ORIGINAL

No. 20-1572

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In The

Supreme Court of the United States

Ramon D. Johnson, II,

Petitioner

v.

Novartis Pharmaceuticals Corporation;
Taro Pharmaceuticals USA, Incorporated;
Bausch Health US, L.L.C.;
Sun Pharmaceutical Industries, Incorporated;
Torrent Pharma, Incorporated,

Respondents

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

PETITION FOR WRIT OF CERTIORARI

Ramon D. Johnson, II
Pro Se
9502 Vallecito Pass
San Antonio, TX 78250
(734) 320-8834
rdougjohnsonii@gmail.com

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QUESTIONS PRESENTED FOR REVIEW

In *Pliva, Inc. v. Mensing* 564 U.S. 604 (2011) the only question before this Court was whether a state law duty for a generic drug manufacturer to provide a safer label was preempted by a federal duty for that generic drug manufacturer to ensure its label was the same as the label for the brand name. This Court held that the state law duty to provide a safer label was preempted by the federal duty of "sameness" for generic drug manufacturers. As part of this decision this Court stated the different duties of brand name and generic drug manufacturers as:

> A brand name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's. *Mensing* at 516 (citations omitted).

The finding in *Mensing*, along with its description of the manufacturers' duties, lead naturally to the first two of the five questions that are at issue in the instant case:

(1) Whether a brand name drug manufacturer who designed the label that is distributed as part of a generic drug product can be held liable when it is that label that is the defective part of the product that caused the injury.

(2) Whether a generic drug manufacturer can be held liable for state law claims that are not based on a duty to provide a safer label, but are instead based on other state law duties or the condition of the product as distributed. (e.g. In Texas, a strict liability marketing defect claim merely looks at the product itself and determines if it is defective.)

(3) Whether the relevant information rebuttal to the Texas presumption of no liability for a drug manufacturer with an FDA approved label is preempted, and whether if it is preempted does that render the presumption of no liability also preempted or unconstitutional.

(4) Whether Petitioner alleged facts supporting the unapproved indication rebuttal to the Texas presumption of no liability for a drug manufacturer with an FDA approved label, and whether the District Court was derelict in it duties or abused its discretion in deciding Petitioner had not.

(5) Whether the District Court abused its discretion in not granting Petitioner leave to amend his complaint when the amended complaint was submitted in accordance with instruction provided on the District Court's own website and with prevailing precedents.

PARTIES TO THE PROCEEDINGS AND RELATED CASES

All parties to the proceedings are as listed on the cover. The related cases are:

- Ramon D. Johnson, II v. Novartis Pharmaceutical Corp. et al, No. 5:19-cv-01087-OLG, U.S. District Court for the Western District of Texas – San Antonio Division. Judgement entered May 7, 2020.

- Ramon D. Johnson, II v. Novartis Pharmaceutical Corp. et al, No. 20-50462, U.S. Court of Appeals for the Fifth Circuit. Judgement entered Feb. 5, 2021.

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PETITION FOR WRIT OF CERTIORARI

Petitioner Ramon D. Johnson, II respectfully seeks a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case.

OPINIONS BELOW

The Order of the U.S. District Court for the Western District of Texas – San Antonio Division in this matter, Civil Action No. 5:19-cv-01087-OLG, is unpublished. It is reprinted in the Appendix.

The Opinion of the U.S. Court of Appeals for the Fifth Circuit in this matter, No. 20-50462, is unpublished and not to be used as precedent, per the Court. It is reprinted in the Appendix.

JURISDICTION

The U.S. Court of Appeals for the Fifth Circuit entered its Opinion on February 5, 2021. This Court has jurisdiction under 28 U.S.C. § 1254(1). As the constitutionality of a statute of the State of Texas is in question, 28 U.S.C. § 2403(b) may apply and this document will contemporaneously be served on the Attorney General of the State of Texas.

PROVISIONS INVOLVED

The pertinent constitutional, statutory, and regulatory provisions involved in the case are:

- Amendment I of the Constitution of the United States of America

- Mich. Comp. Laws § 600.2946(5)(a)
- Tex. Civ. Prac. Rem. Code § 82.001(4)
- Tex. Civ. Prac. Rem. Code § 82.007
- Tex. Const. Act. I, § 13
- Tex. Gov't Code § 311.023

The full texts of the applicable provisions are printed in the Appendix.

STATEMENT OF THE CASE

Petitioner (Plaintiff) alleges Respondents (Defendants) are liable for personal injuries he suffered due to marketing defects in their products. The Respondents products either caused or worsened Petitioner's Peyronie's Disease (PD). PD causes plaques of scar tissue to form in the penis and has resulted in severe bending, narrowing (bottlenecking), shortening, and erectile dysfunction for the Plaintiff. In addition to deformity and dysfunction, PD has caused physical pain and emotional pain in the form of anxiety, depression, and loss of an intimate relationship with his wife, which has severely stressed their relationship.

Petitioner was prescribed Minocycline (brand name Minocin) on or about April 19, 2013 by dermatologist Dr. Jeffrey Meffert for acne keloidalis, hidradenitis, folliculitis, and cellulitis and abscess of trunk. The Minocycline product Petitioner received and used from his local pharmacy was from Ranbaxy Laboratories Limited (Ranbaxy), with label designed by Bausch Health US, L.L.C. (Bausch) for its brand name drug Minocin. Ranbaxy was acquired by Sun Pharmaceutical Industries, Incorporated (Sun), but as part of that acquisition was required to spin off

the Ranbaxy Minocycline to Torrent Pharma, Incorporated (Torrent). Patient information from the label was distributed to Petitioner with the capsules and Petitioner read the information.

On or about April 20, 2014 Petitioner noticed nodules in his penis. Petitioner had a previously scheduled appointment with Dr. Meffert on April 22, 2014. Petitioner told him about the nodules and Dr. Meffert referred him to urology. Petitioner saw urologist Dr. Ian Thompson, III on June 5, 2014 and July 17, 2014. Dr. Thompson suspected PD and initially took a "wait and see" approach. The disease progressed so Dr. Thompson referred Petitioner to another urologist that specialized in PD, urologist Dr. LeRoy Jones. Petitioner first saw Dr. Jones on August 29, 2014. Dr. Jones prescribed a medication and some supplements, but the disease continued to progress.

Because it had been less effective, Petitioner stopped the Minocycline in late October, 2014. The pain Petitioner had developed in his penis went away quickly. Thinking it was just coincidental, Petitioner decided to continue the Minocycline until he returned to Dr. Meffert to discuss his dermatological issues. Shortly after restarting the medication, Petitioner's pain returned. He stopped the Minocycline immediately and his pain quickly went away again.

Petitioner conducted his own research and initially found no connection between Minocycline and PD. Petitioner did, however, confirm a connection between Minocycline and drug induced lupus, a different connective tissue disorder.

Petitioner saw Dr. Jones on October 30, 2014 and saw Dr. Meffert on November 12, 2014.

Petitioner told both about what happened when he stopped the Minocycline, about Minocycline causing another connective tissue disease, and that he thought it had caused his PD. Dr. Jones, the PD specialist, told Plaintiff unequivocally that drugs don't cause PD. Dr. Meffert, a dermatologist who regularly prescribes Minocycline, told Petitioner that PD is not a listed side effect of a Minocycline.

With two doctors telling Petitioner that Minocycline doesn't cause PD and Petitioner's own research, before and after seeing his doctors, not yielding any connection between Minocycline and PD, he left it alone at that point. Plaintiff continued to see Dr. Jones and tried some noninvasive treatments to no avail. Plaintiff felt other treatment options posed too much risk.

On or about June 15, 2017 Petitioner was prescribed Carbamazepine (brand name Tegretol) by nurse practitioner Lydia Trejo of pain management physician Dr. Shaun Jackson's office. This prescription was recommended by neurologist Dr. Rebecca Romero for the treatment of severe small fiber neuropathy. However, Dr. Jackson later indicated he would prefer the prescription come from Dr. Romero since it was for a condition she was treating. On August 24, 2017 Dr. Romero took over the prescription. The Carbamazepine product Petitioner received and used from his local pharmacy was from Taro Pharmaceuticals USA, Incorporated (Taro), with the label designed by Novartis Pharmaceuticals Corporation (Novartis) for its brand name drug Tegretol. Patient information from the label was distributed to Petitioner with the tablets and Petitioner read the information.

On or about September 10, 2017 Petitioner developed pain in his penis and observed new PD symptoms. There were new indentations along the side, narrowing at the head, more dramatic bottlenecking and bending, and more difficulty getting and maintaining an erection. On or about September 11, 2017 Petitioner researched Carbamazepine and found that it has been known to cause drug induced lupus just like Minocycline, but he did not find any connection to PD.

On September 11, 2017 Petitioner also notified Dr. Romero through MyChart what was happening and that it seemed that the Carbamazepine had reactivated his PD. Dr. Romero replied that to her knowledge this is not a common reaction to Carbamazepine and referred Petitioner to his urologist.

On September 12, 2017 Petitioner saw rheumatologist Dr. Jose Roldan. Since Petitioner's research on September 11, 2017 indicated that there was a correlation between high levels of TGF-beta and PD, he asked Dr. Roldan to order a TGF-beta blood test.

On September 13, 2017 Petitioner saw urologist Dr. Jones again. He told Dr. Jones that he had returned because Carbamazepine had caused a reactivation of his PD. Petitioner recounted what happened with the Minocycline and told him about both drugs being on a list of medications that can cause drug induced lupus. Dr. Jones, again, unequivocally stated that drugs don't cause PD.

On or about September 13, 2017 Petitioner stopped the Carbamazepine and the PD pain he was having quickly went away. He did not retry this drug. Petitioner took the TGF-beta test ordered by

Dr. Roldan on or about September 14, 2017 and it came back high. On or about December 8, 2017 Petitioner had the TGF-beta test redone and the results were normal now off the Carbamazepine.

On August 19, 2019, while researching alternate methods of treatment, Petitioner happens upon an article dated 1989 that links Carbamazepine to PD and other auto-immune disorders. Petitioner also finds articles that show both Minocycline and Carbamazepine can increase TGF-beta levels and that injections of TGF-beta are used to induce PD in laboratory animals. Additionally, Petitioner finds that Minocycline can cause other forms of fibrosis; PD is considered penile fibrosis. Lastly, Petitioner for the first time finds websites that say medications can cause PD – a couple of sources even mention anti-seizure drugs specifically, of which Carbamazepine is one. This new evidence now refutes his doctors' statements that drugs don't cause PD. Only at this point does Petitioner have enough evidence to substantiate that both products caused his PD. He now knows that he has been injured by the Respondents.

Neither Minocycline nor Carbamazepine had Peyronie's Disease, "penis disorder," or "penile size reduced" listed as a side effect on the label or in the patient information that was given with the prescription. There were previous reports of "penis disorder" for both drugs, and previous reports of "penile size reduced" for Carbamazepine. Prior to filing suit, Petitioner notified all Defendants of the side effects he experienced and that he had claims against them.

Petitioner filed his Complaint for a Civil Case on September 10, 2019 in the U.S. District Court for

the Western District of Texas, San Antonio Division. The basis for jurisdiction was diversity of citizenship under U.S.C. § 1332, as Petitioner is a citizen of State of Texas, all events took place in Texas, and Respondents are all citizens of other states. Petitioner stated five causes of action: strict liability, negligent manufacturing, negligent failure to warn/ fraudulent misrepresentation, breach of warranty (express and/or implied), and loss of consortium.

All Respondents filed Motions to Dismiss. Petitioner filed a combined response, Respondents filed replies, and Petitioner filed a sur-reply.

Subsequently, Plaintiff filed a motion for leave to amend his complaint, with said amendment attached. Plaintiff's First Amended Complaint for a Civil Case modified the causes of action to strict liability, negligent manufacture, negligent failure to warn, fraudulent and/or negligent misrepresentation, deceptive trade practices, common law negligence, and breach of warranty (express and/or implied). Plaintiff requested his loss of consortium be held by the Court for his wife should she be added to the claim once Plaintiff find proper representation. This motion was opposed by all Defendants.

The District Court issued its Order on May 7, 2020 (App. 12a). The Order granted the Motions to Dismiss of brand name manufactures Novartis and Bausch based on the fact that Petitioner did not ingest pills manufactured by Novartis and Bausch. The Order also granted the Motions to Dismiss of generic manufacturers Taro, Sun, and Torrent by finding that Petitioner's claims did not rebut Texas law's presumption of no liability resulting from an FDA approved label, and alternatively by finding that Plaintiff claims are preempted by federal law

under Supreme Court and Fifth Circuit precedent. The Order further granted Plaintiff's Motion for Leave to File a Combined Rebuttal to Defendants' Replies in Support of Their Motions to Dismiss, but denied Petitioner's Motion for Leave to File a First Amended Complaint for a Civil Case and to Edit the Style of the Case as futile and unduly prejudicial to Defendants.

Petitioner timely filed his Notice of Appeal to the United States Court of Appeals for the Fifth Circuit on June 5, 2020. After briefing, but without oral arguments, the Fifth Circuit affirmed the decision of the District Court on February 5, 2021 (see App. 1a). The Court found that Petitioner's claims against generic manufacturers Taro, Sun, and Torrent were preempted by federal law. The Court further found that brand name manufacturers Bausch and Novartis owed no duty to Petitioner since he ingested generic drugs. Based on these two findings the Court stated it did not reach the issues surrounding the presumption against liability and, therefore, did not consider Petitioner's arguments regarding rebuttal of the statute, including Petitioner's challenges to the validity of the presumption statute. No finding was made regarding the District Court denying Petitioner leave to amend.

REASONS FOR GRANTING THE WRIT

I. Public Safety

The issues in this case are important to the landscape of pharmaceutical litigation, not only in the State of Texas, but throughout the United States

as well. The outcome will greatly affect the safety and the rights of every U.S. citizen who take generic drugs. Whether through direct prescription or pharmacy substitution, generic drugs make up an overwhelming majority of prescriptions filled.

Nationally, from 2009 to 2019 the population of the United States grew roughly from 307 million to 329 million, an increase of 7 percent. During the same span, however, adverse event reports in the FDA Adverse Event Reporting System grew roughly from 490,000 to 2,190,000, an increase of 347 percent. Adverse event reporting grew at a rate nearly 50 times that of the population. Deaths reported as an adverse event grew from roughly 9,700 to 55,800, an increase of 475 percent. Deaths grew at a rate nearly 68 times that of the population

Court rulings at issue in this case have helped foster an environment of unaccountability for pharmaceutical companies. Without accountability, these companies are not complying with state law duties to discover the dangerous propensities of their products and to exercise reasonable care to prevent harm that can reasonably be foreseen. Consumers are getting hurt in the process. With consumer safety being paramount, this Court should grant writ of certiorari and give full consideration to the merits of this case.

II. Brand Name Manufacturer Liability for Its Label Information

A. Supervisory Powers of the Court. The Fifth Circuit has not decided this case and the precedents involved by applying Texas law in a fair and equitable manner, but have instead acted with

an end goal to dismiss consumer claims against drug companies. This Court should exercise its supervisory powers to return the Fifth Circuit back to Texas law and away from its biases.

In Texas there are three categories of defects: design, manufacturing, and marketing. *American Tabacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997). Petitioner does not allege a design defect or a manufacturing defect of the pills. Instead, we are dealing with a marketing defect, as the label is the part of each drug product that is defective. Petitioner has always maintained that it was the defective labels that caused his PD. Therefore, the Fifth Circuit's emphasis on the ingestion of the pill is misplaced because the defect does not lie within the pill itself, but within the label. The pill is simply not defective under Texas law.

The District Court and the Fifth Circuit erroneously place emphasis on ingestion of the pill and brand name manufacturers' "innovator liability" theory. "Innovator Liability could only relate to the pill since the label is the direct work product of the brand name manufacturers. An element of Petitioner's strict liability marketing defect claim against the brand name Respondents is "A causal link between the failure to warn or instruct and the product user's injury." *DiamlerChrysler Corp. v. Hillhouse*, 161 S.W.3d 541,547 (Tex. App. – San Antonio 2004, pet. granted, judgement vacated w.r.m.) This clearly shows that the causal relationship that is under review is the link between the label and the injury, and not between the pill and the injury. Petitioners other claims against the brand name manufacturers also focuses on the label.

The lower courts used *Eckhardt v. Qualitest Pharmaceuticals, Inc.*, 751 F.3d 674 (5th Cir. 2014) and *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 472 (5th Cir. 2014) to dismiss the instant case. These two cases were both submitted to the Fifth Circuit around the same time, by the same attorney, improperly as design defect cases in what seems to be an attempt to get around *Mensing*. As design defect cases, each wrongly stated that the ingestion of the pill caused the Plaintiffs' injuries. Instead of recognizing these two cases as marketing defect cases, the Fifth Circuit honed in on the pill against Texas law. The instant case is distinguished from *Eckhardt* and *Lashley* in that Petitioner has claimed that it was the defective label, not ingestion of the pill, that caused his injuries.

Had Bausch listed PD (or even "penis disorder," which had previously been reported) as a side effect when it designed the label that was part of the Minocycline product, the medication could have been stopped once the nodules were first discovered, not some six months later while allowing full blown PD to develop. When the nodules were first noticed there was not yet any deformity, dysfunction, or pain, and since PD sometimes spontaneously recovers, Petitioner may have had a full recovery if the Minocycline had been stopped when the nodules were first discovered. Had Bausch included instructions limiting the length of time the drug is taken like it does for its other brand name Minocycline product, Solodyn, Petitioner would have never even developed the nodules.

Had Novartis listed PD (or even "penile size reduced" or "penis disorder," which had previously been reported) as a side effect when it designed the

label that was part of the Carbamazepine product, the drug would never have been tried due to the Plaintiff's prior history with Minocycline.

The "but for" in this case as it pertains to the brand name Respondents is simply: if it was not for the defective label designs of Bausch and Novartis, the Mr. Johnson would not have been injured. Neither Bausch nor Novartis deny that the defective labels that caused the injuries are their designs. However, brand name Respondents do say they are not manufacturers in this case so they can't be held liable. Texas law says otherwise.

If under *Grinnell* above, a marketing defect is a type of product defect, the marketing must be part of the product. Both Federal and Texas law require labels as part of the product. The Federal Food, Drug, and Cosmetic Act uses the phrase "A drug or drug product (as defined in 320.1 of this chapter) in finished package form" 21 CFR 201.1. This finished package form of the product surely includes the pill, the container, and the required labeling.

As designers of the labels, Bausch and Novartis are considered manufacturers in this case. Under Tex. Civ. Prac. Rem. Code § 82.001(4): "Manufacturer" means a person who is a designer, formulator, constructor, rebuilder, fabricator, producer, compounder, processor, or assembler of any product or any component part thereof and who places the product or any component part thereof in the stream of commerce. Bausch and Novartis designed the labels, entered them into the stream of commerce, and those labels were the defective part of the drug products that cause Petitioner to develop PD. Bausch and Novartis are, therefore, liable for Petitioner's injuries.

Holding on to it bias against the consumer, the Fifth Circuit inexplicably still uses *Eckhardt* and *Lashley* to dismiss Petitioner's claims, even when confronted with the fact that Petitioner has presented different theories of liability that are consistent with Texas law. This Court decided to hear *Mutual Pharmaceutical Co., Inc. v. Bartlett* 570 U.S. 472 (2013) and applied standards appropriate for a design defect even though it had previously decided *Mensing* under a different theory of liability. This Court should exercise it supervisory powers and apply the applicable standards to Petitioner's claims where the Fifth Circuit has failed to do so.

B. Matter of First Impression with Differing Opinions. This Court has not yet decided whether a brand name drug manufacturer who designed the label that is distributed as part of a generic drug product can be held liable when it is that label that is the defective part of the product that caused the injury.

Brand name Defendant have known that since the passage of the Hatch-Waxman Amendments that generic drug manufacturers are required to use the labels of the brand name drugs their generic is based on. It is, therefore, easily foreseeable that defects in their brand name labels could not only harm the users of the brand name products, but also users of the generic products required to use their labels. They owe a duty of care to anyone who uses the label information they are responsible for. *Mensing* at 613 indicates brand name manufacturers are responsible for the accuracy and adequacy of their labels while the responsibility of generic manufacturers is

sameness. With *Mensing* in mind other courts have offered:

> *Mensing's* acceptance of the FDA's "newfound opinion" created a different landscape in pharmaceutical litigation. Brand-name drug manufacturers now stand in direct relationship with consumers who ingest generic drugs because only the brand-name manufacturers can control and change labeling to strengthen warnings about drug safety. *Strayhorn v. Wyeth Pharmaceuticals, Inc.* 737 F.3d 378 (2013) (Stranch, J. concurring in part and dissenting in part).

> The "privileged position accorded to the brand manufacturers may alter their state law relationship to the generic drugs whose composition and labeling they control." *Fullington v. Pfizer, Inc.* 720 F.3d 739, 748 (8th Cir.2013) (Murphy, J., concurring).

Several state courts of last resort have coupled the *Mensing* decision with the foreseeability argument and allowed for the advancement of various negligence and misrepresentation claims against brand name manufacture in cases where there was only exposure to generic products. Those cases include *T.H. v. Novartis Pharmaceuticals Corp.,* 4 Cal. 5th 145 (2017) in California, *Rafferty v. Merck* & Co., Inc. 479 Mass. 141 (2018) in Massachusetts, *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010) in Vermont, and *Wyeth, Inc. v. Weeks,* 159 So. 3d 649 (2014) in Alabama.

Additionally, it should be pointed out that Petitioner has expressed common law claim against the brand name manufacturers, and even before *Mensing* this was decided:

> We hold that the common law duty to use due care owed by a name-brand prescription drug manufacturer when providing product warnings extends not only to consumers of its own product, but also to those whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug. *Conte v. Wyeth, Inc.*, 168 Cal.App.4th 89, 94-95 (Cal. Ct. App. 2008)

With the Fifth Circuit and other jurisdictions, including state courts of last resort, having varying opinions, it is up to this Court to decide if the statutory scheme provided by the Hatch-Waxman Amendments extends a brand name manufactures duty of care to user of generic drugs that are required to have their labels as part of the product.

III. Generic Manufacturer Liability

A. Supervisory Powers of the Court. The Fifth Circuit has engaged in improper judicial proceedings and this Court should exercise its supervisory powers. The Fifth Circuit has expanded the reach of *Mensing* and *Bartlett* far beyond the holdings of this Court. The Fifth Circuit opinion related to Petitioner's strict liability marketing defect goes against the opinion of Texas Supreme

Court. The Fifth Circuit failed to properly consider other state law duties other than the duty to change the label. And, in order to expediently dispose of consumer claims, the Fifth Circuit improperly lumps all the claims together instead of evaluating the merits of each claim – this includes the dismissal of Petitioner's breach of warranty when Fifth Circuit precedent in *Massey v. Novartis Pharmaceuticals Corporation*, 46 F. Supp. 3d 688 (W.D. Tex. 2014) would have allowed the claim to proceed since Petitioner in this case had notified Respondents of his claim.

In its opinion regarding the instant case, the Fifth Circuit starts off by overstating the holding in *Mensing* by saying, "In *PLIVA v. Mensing*, the Supreme Court held that state law claims against generic drug manufacturers that turn on the adequacy of the drug's label are preempted. 564 U.S. 604, 618 (2011)." This is not said at 618, or anywhere else in *Mensing*. This greatly expands what the Fifth Circuit itself had previously said: "The Court held that federal law preempted state laws imposing a duty to change a drug's label upon generic drug manufacturers." *Lashley*, footnote 4.

The decision in *Mensing* hinged on the impossibility of a generic drug manufacturer's ability to unilaterally change its label and still comply with federal law. Petitioner's claims against the generic manufacturers in the instant case are not about their ability to change the label. Instead, Petitioner is holding the generic manufacturers responsible for distributing a defective label as part of their product, as well as other tort duties for which they failed to comply. There is no impossibility with any of

Plaintiffs' claim against the generic manufacturers in this case.

Additionally, by taking a label designed by another party, branding that label with their own names, and distributing it with their pills and packaging, the generic manufacturers assume the same liability as if they had designed the label themselves. What they could do about it becomes irrelevant. From the *Texas Litigation Guide* we have the following:

> If the seller of a product manufactured by another party sells the product knowing that it is dangerous, or that is likely to be dangerous, the seller is subject to the same liability as any other supplier of a dangerous product [Restatement (Second) of Torts § 399].
>
> A person who sells a product that is manufactured by another as the seller's own product is subject to the same liability as the manufacturer of the product [Restatement (Second) of Torts § 400]. Thus, the manufacturer of an automobile may be held liable for damages caused by a negligently component part, although that part is made by another party and was merely assembled by the auto manufacturer [*Ford Motor Company v. Mathis*, 322 F.2d 267, 273-274 (5th Cir. [Tex] 1963)]. Similarly, a department store was held liable for a negligently manufactured washing machine even though the machine was manufactured by another company because the department store had put its brand name on the machine [*Sears, Roebuck& Co. v. Black*, 708

S.W.2d 925, 928 (Tex. App. – Eastland 1986, no writ)].

The generic manufacturers are liable because they branded the defective labels with their own names and they distributed those labels as part of their own product while they knew or should have known of the labels defects.

Turning to *Bartlett*, it is not applicable to the instant case since, as the District Court pointed out in its Order (App. 21a), it pertains to "design defect claims." What we have in the instant case is a marketing defect. While *Eckhardt,* analyzing *Bartlett*, found that a strict liability design defect claim in Texas was not required to balance the product's harms and benefits as in New Hampshire, it was still preempted because in order to prove a strict liability design defect claim under Texas law as alleged here, the plaintiff must prove that "a safer alternative design existed." *Eckhardt* at 679 citing *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009). With the marketing defects in this case, there is no requirement for a safer alternative design. *Mensing* and *Bartlett* do not preempt Plaintiff's claims.

1. Strict Liability Marketing Defect: The only claim of Petitioner's that the Fifth Circuit somewhat examined was his strict liability marketing defect claim. It did so only by examining the definition of a marketing defect: "[a] marketing defect occurs when a defendant knows or should know of a potential risk of harm presented by the product but markets it without adequately warning of the danger or providing instruction for safe use." *Diamler Chrysler Corp. v. Hillhouse*, 161 S.W.3d 541, 546 (Tex. App. –

San Antonio 2004, pet. granted, judgement vacated w.r.m.).

The Fifth Circuit somehow mistakes this as a "law" requiring the Respondents to update their label when they have knowledge of a risk. It is not. This definition only looks at Respondents knowledge and the condition of the product when it was distributed, asking two simple questions: (1) Did Respondent know, or should they have known, of the risk? The answer here is clearly yes. (2) Did Respondents market the product without warning of the risk? Again, the answer is yes. With a yes to both questions, we have a marketing defect.

The Texas Supreme Court agrees with Petitioner on this issue by stating:

> The care taken by the supplier of a product in its preparation, manufacture, or sale, is not a consideration in strict liability; this is, however, the ultimate question in a negligence action. Strict liability looks at the product itself and determines if it is defective. Negligence looks at the act of the manufacturer and determines if it exercised ordinary care in design and production. *Gonzales v. Caterpillar Tractor Co.*, 571 S.W.2d 867, 871 (Tex. 1978).

Negligence looks at the act, and updating the label is simply an act that strict liability in Texas does not care about.

Petitioner provided the Fifth Circuit with the elements of the strict liability marketing defect claim. It inexplicably refused to evaluate them for this case. From the *Texas Litigation Guide*: A claimant establishes a "marketing defect" by showing

all of the following [see *DiamlerChrysler Corp. v. Hillhouse*, 161 S.W.3d 541,547 (Tex. App. – San Antonio 2004, pet. granted, judgement vacated w.r.m.)]:

> 1. A risk of harm that is inherent in the product or that may arise from the product's intended or reasonably anticipated use.
>
> 2. Actual knowledge or foreseeability of the risk of harm by the product supplier at the time the product is marketed.
>
> 3. The absence of a warning or instructions that renders the product unreasonably dangerous to the product's ultimate user or consumer.
>
> 4. A causal link between the failure to warn or instruct and the product user's injury.

There is no requirement that the Defendants are able to update the label. There is no requirement for a "safer alternative design." There is, thus, no impossibility. This claim simply looks at the label at a moment in time to determine if it was defective. Petitioner demonstrated to the Fifth Circuit during briefing that each element was met (Appellant's Original Brief 40-41). Defendants are liable for the Plaintiff's injuries.

2. Breach of Warranty: In a dereliction of its duties, the Fifth Circuit also failed to evaluate the elements of this claim as well. The elements of a cause of action for breach of the implied warranty of merchantability are: (1) the defendant sold or leased

a product to the plaintiff; (2) the product was unmerchantable; (3) the plaintiff notified the defendant of the breach; and (4) the plaintiff suffered injury [*Polaris Industries v. McDonald*, 119 S.W.3d 331, 336 (Tex. App. – Tyler 2003 no pet.)].

Again, Petitioner demonstrated to the Fifth Circuit during briefing that each of these elements was met (Appellant's Original Brief 42). There is no requirement that the Defendants are able to provide updated labels. There is also no requirement for a "safer alternative design." There is, thus, no impossibility. Further, it should be noted that as stated above in *Massey*, the Court separated the warranty claim from the failure to warn claim, and only dismissed it because the plaintiff had failed to notify the defendant of the claim prior to filing suit. Plaintiff did so in this case, so Defendants are liable.

3. Fraudulent and/or Negligent Misrepresentation: Yet another claim the Fifth Circuit failed to evaluate on its own merits. From the *Texas Litigation Guide*:

> Misrepresentation may be asserted as the basis for a products liability action [see C.P.R.C. § 82.001(2)]. In some situations, liability may be imposed on the seller of a product who, by advertising, labeling, or some other communication, makes a misrepresentation to the public of a material fact about the character or quality of a product and a consumer suffers some physical harm from the product by relying on the misrepresentation [see *Crocker v. Winthrop Lab., Div. of Sterling Drug, Inc.*, 514 S.W.2d 429, 431 (Tex. 1974)]. This liability will apply if the consumer justifiably relies on the

> misrepresentation, even though the misrepresentation is not made fraudulently or negligently, and even if the consumer does not have a contractual relationship with the seller [Restatement (Second) of Torts § 402B].

Yet again, there is no requirement that the Defendants are able to provide updated labels. And there is no requirement for a "safer alternative design." The criteria established here for misrepresentation only look at the state of the product as distributed.

The Minocycline label says, "The following adverse events have been observed in patients receiving tetracyclines." However, this label does not indicate to list "penis disorder" and "erectile dysfunction," which both show up in the FDA Adverse Event Reporting System (FAERS). Plaintiff relied on this misrepresentation and continued to using this product causing further damage to his body. Plaintiff may have had a full recovery had the known side effects been listed.

The Carbamazepine label says, "The following additional adverse reactions have been reported." However, this label does not indicate "penis disorder" and "penile size reduced," which both show up in the FAERS database. Plaintiff relied on this misrepresentation and used this product, causing more damage to his body.

All criteria for misrepresentations have been met, so Defendants are liable. It should be noted here that an analysis of Plaintiff's Deceptive Trade Practices Act (DTPA) claims would be similar in nature to this misrepresentation analysis.

4. Negligence Claims & Duty of Care: The Fifth Circuit completely ignored the manufacturers' duties of care as laid out by the Texas courts and presented during briefing. The manufacturers' duties of care that relate to Plaintiff's negligent manufacture, negligent failure to warn, and common law negligence claims are as stated in the Texas Litigation Guide:

> [1] Manufacturers must exercise reasonable care to prevent physical harm that reasonably can be foreseen to result from the use of the product for its intended purpose. [2] They also must take reasonable care to discover the dangerous propensities of the product and to warn persons who might be endangered by it [see *Starr v. Koppers Company*, 398 S.W.2d 827, 830-831 (Tex. Civ. App. – San Antonio 1965, writ ref'd n.r.e.).]

To avoid liability, manufacturers must satisfy both duties. With respect to [1] above, the question for the generic manufacturers becomes, "What does reasonable care to prevent physical harm look like for a generic manufacturer who was unable to directly change the label?" The answer is that the manufacturer would have to provide the information to the FDA, possibly even filing a citizen's petition. Respondents here clearly haven't exercised reasonable care to prevent physical harm to the user.

Duty [2] above has two parts. First, the generic manufacturers would have to exercise reasonable to identify side effects. That would involve doing proper post market evaluations as they are required to do. Petitioner alleges this has not

been done. Second, if a generic manufacturer found a new side effect, reasonable care to warn its users would again be to provide the information to the FDA, possibly even filing a citizen's petition.

According to the FDA in *Mensing* (at 616), the generic manufacturers are required to ask for assistance in getting the label changed, so the manufacturer would be satisfying both state and federal duties. While *Mensing* (at 624) states "The only action the Manufacturers could independently take—asking for the FDA's help—is not a matter of state-law concern," it is clearly a matter of state-law concern regarding the Texas duties of care.

It is worth noting here that the generic manufacturers could even contact the brand name manufacturers from whom they get their labels directly, just as an automaker would have to contact a supplier if they found that supplier's part to be defective. What they are not allowed to do is simply do nothing.

B. Matter of First Impression Involving Federal Preemption. Petitioner's claims against the generic manufacturers do not rely on their ability to update the labels as in *Mensing*. Nor are they design defect claims as in *Bartlett*, *Lashley*, and *Eckhardt* that rely on there being a "safer alternative design." Plaintiff's claims against the generic manufacturers are, therefore, not preempted by *Mensing* or *Bartlett*. Federal preemption analysis of Petitioner's strict liability marketing defect, negligent manufacture, negligent failure to warn, fraudulent and/or negligent misrepresentation, deceptive trade practices, common law negligence, and breach of warranty claims are matter of first impression for

this court and it is most appropriate for this Court to perform this analysis. Just as this Court was compelled to hear *Bartlett* because of its differences from *Mensing*, the Court should be compelled to hear the instant case which differs from both *Mensing* and *Bartlett*.

IV. Relevant Information Rebuttal to the Texas Presumption of No Liability.

A. Supervisory Powers of the Court. The Fifth Circuit has again engaged in improper judicial proceedings and this Court should exercise its supervisory powers. Although the Fifth Circuit said it did not reach the issues surrounding the Texas presumption of no liability statute in this case, it is the Fifth Circuit's ruling in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372 (2012) that the District Court uses to discount Petitioner's § 82.007(b)(1) relevant information rebuttal. In *Lofton*, the Fifth Circuit strains in order to turn a provision that says nothing about fraud into some "fraud on the FDA" provision that it can preempt, thus voiding a protection the legislature provided for the consumer. *Lofton* first rearranges the wording of the statute to establish that FDA requirements are involved. Then, twice for invalid reasons it chooses between different precedents just to support its end goal.

Tex. Civ. Prac. Rem. Code § 82.007(a) provides a drug manufacturer a presumption of no liability when their drug is accompanied by an FDA approved label. Tex. Civ. Prac. Rem. Code § 82.007(b) provides Plaintiff five enumerated ways to rebut this presumption. Plaintiff has pled the relevant

information rebuttal of § 82.007(b)(1) under which a Defendant can be held liable if:

> "the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury."

The *Lofton* Court reorders the words to create the word chain "information required by the FDA." The *Lofton* Court (at 376) restates § 82.007(b)(1) as:

> Under § 82.007(b)(1), the relevant exception here, the presumption against liability can be rebutted if the plaintiff can "establish" that the drug manufacturer "withheld" from the agency or "misrepresented" "material" information "required" by the FDA.

The actual statute, as indicated above, makes no mention of "information required by the FDA" or "FDA requirements." In fact, the *Texas Litigation Guide*, a resource often cited by the courts, restates § 82.007(b)(1) by saying:

> "That the defendant misrepresented or withheld relevant information from the FDA that relates to the performance of the product and was causally related to the claimant's injury."

This says nothing about FDA requirements. FDA requirements do not have to be evaluated and there is no infringement on FDA duties. Drug manufacturers have their own discretion as to what is submitted as relevant information, and the fact finder would only be reviewing that discretion.

Having manufactured a "fraud on the FDA" provision, the Lofton Court now says that the FDA must have found fraud in order for a plaintiff to use the § 82.007(b)(1) rebuttal. Adding that the FDA must have found fraud is adding a requirement that the legislature never intended, substantially alters the law, and amounts to judicial construction. As written the law would encompass scenarios involving negligence, and Plaintiff's claims in the instant case are full of negligent behavior. Not all misconduct will rise to the level of fraud, and the legislature surely understood that by not requiring fraud to be proven by the FDA before a lawsuit can be filed. Plus, this fraud requirement would put a significant undue burden on plaintiffs to try to have the FDA open an investigation, go through its investigation process, and then rule on its findings all prior to filing suit before the statute of limitations runs out.

Having falsely established § 82.007(b)(1) as a "fraud on the FDA" provision, *Lofton* analyzes *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) and *Wyeth v. Levine*, 555 U.S. 555, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009) and chooses *Buckman* because the sole claim in *Buckman* was that the Defendant committed fraud against the FDA. "Fraud on the FDA" is not basis for any of Plaintiff's claims in the instant case, making *Buckman*, and thus *Lofton* which relies on *Buckman*, not relevant for the

instant case. Further, fraud requires intention to deceive, and that is not so stated in the provision.

Without the intention to deceive, the provision is more in line with common law duties that parallel federal duties. Also, the instant case has common law state tort elements that are not based on committing "fraud on the FDA." With common law elements in the instant case, *Lofton* (at 377) itself indicates *Levine* would be the more appropriate chose. The *Lofton* Court erred in ruling that § 82.007(b)(1) is a "fraud on the FDA" provision.

Next the *Lofton* Court equates § 82.007(b)(1) with a Michigan statute so that it can look at two diverging opinions relating to preemption of that statute under *Buckman*. The two are not equal as, Mich. Comp. Laws § 600.2946(5)(a) (App. 25a) requires intention, actually lists FDCA provisions, and requires that approval of the drug would have had to have been withdrawn or never given. Despite these substantial differences, *Lofton* reviews the two decisions concerning the Michigan law: *Garcia v. Wyeth–Ayerst Labs.*, 385 F.3d 961 (6th Cir.2004) and *Desiano v. Warner–Lambert & Co.*, 467 F.3d 85 (2d Cir.2006), *aff'd by an equally divided court sub nom. Warner–Lambert Co., LLC v. Kent*, 552 U.S. 440, 128 S.Ct. 1168, 170 L.Ed.2d 51 (2008).

The Sixth Circuit held in *Garcia* that the Michigan statute is preempted in some applications. The Second Circuit, however, held in *Desiano* that the same Michigan statute was not preempted. While Lofton focused again on its fraud argument and chose preemption in *Garcia*. If one was to take a moment to give consideration to the legislative intent of Tex. Civ. Prac. Rem. Code § 82.007 one would clearly see that the provision of § 82.007(b)(1) is more

in line with *Desiano* (from *Lofton* at 378) reasoning that the statute was merely a prerequisite to allow victims to recover under state product liability laws and not an attempt to police fraud on the FDA. *Desiano* also found that the underlying claims were traditional product liability claims, and pairing these claims with the provision distinguished the case from *Buckman*. *Desiano* should prevail here.

For it is the duty of the courts to construe a law as written and, if possible, ascertain its intention from the language used and not look for extraneous reasons to be used as a basis for reading into law an intention not expressed or intended to be expressed therein. *MCI Sales & Serv., Inc. v. Hinton*, 329 S.W.3d 475, 500–01 (Tex. 2010). The *Lofton* Court failed here.

B. *Question of Federal Preemption with Differing Opinions*: Having decided both *Buckman* and *Levine*, this Court should make the determination as to which is more appropriate to the relevant information rebuttal to the Texas presumption of no liability, Tex. Civ. Prac. Rem. Code § 82.007(b)(1). If this Court determines *Buckman*, this Court is needed to decide whether the Second Circuit or the Sixth Circuit interpretation of *Buckman* is more appropriate for the Texas statute, keeping in mind the significant differences between the Texas statute and the Michigan statute the Second and Sixth Circuits reviewed.

C. § 82.007 is Either Fully Preempted or Unconstitutional: If this Court agrees with Lofton and determines that § 82.007(b)(1) is preempted in any way, that would mean that § 82.007(a) would be

preempted as well since it is not severable from § 82.007(b)(1) without changing the intent of the legislation. Preempting § 82.007(b)(1) in any way would give blanket immunity even in cases where they were clearly negligent. One surely would not believe that this was the intent of the legislature.

It is worth noting here that Petitioner demonstrated to the Fifth Circuit that, based on the legislative history, the presumption of no liability in § 82.007(a) would not exist if it were not for the rebuttal provided by § 82.007(b)(1). The House tried to include the presumption without any rebuttals, and it is only by adding § 82.007(b)(1) that the measure was able to pass the House and move to the Senate. According to Tex. Gov't Code § 311.023, legislative history is one of the considerations to be used when construing a statute. § 82.007(a) is thus dependent on § 82.007(b)(1) and must be preempted if § 82.007(b)(1) is preempted.

Alternatively, preemption of § 82.007(b)(1) renders § 82.007 as a whole is unconstitutional. Preemption of § 82.007(b)(1) in any form inhibits Plaintiff's, and any Texas consumer's, access to the courts to seek redress, in violation of Amendment I of the Constitution of the United States of America.

Additionally, Tex. Const. Art. I, §13 from the Bill of Rights of the Texas Constitution would be violated as well. Tex. Const. Art. I, §13 reads in part: "All courts shall be open, and every person for an injury done him, in his lands, goods, person or reputation, shall have remedy by due course of law."

Following this is a constitutional right that meaningful remedies must be afforded, "so that the legislature may not abrogate the right to assert a well-established common law cause of action unless

the reason for action outweighs the litigants' constitutional right of redress." *Texas Workers' Compensation Com'n. v. Garcia*, 893 S.W.2d 504, 520 (Tex. 1995); quoting *Trinity River Authority v. URS Consultants, Inc.*, 889 S.W.2d 259, 261 (Tex. 1994). Therefore, *Lofton's* interpretation of § 82.007 renders the entire provision unconstitutional, as it abrogates to right seek redress far in excess of what the legislature intended.

V. Unapproved Indication Rebuttal to the Texas Presumption of No Liability.

A. Supervisory Powers of the Court. While, again, the Fifth Circuit did not reach this issue, the District Court has again engaged in improper judicial proceedings and this Court should exercise its supervisory powers. The Order from the District Court says (App. 20a-21a):

> Plaintiff fails to allege any facts related to Minocycline's "off-label" marketing. See docket nos. 1 & 39. Nor does he allege any facts related to Defendants Sun Pharmaceuticals or Taro's marketing of Carbamazepine for off-label uses, or, that his use of the drug was off-label.

This is a clear and obvious misstatement and either shows a lack of familiarity with the pleadings or some malfeasance. Plaintiff has clearly pled the rebuttal of § 82.007(b)(3) under which a Defendant can be held liable if:

> (A) the defendant recommended, promoted, or advertised the pharmaceutical product for an

> indication not approved by the United States Food and Drug Administration; (B) the product was used as recommended, promoted, or advertised; and (C) the Plaintiffs injury was causally related to the recommended, promoted, or advertised use of the product."

Plaintiff first pled his §82.007(b)(3) rebuttal for Minocycline on page 10 of Plaintiff's Combined Rebuttal to Defendants' Replies in Support of Their Motions to Dismiss (Dkt. 44) (ROA.354). Based on evolving information Plaintiff was learning from access to his medical records, Plaintiff amended his pleading of his §82.007(b)(3) rebuttal for Minocycline on attachment page 7 of his First Amended Complaint for a Civil Case (Dkt. 47). Plaintiff alleges that:

> "the Minocycline label states it is indicated for use against various listed infections. Plaintiff was prescribed Minocycline for acne keloidalis, hidradenitis, folliculitis, and cellulitis and abscess of trunk." (ROA.388)

Plaintiff was injured because he was prescribed Minocycline for these acne related conditions. Among the facts Plaintiff alleges supporting the §82.007(b)(3) rebuttal for Minocycline is:

> The label itself provides evidence of over-promotion when it says, "In severe acne, minocycline may be useful adjunctive therapy." The label clearly does not say that severe acne is an approved indication for Minocycline, but by saying "may be useful," the label is

> promoting it for the use of an unapproved indication for which it was prescribed for the Plaintiff. (ROA.389)

This statement is made in the label and the label is considered marketing. Thus, this is considered direct marketing to Plaintiff's doctor.

Plaintiff first pled his §82.007(b)(3) rebuttal for Carbamazepine starting on page 11 of Plaintiff's Combined Response to Defendants' Motions to Dismiss (Dkt. 39) (ROA.291). Plaintiff amended his pleading of his §82.007(b)(3) rebuttal for Carbamazepine on attachment page 9 of his First Amended Complaint for a Civil Case (Dkt. 47). Plaintiff alleges that:

> the Carbamazepine label states it is "indicated for use as an anticonvulsant drug" and it is "indicated in the treatment of the pain associated with true trigeminal neuralgia." Plaintiff was prescribed Carbamazepine for small fiber neuropathy. (ROA.390)

Plaintiff was injured because he was prescribed Carbamazepine for his small fiber neuropathy. Among the facts Plaintiff alleges supporting the §82.007(b)(3) rebuttal for Carbamazepne is:

> The label itself provides evidence of over-promotion when it says, "Beneficial results have also been reported in glossopharyngeal neuralgia." The label does not say that Carbamazepine is indicated for use in the treatment of glossopharyngeal neuralgia, but this statement could lead doctors to believe that

> Carbamazepine would be "beneficial" to other form on neuralgia (neuropathy) if it has been "reported" to be. The label further goes on to say "Medicines are sometimes prescribed for purposes other than those listed in the Medication Guide. Do not use Carbamazepine for a condition for which it was not prescribed." With these statements the Carbamazepine (Tegretol) manufacturers clearly seek to benefit from the prescribing of their medication for non-approved indications, including the Plaintiff's small fiber neuropathy. (ROA.390)

Again, these statements are made in the label and the label is considered marketing. Thus, they are considered direct marketing to Plaintiff's doctor.

Additionally, Plaintiff has pointed out in both his Response (Dkt. 39) and his Amended Complaint (Dkt. 47) that the Tegretol and Carbemazepine manufacturers have over-promoted the use of the drug to the Court:

> Novartis says of Tegretol that "it has been a widely prescribed medication used to prevent and control epileptic seizures, in addition to the treatment of certain types of chronic pain." Novartis says "types" which is plural and simply "chronic pain" as opposed to the one single type of neuralgia it is indicated for. Sun Defendants say, "Carbamazepine is an anticonvulsant also indicated to the treatment of neuralgia." This is nonspecific and could include any type of neuralgia (neuropathy). Torrent says, "Carbamazepine is an anticonvulsant that is used to treat seizures

> and nerve pain." This too is nonspecific and could include any type of nerve pain (neuropathy). (ROA.390)

If Defendants over-promote the drug to the Court, one would expect that they would over-promote the drug to doctors as well.

From the above it is clear that Plaintiff has provided facts related to Defendants' marketing of both drugs for indications not approved by the FDA. Plaintiff's §82.007(b)(3) rebuttal should be allowed by this Court.

VI. Leave to Amend,

A. Supervisory Powers of the Court. While the Fifth Circuit did not mention this issue, the District Court has again engaged in improper judicial proceedings and this Court should exercise its supervisory powers. The amendment was submitted in accordance with instruction provide by the District Court on their own website and is in line with prevailing precedents.

Plaintiff's First Amended Complaint for a Civil Case more appropriately stated his claims, made clarifications, appropriately added causes of action based on previously presented facts, and put all claims in one place which should have been beneficial to the Court and all litigants.

Federal Rule of Civil Procedure 15(a)(2) states in part, "The court should freely give leave when justice so requires." Generally, the rule "evinces a bias in favor of leave to amend," *Rosenzweig v. Azurix Corp.*, 332 F.3d 854,863 (5th Cir. 2003), and absent a significant reason, "such as undue delay,

bad faith, dilatory motive, or undue prejudice to the opposing party, 'the discretion of the district court is not broad enough to permit denial.'" *Martin's Herend Imports, Inc. v. Diamond & Gem Trading United States of Am. Co.*, 195 F.3d 765, 770 (5th Cir. 1999) (quoting *Dussouy v. Gulf Coast Inv. Corp.*, 660 F.2d 594, 598 (5th Cir. 1981)). Further, "the Court often looks warily at efforts to preempt an analysis of a new cause of action in the context of a dispositive motion by denying leave in the Rule 15(a) context on the basis of futility." *Barbour v. City of Forney*

The District Courts decision to deny Plaintiff leave to amend violates the entire preceding paragraph. The new DTPA claim should have gotten full analysis. Considering the Court's misstatements around Plaintiff's § 82.007(b)(3) rebuttal, admitting the amendment may have led to the acceptance of the rebuttal.

Plus the Court didn't consider its own role in the timing of the amendment. Plaintiff believed he could file an amended complaint at any time before Defendants answered the complaint based on answers to Frequently Asked Questions on the website for the United States District Court – Western District of Texas. On the website, the answer to the question "Can I amend my complaint without a motion?" is:

> No. You must file an original and one copy of the motion for leave to amend complaint with a copy of the proposed amended complaint with the U.S. District Clerk's Office in any case where the defendant has filed an answer. If no answer has been filed then you can file your

amended complaint without obtaining leave of the court.

While Defendants may have filed responsive pleadings, they have not answered the Complaint. Based on the information on the Court's website Plaintiff believed he could freely amend his Complaint until it was actually answered.

Additionally, the Court should have considered that with the Rules allowing for free amendment for a period of time after a motion to dismiss is filed, any amount of rework is already anticipated by the Rules. The timing in which Plaintiff had filed his Motion for Leave to Amend had not made that any worse. Plus, in their Responses to Plaintiff's Motion for Leave to Amend, each Defendant had in some form expressed that the Amended Complaint would not change their Motions to Dismiss. By their own admission, granting leave to amend does not prejudice the Defendants.

Plaintiff's motion for leave to amend should have been granted by the Court.

CONCLUSION

Petitioner respectfully requests that this Court grants certiorari.

Respectfully submitted,
/s/ Ramon D. Johnson, II
Ramon D. Johnson, II – Pro Se
9502 Vallecito Pass
San Antonio, TX 78250
(734) 320-8834
rdougjohnsonii@gmail.com