufficient to assure the safety and effectiveness of Class III devices, the FDA subjects breast implants to the more rigorous premarket approval ("PMA") process. Through the PMA process, the FDA conducts a scientific and regulatory evaluation of the safety and

effectiveness of Class III medical devices. When a manufacturer submits a PMA application, the application is to be denied where the manufacturer fails to give "reasonable assurance" of the products' safety and effectiveness. 21 U.S.C. § 360e(d)(2).

In 1991, the FDA finalized its regulations implementing the PMA process for silicone gel-filled breast implants. Later that year, the FDA determined that the PMA application data submitted by manufacturers, including Mentor Worldwide LLC ("Mentor") for its MemoryGel Silicone Gel Breast Implants, was insufficient to support approval.

In January 1992, the FDA announced a voluntary moratorium on silicone gel-filled breast implants, while the FDA reviewed new safety and effectiveness information that had been submitted.

On April 16, 1992, the FDA made the moratorium mandatory, when it announced it would allow implantation of silicone gel-filled breast implants only after mastectomy, correction of congenital deformities or replacement of ruptured silicone gel-filled implants due to medical or surgical reasons. The FDA would consider silicone gel-filled implants to be investigational devices, requiring women who received them to be monitored through adjunct clinical studies. This moratorium included Mentor Memorygel breast implants.

In December 2003, Mentor submitted a PMA for its MemoryGel Silicone Gel Breast Implants. In 2006, the FDA approved Mentor's PMA, ending the 14- year moratorium against marketing silicone gel-filled breast implants for augmentation. Mentor's approval was conditioned on the performance by Mentor of six specific post-approval studies.

B. Adverse Event Reporting

Separate from the requirements of the Mentor specific post-approval studies that were imposed upon Mentor by the FDA, Mentor was required to meet the reporting requirements imposed upon all manufacturers by 21 C.F.R. § 812.150(b), including the duty to report unanticipated adverse device effects (with evaluation) to the FDA, all Institutional Review Boards, and investigators within 10 working days after notification by the investigator.

Mentor is further required to maintain and submit information required by 21 U.S.C. § 360i, including adverse reaction reports, 21 C.F.R. § 803.50, and to establish internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198(a). 21 C.F.R. § 803.50 requires a manufacturer to report information no later than 30 days after it is received, from any source, if that information suggests that the device may have contributed to a serious injury or has malfunctioned in a manner likely to contribute to a serious injury.

On August 20, 2020, the FDA released its own study across its history of adverse event reports. The FDA tabulated the adverse event reports it had received that contained reference to BII symptoms. The agency reported that it received only 1,080 such reports during the 11 years encompassed by the period of January 2008 to October 2018. The FDA received more than twice as many such reports, a total of 2,497 reports, during the next 11 months.[1] Manufacturers

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[1] *See* FDA Press Release, *supra* note 2; *See also* FDA, *Medical Device Reports for Systemic Symptoms in Women with Breast Implants* (Aug. 20, 2020) ("Medical Device Reports for Systemic Symptoms"), https://www.fda.gov/medical-devices/breast-implants/

were systematically under-reporting breast implant illness symptoms, for more than a decade.

C. Breast Implant Illness

Breast implant illness ("BII") is a term that the FDA has recognized, identified the list of symptoms and finalized the Black Boxed Warning as of September 29, 2020 and the FDA has updated their Warnings on March 31, 2021. As of October 27, 2021, now the FDA has imposed stricter warnings which includes restrictions on the sale of breast implants.

Commonly diagnosed, reported and now identified as being caused by silicone gel breast implants are conditions include fibromyalgia, Hashimoto's thyroiditis, mixed connective tissue disease, and pulmonary fibrosis, among other illnesses in study datas. Recent research suggests that BII is an autoimmune or inflammatory response to silicone. Histological analysis of tissue surrounding implants reveals infiltration of inflammatory cells into tissue surrounding the implants.

After years of denial by manufacturers, the FDA has acknowledged that breast implants increase the risk of an especially serious autoimmune disease known as breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL") – BIA-ALCL, which is a cancer of the immune system.

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medical-device-reports-systemic-symptoms-women-breast-implants (last visited June 19, 2021) (identifying most common systemic signs and symptoms from MDR database review) See also FDA Strengthens Safety Requirements and Updates Study Results for Breast Implants, Press Release October 27, 2021 (https://www.fda.gov/news-events/press-announcements/fda-strengthens-safety-requirements-and-updates-study-results-breast-implants last visited on October 28, 2021).

D. Facts Specific to Petitioners

The Petitioners include three implant recipients and two spouses and their experiences with MemoryGel breast implants are concerningly similar. Of the three implant recipients, all have had both breast implants explanted. These three women suffered at least one implant rupture or experienced gel bleed. Explant post inspection reports revealed manufacturing defects, including impaired durability in shell materials, internal ruptures, capsular tears, shell elastomer failures, multiple defects found on the device and gel anomalies.

Petitioners suffer from a list of symptoms which first appeared after the implant of their Mentor devices in their breasts. The symptoms are in relation to BII, and many are common across Petitioners. Of the three implant recipients, their symptoms echoed each others such as: fatigue, joint pain, memory loss, vision problems, skin rashes, hair loss, numbness, muscle pain, cognitive dysfunction, chest pain, swelling, dizziness, nausea, dry eyes, shortness of breath, night sweats, migraine and metallic taste. Ailments and disorders are common of the Petitioners.

Had the women been aware of or known of the risk that silicone would be injurious to their bodies, they would not have elected to receive Mentor Memory Gel Breast Implants. *Sewell* Complaint ¶¶ *Leach* Petition For Rehearing En Banc.

Petitioners bring claims under the common law of nine states, spread across the Fifth, Eighth, Ninth, Tenth, and Eleventh Circuits.

E. Facts and Allegations Specific to Mentor

There are many concerning allegations relating to Mentor's checkered manufacturing past. The allegations include testimony from Mentor's management-level employees in the late 1990s about deliberately false reporting of rupture rates, systemic inadequacies in Mentor's manufacturing processes, concealment of data relating to rupture rates and defective manufacturing, omitted finished device testing, and omitted materials sterilization testing.

Petitioners further allege that additional witnesses reported that Mentor was still fraudulently reporting its test results and device failure rates and was destroying and is concealing evidence relating to such witnesses. *Leach Petition for Rehearing, Leach Petition for Rehearing En Banc* The record on dismissal in the trial and appellate courts included specific evidence of Mentor "whistleblower" reports, including a letter published by a non-profit consumer rights advocacy group, precisely detailing Mentor's false reporting practices and false test result data

Petitioners allege that detailed information relating to a manufacturer's experiences rests solely with the manufacturer. *Sewell* Complaint, *Leach* Petition For Rehearing En Banc. Only Mentor, however, is responsible for the manufacturing process and reporting adverse events to the FDA. That is, in the absence of accurate reporting, no plaintiff can possess, at the time she files her complaint, detailed information about inadequacies in a manufacturer's reporting, or about its inaccurate manufacturing processes and experiences. Only Mentor can accurately report its own knowledge relating to rates and causes of ruptures and linkage between any claimed symptoms or injuries

and its breast implants. Similarly, only Mentor can maintain accurate records of its own processes, records that, absent court permitted discovery, will never be available to patients who fear or discover that dangerous devices have been surgically implanted into their breasts. *Leach* Petition For Rehearing En Banc.

Petitioners specifically allege that Mentor failed to accurately "report newly acquired information [and] true information about: instances of silicone toxicity; adverse events such as; requiring removal of the implant(s), symptoms of now recognized BII symptoms; instances of chronic/ persistent autoimmune-like complaints and inflammatory issues; rupture rates; and more." Leach Petition For Rehearing En Banc.

Petitioners allege that if Mentor had accurately reported its experience and knowledge relating to ruptures, they would have been on notice of a rupture rate for Mentor MemoryGel Breast Implants that is significantly higher than the rates publicly disclosed by Mentor and touted in Mentor's product insert.

Petitioners further specifically allege that if Mentor had accurately reported its experience and knowledge of patient symptoms, they would have been on notice of risks attendant to Mentor's MemoryGel Breast Implants that are significantly greater than the risks publicly reported by Mentor and touted in Mentor's product insert.

Petitioners allege that if Mentor had accurately reported adverse events known to it, "additional information would have been available to the public, including Plaintiffs' treating physicians, [and] [i]f Plaintiffs had been adequately warned of the serious risks and adverse events by Defendant Mentor, they would not have agreed to implantation of Mentor MemoryGel

Silicone Gel Breast Implants." *Sewell* Complaint Likewise, if post-implant adverse events had been accurately reported, risk data and patient experiences would have been available to explant their breast implants to regain their quality of life back without their ongoing symptoms of BII. Leach Petition for Rehearing En Banc.

The medical community at a significantly earlier date echos that Plaintiffs would have been able to undergo the explantation surgery at an earlier date and would have been less severely damaged and injured.

The Complaints allege that under applicable state law, once a manufacturer is called upon to report information relating to the safety of its products, it must do so accurately. *Sewell* Complaint, *Leach* Petition for Rehearing En Banc. This duty, to accurately report safety experience, is parallel with, and no broader or stricter than, the same duty that is imposed upon Mentor by the FDCA.

Mentor defectively manufactured the implants by failing to follow the product specifications approved by the FDA, using unapproved materials and components, using materials and components that were not commercially reasonable, failing to follow standard manufacturing processes, failing to follow FDA-approved manufacturing processes, failing to use reasonable care inspecting and testing, and in quality control and quality assurance. . The devices' "rupture, leakage, and bleeding of silicone . . ., due to porous or weak containment in the Implant shell, is inconsistent with [FDA regulations]." As with failure to warn, the Plaintiffs expressly alleged that the duties and standards imposed by California law upon Mentor in its manufacturing processes, and its reporting are no different than and parallel with the duties imposed upon

Mentor by federal law. *Sewell* Complaint, *Leach* Petition For Rehearing En Banc.

F. This Court's Pronouncements Regarding MDA Preemption

On three prior occasions, this Court has considered preemption under Section 360k of the MDA. In 1996, the Court ruled that the MDA does not expressly preempt state law requirements that parallel federal requirements. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494-497 (1996). *Lohr* established that the MDA preemption analysis is appropriate when a duty imposed under state law relates to a particular device that is also the subject of a duty imposed under federal law. In that event, a common law claim arising from breach of a duty imposed by state law which parallels a duty imposed by federal law is not preempted by the MDA. *Id.* at 492-494, 499-501. Because Congress intended to preempt state law only where it creates a broader duty that is specific to a particular device, the FDA's labeling and manufacturing regulations, which apply generally on an industry-wide basis, do not trigger preemption as they do not include device-specific requirements. *Id.* at 501.

In 2001, the Court decided *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, the Court held that the MDA preempts claims that effectively allege "fraud on the FDA." That is, where a manufacturer lies to the FDA, inducing the FDA to approve the public sale of a device, a plaintiff cannot con tort the claim into a common law tort. The so called "fraud on the FDA" is impliedly preempted. The Court explained that this unusual fraud-based claim stems from the breach of a duty that exists solely under federal law – a duty to be truthful in making statements to the FDA which are intended to induce FDA reliance

during the product approval process. *See Buckman*, 531 U.S. at 352-353. Because manufacturers might lie to the FDA to induce the FDA to approve a product for public sale, "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration." *Id.* at 348.

In 2008, the Court issued its decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). In *Riegel*, the Court held that the PMA through which some medical devices secure marketing permission from the FDA establishes device-specific requirements that, under § 360k(a), expressly preempt different or additional state-law requirements, but not, the Court reiterated, state-law claims that parallel federal requirements. In section 360k(a), the Court stated, it "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Riegel*, 552 U.S. at 330. The Court also restated *Lohr*'s conclusion that federal labeling requirements that apply "across the board to almost all medical devices" generally do not preempt state requirements. *Id.* at 322.

III. PROCEEDINGS BELOW

In 2018 and 2019, Petitioners filed their complaints in California Superior Court and Federal District Court. The case was removed to the United States District Court for the Central District of California, after which Mentor moved for dismissal of the case on preemption grounds. The District Court granted Mentor's motions and dismissed the complaint in August 2019 with prejudice and without leave to amend. The Plaintiffs filed motions for reconsideration, which the District Court denied on October 29, 2019. The Plaintiffs filed notices of appeal, and the United States Circuit Court of Appeals for the Ninth Circuit, issued its judgment on the appeals on February 5, 2021 *without*

having any Oral Argument. From that point on, several Plaintiffs withdrew from counsel and filed pro se motions for Petition for Rehearing, Petition for Rehearing En Banc and Motion for Reconsideration and a Stay of the Mandate for Purposes of Writ of Certiorari in the California Court of Appeals.

REASONS FOR GRANTING THE PETITION

I. LOWER COURTS WIDELY ACKNOWLEDGE DIFFICULTY IN APPLYING THE *BUCKMAN* AND *RIEGEL* "PARALLEL CLAIM" ANALYSIS, LEADING TO INCONSISTENT RULINGS AMONG THE CIRCUITS; THE COURTS ARE ERRONEOUSLY APPLYING AN EVER-NARROWING "NARROW GAP"

The court below begins its preemption analysis by noting a phrase first adopted at the appellate level by the Eighth Circuit and since cited and repeated by the federal judiciary nearly 200 times:

> *Riegel* and *Buckman* create a narrow gap through which a plaintiff 's state-law claim must fit if it is to escape express or implied preemption. 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 Prod. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010), *quoted in part in Leach et al Petition for Rehearing En Banc.*

The basis for finding a "narrow gap" to exist is unclear, as this Court has not used the term. More importantly, no "narrow gap" should exist between *Buckman* and other decisions, as *Buckman* itself is a narrow ruling. By its language, *Buckman* applies where a claim is alleged to arise out of a "fraud on the FDA"; that is, out of a representation made to the FDA to induce the FDA's reliance in approving a product.

The Eighth Circuit's oft-cited "narrow gap" has created widespread ambiguity and inconsistency among the circuits as they attempt to decide the parameters of this narrow gap.

"Lower courts have struggled ever since [*Lohr*] when it comes to trying to decide whether particular state claims do or don't 'parallel' putative federal counterparts." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1338 (10th Cir. 2015). Applying Congress's and the Court's "competing instructions [is] 'no easy task.'" *Id.* at 1340, *quoting Martin v. Medtronic, Inc.*, 254 F.3d 573, 578-579 (5th Cir. 2001) (noting difficulty in "extracting the final meaning" of the Supreme Court's preemption decisions). "The Supreme Court has issued a number of opinions that embody 'divergent views' about the proper role of the MDA's preemption provision, a fact that has yielded considerable 'uncertainty' among the lower courts seeking to apply the statute to cases like this one." *Id.* at 1337.

The Sixth Circuit has likewise noted that "[s]ince *Riegel*, courts have struggled to determine which claims fit into the 'narrow exception' to MDA preemption left open by *Riegel* and *Lohr*." *White v. Medtronic, Inc.*, 808 F. App'x 290, 294 (6th Cir. 2020), *cert. denied*, 141 S. Ct. 239, 208 (2020), *quoting Weber v. Allergan, Inc.*, 940 F.3d 1106, 1114 (9th Cir. 2019), *cert. denied*, 140 S. Ct. 2555 (2020).

The Ninth Circuit, in *Weber*, *supra*, noted the existence of an "intercircuit disagreement" regarding the breadth of the "parallel claim" exception to preemption. *Weber*, 940 F.3d at 1114, *cert. denied*, 140 S. Ct. 2555 (2020); *see generally, Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 700 (S.D. Tex. 2014) ("Courts have struggled with applying the Supreme Court's preemption rulings to cases involving the Infuse device."); *Carrelo v. Advanced Neuromodulation Sys., Inc.*, 777 F. Supp. 2d 303, 310 (D. P.R. 2011) (noting "the present struggle . . . to determine whether state-law claims are preempted by the MDA"); M. Helveston, *Preemption Without Borders: The Modern Conflation of Tort and Contract Liabilities*, 48 Ga. L. Rev. 1085, 1124 (2014); M. Herrmann, D. Alden, B. Harrison, *The Meaning of the Parallel Requirements Exception Under* Lohr *and* Riegel, 65 N.Y.U. Ann. Surv. Am. L. 545, 546 (2010) ("This parallel requirements exception is far from clear."). D. Chang, Note, *Internalizing the External Costs of Medical Device Preemption*, 65 Hastings L.J. 283, 295 (2013) (the Court's decisions have not "provide[d] much guidance as to what constitutes a parallel claim").

Petitioners' claims perfectly show the division among the Circuits, as Petitioners reside in five different Circuits, several of which take different approaches when applying this Court's preemption decisions.

II. *BUCKMAN* DOES NOT APPLY TO MANUFACTURERS' POST-SALE SUBMISSIONS OF FALSE OR INACCURATE ADVERSE EVENT REPORTS

Difficulty applying this Court's prior decisions is evidenced by the present case. The Ninth Circuit cited *Buckman* in support of a preemption bar against

Petitioners' claims that Mentor engages in a practice of inaccurately reporting adverse events. The subject adverse events are not reported to the FDA for the purpose of inducing FDA reliance; instead, they are submitted to the FDA for the purpose of inducing reliance by others, including doctors and patients. The duty to submit such reports is not unique to Mentor or its products, and continues indefinitely into the future, regardless of the date of product approval.

The Court's decision in *Buckman* has no bearing upon any analysis of claims arising from submission of information to the FDA that is intended not for FDA pre-approval reliance but instead for patient and physician post-approval reliance.

A. *Buckman* Does Not Apply to Reports Submitted to the FDA for Reliance by Others

Petitioners allege that Mentor submitted adverse events and deaths caused by the Defendant's faulty breast implants to the FDA by intentionally hiding these adverse events. Instead of reporting each adverse event or death, Mentor hid thousands of adverse events behind one event which made it seem as their breast implants were not harming the public when in fact, the data decoded in September 2019 from the MAUDE database shows *at least half a million* adverse events that were hidden from the public on the safety of breast implants. *Leach* Petition for Rehearing, *Leach* Petition for Rehearing En Banc. In this context, "to the FDA" relates to reports submitted with the express expectation that the FDA will make the reports available for public review and through public websites that are specifically intended for physician and patient reliance. 21 U.S.C. § 360i, 21 C.F.R. §§ 803.1(a), 803.9(a). The database through which

adverse event reports are made available to the public is MAUDE and is not maintained by the FDA. Rather, the FDA uses its website simply to make the reported warnings and concerns publicly available.

In relation to post-sale adverse event reports, Petitioners do not claim that any "fraud on the FDA" occurred, as no reliance by the FDA is directly at issue. Reliance has long been an element of any fraud-based claim. *See, e.g., Pence v. United States*, 316 U.S. 332, 338 (1942); *McGonigle v. Combs*, 968 F.2d 810, 817 (9th Cir. 1992). Reliance by the FDA is at the core of *Buckman*, as the Court focused on manufacturers' untruthful statements to induce the agency's reliance in approving a product for public sale. *Buckman*, 531 U.S. at 348-351.

The court below properly noted, as it had previously ruled, that California law recognizes that a "manufacturer's failure to report adverse events to the FDA can form the basis of a parallel claim that survives preemption." *citing Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013).

The Ninth Circuit appears not to have considered the potential that Mentor can disseminate false information indirectly, *through* the FDA, to the medical and patient community, even though the same court had held so previously. In *Stengel*, the court found that a common law duty to accurately report adverse events and data "through" the FDA will support a parallel claim, because, "[u]nder Arizona law, a warning to a third party satisfies a manufacturer's duty if, given the nature of the warning and the relationship of the third party, there is "reasonable assurance that the information will reach those whose safety depends on their having it"), *quoting Anguiano v. E.I. DuPont*

de Nemours & Co., 808 F. Supp. 719, 723 (D. Ariz. 1992), *affirmed*, 44 F.3d 806 (9th Cir. 1995).

Mentor's duty to submit adverse event reports for public reliance is distinguishable from Mentor's duty to submit datas from mandated studies to the FDA for reliance in approving Mentor's PMA application on November 17, 2006. Such results are submitted to the FDA and are provided to the FDA in response to a requirement of Federal Law that is specific to Mentor's breast implant device premarket approval.

B. *Buckman* Does Not Apply to Manufacturers' Post-Sale Conduct

The Ninth Circuit erred in applying the Court's preemption decisions to post-sale conduct. Mentor cannot conceivably posit that its post-sale adverse event reports, which are required continually and in the ordinary course for many products, are submitted to create retroactive reliance by the FDA to induce approval of a product that has already been pre-approved.

In *Mories v. Boston Scientific Corp.*, 494 F. Supp. 3d 461, 473 (S.D. Ohio 2020), the court properly extended inferences in favor of the plaintiff's pleading, as is appropriate in connection with a Rule 12(b)(6) motion. Upon doing so, the court noted a distinction between pre approval, *Buckman*-barred activity, and post-approval activity, observing that "[t]he difference between the preempted and non-preempted failure-to-warn claim is temporal – i.e., before or after the FDA approved the warnings and literature associated with the [product]." *Mories*, 494 F. Supp. 3d at 473. Logically, based upon this temporal distinction, the court denied the motion to dismiss the plaintiff's failure to warn claim to the extent the complaint alleged "a breach of Defendant's duty under state law to warn

of potential defects, based on information Defendant obtained *after* the FDA's approval of the medical device. In other words, if Plaintiff is alleging that Defendant failed-to-warn of design or manufacture defects after the FDA approved of the warnings and literature, then she is not asking for a court to disagree with any federal determination." *Mories* at 473 (emphasis in original), *citing Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000).

The federal courts are inconsistently applying the Court's *Buckman* "fraud on the FDA" reasoning. The district court in *Babayev v. Medtronic, Inc.*, 228 F. Supp. 3d 192, 212 (E.D.N.Y. 2017), in the absence of Second Circuit authority, surveyed the "parallel claim" decisions and found in 2017 that "[a]t least six Circuit Courts of Appeals have attempted to clarify this issue, but have promulgated standards which are at least somewhat – and sometimes very – different from one another." *Babayev*, 228 F. Supp. 3d at 212. The *Babayev* court's survey found preemption to be more broadly applied in the Sixth and Eighth Circuits, based upon "an expansive view of *Buckman*." *Id.* at 213, *citing In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) and *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 586 (6th Cir. 2013).

In contrast, the Fifth, Seventh, and Eleventh Circuits have more narrowly limited preemption under *Buckman* to fraud-on-the-FDA claims. *Babayev*, 228 F. Supp. 3d at 213, *citing Funk v. Stryker Corp.*, 631 F.3d 777, 779 (5th Cir. 2011), *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010), *Kallal v. CIBA Vision Corp.*, 779 F.3d 443, 447 (7th Cir. 2015) and *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 774-776 (5th Cir. 2011).

The present case cannot be reconciled with the Fifth Circuit's decision in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011). In *Hughes*, the court held that a failure to warn claim is not expressly preempted to the extent it is based on the manufacturer's violation of FDA regulations requiring accurate reporting of serious injuries; such a claim is "parallel" because it does not arise from duties greater or different from those required under the federal regulations. *Id.* at 771.

III. LOWER COURTS, INCLUDING THE COURT BELOW, ARE INAPPROPRIATELY DISMISSING CLAIMS OF DEFECTIVE MANUFACTURE ON PREEMPTION GROUNDS, BECAUSE PREEMPTION IS AN AFFIRMATIVE DEFENSE; A SPLIT AMONG THE CIRCUITS EXISTS

The Court should grant this Petition because dismissal of Petitioners' Complaint was premature, and the premature dismissal is indicative of an unfortunate nationwide trend.

The District Court dismissed Plaintiffs' Federal District Complaint, without leave to amend. The Ninth Circuit affirmed their Opinion without Oral Argument, thus leaving in place the District Court's resolution of the issue from August 2019.

The rulings from Federal District Court and the Ninth Circuit Court of Appeals demonstrate that Petitioners are unfortunate victims of the pleading "quagmire" Apparently, the district court determined that *Iqbal* and *Twombly* require a plaintiff to have precisely identified and alleged a specific flaw in Mentor's manufactured product. The decisions of the courts fail to recognize that in order for a plaintiff to possess the

information deemed necessary to survive Rule 12 dismissal, a plaintiff must possess, during the drafting stage, information that ordinarily cannot be obtained until the Discovery stage. Where the ground for dismissal is an affirmative defense like preemption, Defendants are able to continually use this as their 'carte blanche' to exercise whatever types of business practices they can continually get away with while victims pay the price.

The Seventh Circuit has noted that, even in a jurisdiction in which "federal law does not preempt parallel claims under state law based on a medical device manufacturer's violation of federal law," it is "difficult . . . to plead such a claim sufficiently to survive a motion to dismiss" under Rule 12(b)(6). *Bausch*, 630 F.3d at 558. The court held that district courts applying the *Iqbal/Twombly* plausibility standard "must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal Discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." *Bausch*, at 558. Upon such a ruling, the *Bausch* court reversed a district court's order dismissing, without leave to amend, a complaint alleging defective manufacture of a medical device. *Id.*; *accord Marion v. Smith & Nephew, Inc.*, 2015 WL 7756063, *2 (D. Utah 2015) ("Given the disparate outcomes and uncertainty among the federal courts on this issue, the court understands the Marions' initial uncertainty with respect to the required pleading standard. While 'the difficulty of crafting a complaint sufficient to satisfy all [the] demands' of § 360k(a) is not a proper legal basis for allowing a plaintiff to proceed to discovery, the court does find it sufficient to warrant leave to amend.").

The Seventh Circuit's decision in *Bausch* soundly acknowledges a practical reality that exists for plaintiffs who suffer from having had injurious devices implanted into their bodies. But the decision and line of reasoning are not simply sound as a practical matter. *Bausch* is sound as a matter of law because the federal courts should not be routinely dismissing, on preemption grounds, complaints that allege defective manufacture, or claims alleging other "parallel claims" for that matter, because a Rule 12(b)(6) motion is an inappropriate vehicle for addressing claims of preemption.

This principle was recognized in the Seventh Circuit's recent application of *Bausch*. In *Benson v. Fannie May Confections Brands, Inc.*, 944 F.3d 639 (7th Cir. 2019), the court reversed a district court's dismissal on preemption grounds, noting that preemption is "an affirmative defense upon which the defendants bear the burden of proof," and "[a]ffirmative defenses do not justify dismissal under Rule 12(b)(6)." *Id.* at 645, *quoting Fifth Third Bank ex rel. Tr. Officer v. CSX Corp.*, 415 F.3d 741, 745 (7th Cir. 2005), *Doe v. GTE Corp.*, 347 F.3d 655, 657 (7th Cir. 2003).

Unable to ignore the important distinctions between Rule 12(b)(6) motions and other types of motion practice, the Seventh Circuit concluded that "[t]the district court thus erred by penalizing Benson for failing to anticipate an affirmative defense in her complaint and dismissing the action based on FDCA preemption." *Id.* at 645. The Ninth Circuit decisions that are the subject of this Petition and cannot be reconciled with *Bausch* and *Benson*.

Undoubtedly, "preemption is an affirmative defense." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 251 n.2 (2011) (Sotomayor, J., dissenting), *citing Silkwood v. Kerr-*

McGee Corp., 464 U.S. 238, 255 (1984); *Brown v. Earthboard Sports USA, Inc.*, 481 F.3d 901, 912 (6th Cir. 2007) ("federal preemption is an affirmative defense upon which the defendants bear the burden of proof"), *quoting Fifth Third Bank*, 415 F.3d at 745; *accord Flo & Eddie, Inc. v. Pandora Media, LLC*, 789 F. App'x 569, 572 (9th Cir. 2019); *Muhammad v. Norfolk S. Ry. Co.*, 925 F.3d 192, 196 (4th Cir. 2019); *Bedoya v. Am. Eagle Express Inc.*, 914 F.3d 812, 817 (3d Cir. 2019), *cert. denied*, 140 S. Ct. 102 (2019); *Sickle v. Torres Advanced Enter. Sols., LLC*, 884 F.3d 338, 345 (D.C. Cir. 2018); *Fisher v. Halliburton*, 667 F.3d 602, 609 (5th Cir. 2012).

A Plaintiff is not required to anticipate and negate an affirmative defense in his complaint. *See Gomez v. Toledo*, 446 U.S. 635, 640 (1980); *ABB Turbo Sys. AG v. Turbousa, Inc.*, 774 F.3d 979, 985 (Fed. Cir. 2014); *Flying Food Grp., Inc. v. N.L.R.B.*, 471 F.3d 178, 183 (D.C. Cir. 2006); *Oakes v. United States*, 400 F.3d 92, 98 (1st Cir. 2005); *La Grasta v. First Union Sec., Inc.*, 358 F.3d 840, 845 (11th Cir. 2004); *Tregenza v. Great Am. Commc'ns Co.*, 12 F.3d 717, 718 (7th Cir. 1993). For this reason, it is generally inappropriate to grant a Rule 12(b)(6) motion to dismiss based upon an affirmative defense. Fed. R. Civ. P. 12(b)(6); *see Deswal v. U.S. Nat. Ass'n*, 603 F. App'x 22, 23-24 (2d Cir. 2015); *Omar ex rel. Cannon v. Lindsey*, 334 F.3d 1246, 1252 (11th Cir. 2003); *Scott v. Kuhlmann*, 746 F.2d 1377, 1378 (9th Cir. 1984).

This general rule is subject to an exception where it is unequivocally established from the face of the pleading that the claim is barred as a matter of law. *See ABB Turbo Sys. AG*, 774 F.3d at 985 (dismissal based upon an affirmative defense "ordinarily is improper unless it is 'apparent from the face of the

complaint that the claim is time-barred'"), *quoting La Grasta*, 358 F.3d at 845-846, *quoting Tregenza*, 12 F.3d at 718.

Dismissal based upon an affirmative defense is proper "only when the complaint itself admits all the elements of the affirmative defense by alleging the factual basis for those elements," as when the "plaintiff pleads itself out of court [b]y admit[ting] all [of] the ingredients of an impenetrable defense." *Fernandez v. Clean House, LLC*, 883 F.3d 1296, 1299 (10th Cir. 2018), *quoting Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004)

In application, "[a]lthough a motion to dismiss based upon an affirmative defense may be granted if 'it is apparent from the face of the complaint' that dismissal is warranted, a motion to dismiss should not be granted 'where resolution depends either on facts not yet in evidence or on construing factual ambiguities in the complaint in defendants' favor.'" *N. Am. Elite Ins. Co. v. SW Transp. Servs., Ltd.*, 2014 WL 12452456, *4 (S.D. Fla. 2014), *quoting Lesti v. Wells Fargo Bank, N.A.*, 960 F. Supp. 2d 1311, 1317 (M.D. Fla. 2013), *citing Omar*, 334 F.3d at 1252.

With these principles firmly established, the courts should loathe, and not eager, to grant Rule 12 motions based upon preemption. *See Garcia v. Does*, 779 F.3d 84, 96-97 (2d Cir. 2015) ("It is certainly true that motions to dismiss a plaintiff 's complaint under Rule 12(b)(6) on the basis of an affirmative defense will generally face a difficult road."). Even so, such dismissals are becoming routine. *See, for example, Williams v. Mentor Worldwide LLC*, 2019 WL 4750843, *4, and n.4 (N.D. Ohio 2019) ("the Fifth Circuit and Louisiana federal courts routinely apply Section 360k(a) to dismiss cases against PMA-approved Class III medical

devices based on preemption"; "Similarly, courts within the Sixth Circuit *consistently* dismiss state law claims against PMA-approved Class III medical devices based on preemption.") (emphases added).

Under Rule 12(b)(6), it should *never* be "routine" to dismiss a complaint, particularly without leave to amend, based upon the *affirmative defense* of preemption.

Since the burden of proof is on the defendant in relation to preemption, it is indeed penalizing, as the Seventh Circuit has noted, to dismiss a complaint for a lack of detailed factual allegations relating to issues that cannot be known to a plaintiff in the absence of Discovery. The punitive nature of the ruling is compounded when the complaint is the initial filing, as is the case here, and is dismissed without leave to amend.

The court below should not have dismissed, particularly without leave to amend, Petitioners' defective manufacture claim. Petitioners cannot possess, without discovery, the kind of information that the Ninth Circuit apparently deemed necessary under *Iqbal* and *Twombly*. Even with no Discovery, the dismissed complaint included extensive allegations regarding Mentor's historically horrid manufacturing processes, along with anticipated witness and whistleblower testimony.

Instead of dismissing this case due to plaintiffs' ignorance of information that is impossible for them to know, the court below should have taken the approach espoused in *Mories v. Boston Scientific Corp.*, 494 F. Supp. 3d 461 (S.D. Ohio 2020). The *Mories* court recognized the inappropriateness of granting a Rule 12(b)(6) motion based upon preemp-

tion, ruling that "[i]f, following the completion of discovery, Plaintiff cannot sustain a claim under state requirements that parallel federal requirements, Defendant would be free to file a motion for summary judgment." *Mories*, 494 F. Supp. 3d at 471.

Petitioners are deserving of this Court's attention to grant this Petition due to the federal courts "knee-jerk" preemption-based dismissal.

Decisions involving other Plaintiffs who unfortunately fell into the impossible pleading "quagmire" of having to know and plead information that cannot be known or pleaded, and suffering dismissal on preemption grounds of their defective manufacture claims, include *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272 (10th Cir. 2021); *Ebrahimi v. Mentor Worldwide LLC*, 804 F. App'x 871, 2020 WL 2510760 (9th Cir. May. 15, 2020); *Jankowski v. Zydus Pharm. USA, Inc.*, 2021 WL 2190913 (D.N.J. 2021); *D'Addario v. Johnson & Johnson*, 2021 WL 1214896 (D.N.J. 2021); *Ignacuinos v. Boehringer Ingelheim Pharm. Inc.*, 2020 WL 5659071 (D. Conn. 2020); *Webb v. Mentor Worldwide LLC*, 453 F. Supp. 3d 550 (N.D.N.Y. 2020); *Allo v. Allergan USA, Inc.*, 2020 WL 814855 (E.D. La. 2020); *L. Jacob v. Mentor Worldwide LLC*, 2019 WL 6766574 (M.D. Fla. 2019); *Williams v. Mentor Worldwide LLC*, 2019 WL 4750843 (N.D. Ohio 2019); *Shelp v. Allergan, Inc.*, 2018 WL 6694287 (W.D. Wash. 2018). As this trend of dismissals continues without having further court procedures, this allows the Defendants to continue to get away with serious harms caused by these faulty devices.

Petitioners herein chose to pursue a different direction trusting their Fifth Amendment Rights and their Due Process Rights within the Bill of Rights would be protected by The Constitution of The United States

and would be heard within the Ninth Circuit Court of Appeals. Petitioners herein are natural born citizens of The United States. Even though their prior counsel had represented their court filings within their case well, Petitioners chose to pursue Petition For Rehearing and Petition For Rehearing En Banc, Motion For Reconsideration and asking the Court for filing a Stay for Purposes of Writ of Certiorari. Since there are F.R.A.P Rules to pursue and judges are to follow these Rules, two specific Rules apply to Petitioners due to two current cases that are currently in motion: *Mize v. Mentor Worldwide* and *Gravitt v. Mentor Worldwide*. The Panel overlooked material points of law resulting in conflicts with other decisions of other courts to where national and intercircuit conflicts now have occurred. (*Mize v. Mentor Worldwide, L.L.C.*, Cal. App. July 2, 2020)(9th Cir. 35-1) (*Gravitt v. Mentor Worldwide, L.L.C.*, Fed. Dist. Ct. if Ull. E. Div., Jan. 2018, 1:17-cv-05428) (Fed. R. App. P. 35; 9th Cir. R. 35-1 to -3). Leach et al Petition For Rehearing, Petition For Rehearing En Banc, Motion For Reconsideration.

In addition to the Panel ignoring Petitioners F.R.A.P. Rules presented within the filed Petition For Rehearing, Petition For Rehearing En Banc and Motion For Reconsideration, the Panel decided to cancel the Oral Argument for this case scheduled for Feb 3, 2021 in the Ninth Circuit Court of Appeals. On February 5, 2021, the Panel dismissed the case without having *any* Oral Argument.

In *Goldberg v. Kelly*, the Court found that "a state must provide a full hearing . . . finding that the Due Process Clause required such a hearing . . ." when the Due Process Clause is a legal obligation to all States that all levels of American government must operate within the law ("legality") and provide fair

procedures. Some form of a Hearing is required before an Individual is finally deprived of a Property (or Liberty) interest. This is a basic aspect of the duty of the government to follow a fair process of decision making when it gets to deprive a person of his possessions. The purpose of this requirement is not to only ensure abstract fair play to the Individual. Thus, the notice of Hearing and the opportunity to be heard "must be granted at a meaningful time and meaningful manner". (*Goldberg v. Kelly*, 397 U.S. 254, 90 S. Ct. 1011; 25 L. Ed. 2d 287; 1970, U.S. 254 (1970)), (*Matthews v. Eldridge*, 424 U.S. 319, 333 (1976), (*Baldwin v. Hale*, 68 U.S. (1 Wall.), 223, 223 (1863)).

IV. THE CASE PRESENTS AN ISSUE OF NATIONAL IMPORTANCE

The overused defense of preemption is an issue of national importance for the health and safety of the community. Between 2007 and 2020, American plastic surgeons placed more than 4,000,000 breast implant devices inside Americans' bodies.[2] About 60% of the total, or at least 2.4 million implants, were filled with silicone gel.[3] Meanwhile, the FDA has given heightened focus to the nationwide growth of the adverse effects of silicone implants by finalizing a Black Boxed Warning in September 2020, March 2021 and October

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[2] *See 2020 National Plastic Surgery Statistics Report, Cosmetic Surgical Procedures*, American Society of Plastic Surgeons, https://www.plasticsurgery.org/documents/News/Statistics/2020/plastic-surgery-statistics-report-2020.pdf (last visited June 19, 2021), and corresponding annual reports for each prior year, 2007-2010, 2012-2018 (each last visited June 19, 2021).

[3] *See 2020 National Plastic Surgery Statistics Report, Cosmetic Surgical Procedures, supra* note 18 (2011, 2019 data not available).

27, 2021 stating a list of Breast Implant Illness Symptoms, which Petitioners herein had suffered for years with many of these BII symptoms now acknowledged by the FDA. Advocates worldwide went to the FDA in Washington D.C. in March 2019 after the FDA granted a two day meeting to discuss the harms caused by breast implants. These facts alone present an issue of national importance. *Leach* Motion For Reconsideration.

The Court can realign the judiciary with the need to provide relief to thousands of Americans who are living in pain and fear due to the presence of the dangerous devices that have been implanted in their bodies. In addition, the Court can reinstate Due Process by allowing our Petition to be granted so Petitioners can finally be given their Hearing/Oral Argument.

Fair judicial process will give Petitioners a chance to investigate their own claims and Discovery, in parallel with the FDA, the information the manufacturers have known all along. These phases in litigation in *Mize v. Mentor Worldwide* and *Gravitt v. Mentor Worldwide* have already occurred with both case's Discovery processes which each case is in its jury trial phases therefore Petitioners herein should also be given the same procedural processes, as the same cause of actions exist and the same Defendant is the "usual suspect". Judicial divisions amongst the same intercircuits Opinions and National multi Courts herein that involves the same cause of actions and the same Defendants is beyond unfair and unjust. (*Mize v. Mentor Worldwide, L.L.C.*, Cal. App. July 2, 2020) (9th Cir. 35-1) (*Gravitt v. Mentor Worldwide, L.L.C.*, Fed. Dist. Ct. if Ull. E. Div., Jan. 2018, 1:17-cv-05428) (Fed. R. App. P. 35; 9th Cir. R. 35-1 to -3) *Leach* Petition For Rehearing, *Leach* Petition For Rehearing En Banc.

Only this Court can render fair order from the present injustice and judicial procedural injustice Petitioners herein have experienced in copious examples given within these filings.

CONCLUSION

The Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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