

No. 17-6621

**In The
Supreme Court of the United States**

CARMEN NAOMI WATSON - PETITIONER

VS.

MYLAN PHARMACEUTICALS, MYLAN INC. - RESPONDENT(S)

**ON PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS FOR THE
TENTH CIRCUIT**

**REPLY TO OPPOSITION TO
PETITION FOR WRIT OF CERTIORARI**

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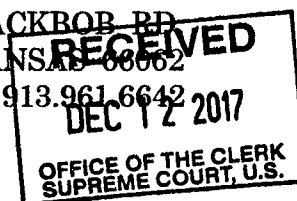


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INTRODUCTION

The petitioner respectfully wishes to respond to the opposing party's BIO", questions presented and concerns of the petition for writ of certiorari and whether the case should be heard before the United States Supreme Court.

Both parties question the theory of preemption in this matter pursuant to *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharmaceuticals Co. Inc., v. Bartlett*, , 133 S. Ct. 2466 (2013), and if the petitioner claims applied. The petitioner, consumed Mylan Pharmaceuticals generic drug Amnesteem, that later resulted in permanent injuries. Neither parties dispute the congestion nor injuries, what is unresolved is whether the petitioner was owed relief pursuant to her claims or if the respondent was rightly protected from any liability come *Pliva v. Mensing*., *Mutual Pharmaceuticals v. Bartlett* and was justifiably granted their motion to dismiss doc.(9,10), that un-notably converted to a motion for summary judgment as the respondent were the first party to present any evidence in the case. The petitioner's certiorari also ask the Supreme Court to make clear, if the court ordered summons states to be "served on" by a specific date, if the mailing of standard U.S. mail, the answer on the due date was in compliance or should the plaintiff had the right to entry for default, judgment. Also in question, is the honorable Judge Carlos Murguia, who formally was on counsel for the pharmaceutical companies and now holds

financial interest via stocks and bonds with the respondents partner company, had the duty to voluntarily recuse or grant the petitioner's motion for recusal.

I. THE CONFLICT AND CONFUSION OVER THE QUESTIONS PRESENTED

The source of confusion, one that was presented by both the petitioner and respondent, pursuant to *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and *Mutual Pharmaceuticals Co. Inc., v. Bartlett*, 133 S. Ct. 2466 (2013), did the respondents in this matter escape liability, from ALL claims by the petitioner for relief, when the respondent openly admitted on record to having failed in providing the petitioner warnings that were not revised as the brand maker come seven years later, and not providing some warnings at all.

The introduction of the respondent accuses the petition of showing no compelling reason as to why the case should be heard before the courts, and believes the matter is well-settled come *Mensing* and *Bartlett*. But has there been a matter where, the drug maker, generic or brand only provided some and not all of the required warnings and the courts deem the maker not liable, has there been a matter held in the U.S. Courts where the generic drug maker failed at both, updating its warning almost a decade later and leaving out other required warnings. Come now, the warnings the generic maker failed to include where not, a missing side-effect here or there, Mylan failed to provide critical, detailed requirements, a two-page warning

insert, and a medication guide booklet form, making the drug unreasonably safe and the warnings inadequate. There has not been a matter where, a Judge of the same Court states to construe the plaintiff's claim to be valid, one which may prevail, therefore ordering discoveries, to then have the opposing party blatantly refuse complying with the order even after their motion to stay discovery was denied, followed with the head Judge abruptly dismissing the case, disregarding the magistrates previous order, for reasons in his own words "has the authority to" for no other reason than the plaintiff was pro se`. In this case the honorable Judge Murguia went against the judicial canon codes and order signed by Chief Justice Lawton R. Nuss, dated September 6, 2016th titled "Rule 601B , Canon 2 Rule 2.6 Ensuring the Right to Be Heard". The lower courts strayed from the Federal Rules of Civil Procedure, depriving the petitioner the use of laws, rights, and standard processes on mere grounds of the inability to attain representation. This case is matter of great confusion and conflict that needs settling in the highest court.

The respondent does not give any examples as to how are why they are protected come *Mensing and Bartlett*. The respondent has only attempted to show compliance pursuant to the *Hatch-Waxman Act*, claiming they're warnings, the limited ones provided, were the same to the brand maker and were prohibited by law from changes. Henceforth the court had concluded in doc.(27), this matter would revolve around *Mensing* and

Bartlett, Pliva Inc., if the labeling and warning were updated and the sameness and not if the respondent could or couldn't change or add to labeling and warnings, pursuant to Hatch-Waxman Act. The resolution in doc.(27) simplified the petitioners various claim civil suit, and eliminated any unnecessary cost or burden for either party. Therefore lower court would now settle the claims for relief pursuant to, KPLA, Strict Liability, Strict Liability-Negligence..., for if the respondent failed to update the products warnings and or mirror the brand, or in the words of the petitioner "had full knowledge of many severe side-effects, and owed the consumer the right to be informed", the court stated the respondent would not be protected by preemption. The respondents motion to dismiss would not survive the petitioners Strict Liability, Strict Negligence, as the warnings were outdated and later discovered inadequate missing other warnings. The lower courts went back on that order, because the petitioning party was pro se. If the discovery was followed and filed as ordered only then, would the court have been adhering to Federal Rules of Civil Procedure, and only then given the discovery on record would follow with the amending of her claim, if necessary.

II.

In the respondents brief of opposition introduction, states " further, the petitioner did not assert any failure-to-update type of claim", this however contradicts their prior arguments see doc.(37 pg.2), states "indeed she has

been in fact claiming inadequate warnings all long”. If the petitioner in fact has been claiming inadequate warnings all long, failure-to-update would in fact be an inadequate warning, which in turn explains the order of the magistrate Judge to limit discoveries to the labeling and warnings on the Amnesteem product and therefore shows was no need to amend or convert the claim. The respondent had not attempted to dodge failure-to-update, nor inadequate warning claims until after the order of the Tenth Circuit that suggested the “language” in the affirmation order. The Tenth Circuit’s order conflicted with the respondents arguments even though the Judges ruled in favor, the order also conflicted with the Kansas District Judges as well.

III. REASON FOR GRANTING THE PETITION FOR WRIT OF CERTIORARI

Instructions to a pro se party on a filing form, is to refrain from making legal arguments, although the petitioner did not go into the legal language depth the respondents would prefer, does not show as to why the petitioner has failed to state a claim in which relief may be granted. Most importantly, this sort of confusion sheds light on, is how imperative the Federal Rules of Civil Procedure is, and how it must be followed, rather a party has or has no representation. In the case, the first scheduling and conference held between the court and both parties, clarified and brought forth legal arguments of the petitioner, the order that followed up,

simplified the case as to what was valid or invalid in the claim, that followed with the order of limited discoveries to show if there was any evidence of the defending party in or out of compliance. The discovery planning with the two parties showed the responding party non-compliance on many accounts, that lead to the respondent refusing to submit the plan to the courts "until Judge Carlos Murguia" made his ruling. It was no coincidence Judge Murguia closed the case on the very final day the respondents had to submit the order, the scheme was abrupt, disrupted the flow of standard procedures, and caught the pro se party off-guard, clueless to what steps may be taken, seeming as the rules of civil proceedings were not as described. It was unjust for Judge Murguia to abruptly dismiss, it was unjust for Judge Murguia to allow the respondents the refusal of filing discoveries knowing they had been ordered twice to do so by the courts. From the beginning of the case Judge Murguia was aware of his obligation to voluntarily recuse being involved financially with the respondents partnering company, overseeing the defending counsels interns, and standing as counsel in similar matters. If it is not Judge Carlos Murguia's background showing his ruling on the case would be bias and prejudice, his actions in the case proved he had no intention on a fair pre-trial or trial regarding the petitioner. The respondent and court orders have refused to acknowledge any of the "factual basis" regarding the recusal of Judge Murguia, the petitioner have presented actual financial

disclosure filed by Judge Murguia, having interest and stock with the respondents partnering company for many years, and although Judge Murguia practiced in his own private law firm (Salazar), the fact remains he still was on counsel.

The respondents opposition brief constantly refers to the petitioner as bringing forth only state laws that have been rejected to overshadow her claims under Strict(tort) law which is Federal laws. The respondent could have complied with both State and Federal yet failed both, as in any state seven years later and still not having the warnings revised violates both, to provide warning inserts and medication-guides to only some consumers and not others, fail both Federal laws and any State laws.

The opposition brief is nothing more than a tornado of smoke, attempting to cloud the petitioners validity, repeating the same concern in different wording and attempt's to test the intelligence of the United States Supreme Court. Points in the opposition such as (A), "finally...the lower courts resolution to the petitioners motion to recuse was a factual determination and does not present issue warranting the Supreme Court review", this statement shows or tells no reasons as to why the motion was justifiably denied. When referencing the Sixth Circuit Courts exception to preemption for failure-to-update, the opposition brief pg.(5) states, "that exception would not apply here; It is not sufficient to simply assert that

Mylan failed to update its label to proceed on a brand new failure-to-update claim”, in this case the petitioner did not “simply assert Mylan failed to update its label”, this was a proven fact with evidence presented by the respondent themselves. Mylan had a revised label see doc.(9,10) exhibits for the year 2012, yet provided the petitioner with packaging dating for year 2007 see doc.(11,14). The respondent continually makes efforts to grasp to the petitioner mentioning the “stop-selling” idea, but in the claim by petitioner states, Mylan was aware of the drugs severe effects and permanent injuries and continued their drug on the market, concealing the information, she further then states, Mylan did not inform the consumer i.e. the petitioner with the same knowledge they were aware of and therefore making the drug unreasonably dangerous, hence providing an inadequate warning. The opposing party ventures to the constant defense, as if the petitioner made unlawful request, such as a “dear doctor letter”, this had not been of any mention until the order see doc.(28), by Judge Murguia, who wrote he believed the petitioner had been suggesting for one. The belief of the judge’ was a far-fetched assumption, the petitioner was fully aware a “dear doctor letter” had been required for the drug years prior, however the FDA deemed insufficient, claiming the “dear doctor letter” was not a strong enough warning. The only thing the petitioner would request at the time were “extra warnings”, or “precaution warning” ones that listed all the drugs side-effects that were offered by the brand-maker. The petitioner believed the package warnings, and blister

Mylan failed to update its label to proceed on a brand new failure-to-update claim. In this case the petitioner did not simply assert Mylan failed to update its label, this was a proven fact with evidence presented by the respondent themselves. Mylan had a revised label see doc(9,10) exhibits for the year 2012 yet provided the petitioner with packaging dating for year 2007 see doc(11,14). The respondent continually makes efforts to grasp to the petitioner mentioning the "stop-selling" idea, but in the claim by petitioner states, Mylan was aware of the drugs severe effects and permanent injuries and continued their drug on the market, concealing the information, and further then states, Mylan did not inform the consumer in the petitioner with the same knowledge they were aware of and therefore making the drug unreasonably dangerous, hence providing an inadequate warning. The opposing party ventures to the court defense, as if the petitioner made unlawful request, such as a "dear doctor letter". This had not been of any mention until the order see doc(28), by Judge Marginal, who wrote he believed the petitioner had been suggesting for one. The belief of the judge was a far fetched assumption, the petitioner was fully aware a "dear doctor letter" had been required for the drug years prior, however the FDA deemed insufficient, claiming the "dear doctor letter" was not a strong enough warning. The only thing the petitioner would request at the time were "extra warnings", or "prescription warning" ones that listed all the drugs side-effects that were offered by the brand-maker. The petitioner believed the package warnings, and blister

pak warnings dated for 2007, were the only warnings, therefore referencing the med-guide, and warning insert as "extra precautions". It was not until later in discoveries, the petitioner learned the product was required to have these warnings and providing them wouldn't be "extra". The respondents insinuate to the courts, they were prohibited from offering "extra precautions" and warnings as if they provided all required, and this is not the case. The Amnesteem product is required by Federal laws to contain warnings on the package, warnings on the blister pak which holds the medication, a warning insert and medication guide. The only time the opposing party would have been prohibited by state or federal laws to give further warnings is if, they gave the petitioner the warnings were each one was required and then added to them. Mylan states in BIO"pg.(4) the petitioner did not imply alleged facts how the outdated packaging resulted in her injuries, but how could one go beyond an allegation to determine a fact, without having discoveries, evidence, or statements of professionals in the field of injuries claimed. Opposition brief pg.(5) states " the petitioner argues that it was error to dismiss her claims after the magistrate Judge found limited discovery would be allowed", but never states as to why the courts did not error, particularly in the discovery process that was abruptly interrupted and saved the respondents from submission of evidence showing them liable.

RESOLUTION OF RECUSAL AND FINAL JUDGEMENT

Respondents state in the opposing brief pg.(6B), whether the petitioner offered sufficient fact to support judicial bias is "Not Properly Reviewed" by the Supreme Court, further stating "It is not the Role" of the Supreme Court. Thus statements along with numerous throughout the respondent's brief, show only indications as to why the Supreme Court shall review the case. The respondent's entitlement and opinion as to what role the Supreme Court has the capability to properly review should not be left up to them. The responding party has provided no valid defense to any claim and presented exhibits that only show they possessed a copy of a revised warnings, that did not match the petitioners'. Mylan's continuous statement, "the petitioner does not have "factual allegations", with respect to whatever the theory means, doesn't or shouldn't be grounds to hold no liability for their errors that's possible fatal to some. If the respondent or courts needs more than "factual allegations", then its only right to allow her to provide proof even beyond the actual prescription shown in her exhibits that treats every injury she alleged. When the petitioner did however present evidence upfront such as, financial disclosures, bio's, ect.. in her motion for recusal, because the ruling was granted in their favor the respondent, refers to and ask the courts to trust the order as a "factual determination". Its of the obvious the petitioner was deprived from her Constitutional rights, rights as a consumer, and fairness by the courts. The respondent listed six cases in the table of authorities, yet not one case has

the petitioner pro se, granted the motion to discoveries but never allowed to proceed, had the case abruptly dismissed for the reasoning the plaintiff was "pro se", the opposing party disobeying the magistrates order, and finally admitting on record "some just don't get them" when referencing the required warnings for the product. The respondent is also on record, recordings advising on more than 2 occasions the petitioner to submit for a settlement offer, then falsely petitions to the 16th Judicial of Jackson County Court for a ex part`, using discoveries and evidence from the case as evidence and swearing the petitioner has been harassing the respondent demanding a settlement beginning January 16th , 2017, see Missouri Case 1716-FC09149. The petitioner has maintained dignity and honesty and would not jeopardize a fair chance before the courts. The petitioner has stated and given facts in her petition for writ of certiorari as to why she appeals the entire final order of doc.(28) and affirmation of the lower courts, that included the denial of the default judgment which the judge included in the same order. Every court and judge seemingly has its own interpretation of "serve on", this issue arisen when the petitioner requested for default judgment, and was not allowed the entry for default, and denied the request. The Federal Court stated, she was denied because the respondent had served the local court the day of the deadline electronically, the Tenth Circuit affirmed, stating the respondent had "placed in the mail" for standard U.S. Postal Service on the final day. However both would still conflict and not comply to the court ordered

subpoena, as it specifically states “answer must be served on” no later than the date listed of July 26, 2016. In essence the respondent made the attempt on the final day to ensure via electronic service, the court received its answer, that started the deadline clock for the pro se petitioner to file a response, but made no effort to serve the answer on the petitioner in a timely manner. The respondent is aware of the local rules and laws, and is aware if, even the sheriff is to “serve” a party via first-class mail the answer is not considered served until three days after mailing. The respondent allegedly placed the answer to the petitioner in standard U.S. Mail on the due-date, so when shall that answer be considered served? The High Court should clarify the different interpretations between the lower courts.

Whether there have a multitude of contradicting statements and orders throughout the case, the decision for the Supreme Court is paramount. The Supreme Court ruling in this particular matter, brings clarity to the consumer, as to, when purchasing and consuming a generic drug, should the consumer rely only on the generic’s interpretation of the warnings, trusting the generic drug maker has disclosed all information received from the brand-maker, or does the consumer have the responsibility after purchasing the generic to due diligence of the products originator before consuming. The Supreme Court hearing and ruling on this case would also give an invaluable clarity of allowance or tolerance the U.S. courts will have with generic drug makers. Will that allowance present to generic makers,

although the generic drug is widely protected under an umbrella of laws in the United States Courts, non-compliance will impose liability if the generic maker shall not adhere to the very limited compliance procedures or present to all, the generic drug-maker holds no liability regardless of known and uncorrected errors and the U.S. consumer remains a "buyer beware".

CONCLUSION

The petition for writ of certiorari pertains questions that have not been addressed by the High Court, and will continually be ruled with inconsistency at the discretion of each lower court's interpretation, it is in the best interest of U.S. and the peoples of the court to grant the petition for review.

*Respectfully Submitted,
Carmen Naomi Watson
December 7th, 2017*

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VS.

MYLAN PHARMACEUTICALS, MYLAN INC. - RESPONDENT(S)

**REPLY TO OPPOSITION TO
PETITION FOR WRIT OF CERTIORARI**

CERTIFICATE OF COMPLIANCE

As required by the Supreme Court rule 33, I certify that the Reply to Opposition for writ of Certiorari contains 2360 words, not including the parts that of the reply brief that are exempt by the Supreme Court Rule 33.I(d).

I declare under penalty of perjury that the forgoing is true and correct.

Carmen Naomi Watson
December 7th, 2017