No. 20-1572

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 REHEARING THE DENIAL OF THE PETITION FOR WRIT OF CERTIORARI

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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.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Other

PETITION FOR REHEARING

Petitioner Ramon D. Johnson, II respectfully requests a rehearing on his Petition for Writ of Certiorari for the Supreme Court to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case.

STATEMENT OF THE CASE

A full statement of the facts and proceedings can be found in the original Petition for Writ of Certiorari. A brief recap will be provided here.

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.

In April, 2014, a Minocycline product from Ranbaxy Laboratories Limited (Ranbaxy) first caused Petitioner's Peyronie's Disease. The label for the Ranbaxy product was designed by Bausch Health US, L.L.C. (Bausch) for its brand name drug Minocin. Ranbaxy was later acquired by Sun Pharmaceutical Industries, Incorporated (Sun), but as part of that acquisition Sun was required to spin

off the Ranbaxy Minocycline to Torrent Pharma, Incorporated (Torrent).

In September, 2017, Petitioner PD was worsened by use of a Carbamazepine product from Taro Pharmaceuticals USA, Incorporated (Taro). The label for the Taro product was designed by Novartis Pharmaceuticals Corporation (Novartis) for its brand name drug Tegretol.

Neither the Minocycline product nor the Carbamazepine product 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. Prior to Petitioner's injuries there were previous reports of "penis disorder" for both drugs, and previous reports of "penile size reduced" for Carbamazepine.

In August, 2019, Petitioner finds evidence that substantiates that both drugs can cause PD. He then files 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. 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.

The District Court issued its Order on May 7, 2020 (see Pet., 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 denied Petitioner's motion for leave to amend his complaint as futile and unduly prejudicial to Defendants. (Plaintiff's First Amended Complaint for a Civil Case attempted to modify 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).)

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 Pet., 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. Respondents Disregard for Public Safety

It has been over two years since Petitioner notified all of the Respondents of his side effects and filed suit in this matter. The labels that are part of the drug products at issue in this case still do not list Peyronie's Disease, "penis disorder," or "penile size reduced" as side effects.

The Respondents here, and the industry as a whole, count on the courts to provide them cover and not hold them accountable for the injuries they cause. Since filing this lawsuit, Petitioner's doctors have tried to prescribe him five different blood pressure medications (Telmisartan, Irbesartan, Chlorthalidone, Metoprolol, and Spironolactone). Each of these drugs had some combination of Peyronie's Disease, penis disorder, penile size reduced, or other related conditions reported in the FDA Adverse Event Reporting System (FAERS) database. These side effects, however, were not listed in those drug labels either. The instant case is not an isolated incident of defective labels being distributed with drugs.

In the pleadings for this case, Respondents were presented with enough information to substantiate PD as a side effect of their respective medications. In the case of Minocycline, Bausch, Sun, and Torrent were presented Petitioner's development of PD, which included a retrial of the medication which brought back the pain associated with PD. They have been presented with the fact that Minocycline causes other forms of fibrosis, and PD is considered penile fibrosis. They have further

been informed that Minocycline increases TGF-beta levels, increased levels of TGF-beta are associated with PD, and injections of TGF-beta are actually used to induce PD in laboratory animals. They have also been informed of previous reports of "penis disorder" and "erectile dysfunction," which is a symptom of PD. In fact, there are several reports of "penis disorder" for other tetracyclines, which is relevant since the Minocyline label list side effects for tetracyclines in general.

In the case of Carbamazepine, Novartis and Taro have been presented Petitioner's development of PD, which included an elevated TGF-beta test while on the medication. They, too, were informed that Carbamazepine increases TGF-beta levels, increased levels of TGF-beta are associated with PD, and injections of TGF-beta are actually used to induce PD in laboratory animals. They were informed of a 1989 article linking Carbamazepine to PD and other autoimmune disorders, as well as the existence of websites saying medications can cause PD. Some of those websites specifically mention anti-seizure medicines, of which Carbamazepine is one. They were further notified of previous reports of "penis disorder" and "penile size reduced" (reports which even happened to have been made by Novartis themselves).

With all of this information, there is no good reason for any of the Respondents to not have taken action to protect the consumer over the past two years. They are required to do so by both federal and state laws. Out of fear that listing a new serious side effect would hurt their revenue and open them up to lawsuits, Respondents have chosen profits over the welfare of the consumer. This Court should hear this

case and not condone the United States Court of Appeal for the Fifth Circuit providing cover for big pharma. Failing to hear this case would further contribute to rising adverse events and rising deaths from pharmaceutical drugs, which, as indicated in the original petition, have respectively grown at rates of 50 and 68 times the rate of population growth.

II. Respondents Did Not Known of PD as a Side Effect to Their Respective Medications, but Should Have – *Mensing* is not Reached

Before the question of what a manufacturer can do about a newly discovered side effect, that manufacture must first actual discover that side effect. Based on the above information the Petitioner found and presented through pleadings, the all Respondents should have known of PD, "penis disorder," and "penile size reduced" as side effects to their medications. All of this information was available prior to the Petitioner's injuries. Respondents failed to do proper post marketing evaluations as required by the federal government.

All Respondents have failed to meet their State of Texas required duty to "take reasonable care to discover the dangerous propensities of the product" [see Starr v. Koppers Company, 398 S.W.2d 827, 830-831 (Tex. Civ. App. – San Antonio 1965, writ ref'd n.r.e.).] and are thus liable under Texas law. Because Respondents already failed in their duty to find the dangerous propensities of their products, there is no need to evaluate the performance of their other state law duties. The question in *Mensing* is, therefore, not reached.

In *Mensing*, the defendant generic drug manufacturers knew of the side effect at issue, and that its prevalence was underrepresented in the label. The *Mensing* plaintiffs said that because of this knowledge, the defendants should have updated their labels to comply with state law. Thus, the only question in *Mensing* was whether or not the defendants were able to update their labels without violating federal law. This question is premised on the defendants having knowledge of the side effect and its misrepresentation.

The instant case is differentiated from *Mensing* in that the Respondents did not know PD to be a side effect of their drugs, but should have. This case is further differentiated from *Mensing* in that the Petitioner does not state that the generic drug manufacturers should have changed the label and none of his claims are based on their ability to do so. *Mensing* and other rulings based on it are simply not appropriate precedents for this case. The Supreme Court should hear this case, as the claims presented are different than those in *Mensing* and *Mutual Pharmaceutical Co., Inc. v. Bartlett* 570 U.S. 472 (2013)

III. *Boechler, P.C. v. Commissioner of Internal Revenue* is Certainly Not More Impactful or Important than the Instant Case

This Court has recently granted certiorari in *Boechler, P.C. v. Commissioner of Internal Revenue* Case No. 20-1472. *Boechler* questions whether the 30-day time limit to file a petition for review in the Tax Court of a notice of determination from the Commissioner of Internal Revenue in Section

6330(d)(1) is a jurisdictional requirement or a claim-processing rule subject to equitable tolling. In its Petition (at page 23), *Boechler* quotes an annual report as saying, "Of the 27,844 collection due process hearings requested in 2020, 1,185 resulted in petitions to the Tax Court." Assuming 20 percent of those petitions are filed late, you have merely 237 people affected. Even if every single one of those petitions was late, less than 1,200 would be affected.

With respect to the instant case, the CDC reports that 48.6 percent of the US population took at least one prescription drug in a 30-day prior to being asked (https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm). So at roughly 50 percent, over 150,000,000 people are taking prescription drugs in a given 30-day period. Vastly more people are affected by the drug safety issues relevant to the instant case.

Further, while *Boechler* talks about a split between the circuits and conflict with Supreme Court precedent, the Petition for Writ of Certiorari in the instant case identifies a matter of first impression with differing opinions, a matter if first impression involving federal preemption, a question of federal preemption with differing opinions, a Constitutional question, and blatant misapplications of Texas laws by the Fifth Circuit that require the Supreme Court's intervention – including the Fifth Circuit's expansion of the Supreme Court's *Mensing* decision. This Court should hear this case, as it clearly meets the "compelling reasons" standard of Rule 10 of the Rules of the Supreme Court of the United States.

IV. Petitioner Should Not be Denied His Constitutional Rights Because of His Pro-Se Status

. It is clear in this case that the Respondents caused the Petitioner's injuries. Despite the evidence being available prior to Petitioner's injuries, all respondents failed to identify PD as a side effect. Since Respondents should have known of the side effect, their labels are considered defective under Texas law (see Section III.A.1 of Pet., Pages 18-20). Brand name manufacturers Novartis and Bausch designed the defective label. Generic manufacturers Taro, Sun, and Torrent distributed the defective label as part of their products. The defective label caused Petitioner's injuries.

This should be an open and shut case, but the district and appeals courts of the Fifth Circuit have trampled on Petitioner's US Constitution First Amendment right to seek redress for grievances and Petitioner's Texas Constitutional right to have remedy by due process of law (Tex. Const. Act I, §13). The Fifth Circuit has treated Petitioner more like a gnat to be shooed away. They have done so by ignoring Petitioner's arguments (at times, even appearing not to have read them), manufacturing barriers to filing suit that are not found in Texas laws as written, using improper precedents, and improperly expanding Supreme Court precedents. A more complete account of the Fifth Circuit's misdeeds can be found in the five "Supervisory Powers of the Court" sections in the original Petition for Writ of Certiorari. The Supreme Court's refusal to take up Petitioner's case condones the behavior of the Fifth Circuit courts.

Additionally, not taking up the instant case violates Petitioner's US Constitution Fourteenth Amendment rights. *Mensing* and *Bartlett* are only similar to the instant case in that they all involve generic drug products that caused side effects. *Mensing* was brought to this Court by pharmaceutical companies with plaintiffs' claiming that the companies failed to update their labels; the pharmaceutical companies were granted certiorari. *Bartlett* was then brought to this Court by a pharmaceutical company with a plaintiff claiming a design defect; again, the pharmaceutical company was granted certiorari. Now, pro-se Petitioner brings this case to the Court with claims of 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 (express and/or implied); Petitioner was denied certiorari.

Petitioner has been treated differently than pharmaceutical companies who bring similar cases in front of the Supreme Court, and has been denied his Constitutional right to equal protection of the laws under the Fourteenth Amendment. Just as the pharmaceutical companies were given the opportunity to be heard by the Court, Petitioner should be given that same opportunity.

CONCLUSION

While it is easy to look at this case as simply one man's issue with PD caused by pharmaceutical products, Petitioner can assure the Court that if it were just about him, he would have never advanced

this issue of such a sensitive nature to the courts. Petitioner is here *pro-se* representing the over 150,000,000 million people using prescription drugs at any given moment, the over 2,000,000 people a year reporting adverse events, and the nearly 60,000 people a year who die from prescriptions drugs. Petitioner also asks that the Court to consider that his pro-se status is a direct result of Fifth Circuit's pattern of not apply Texas laws as written in a fair and equitable manner.

Petitioner respectfully requests that this Court grants this Petition and, in conjunction with further review of Petitioner's original Petition for Writ of Certiorari, grants certiorari in this matter.

Respectfully submitted,
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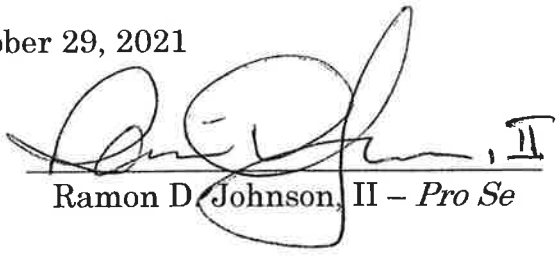
CERTIFICATION

I declare under penalty of perjury that the petition for rehearing is presented in good faith and not for delay.

Executed on October 29, 2021



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