UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
WEST PALM BEACH DIVISION

CASE NO. 20-md-02924-ROSENBERG

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION.

West Palm Beach, FL
June 7, 2021

MOTION to DISMISS PROCEEDINGS (through Zoom)
BEFORE THE HONORABLE ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE and

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THE COURT: Okay, good afternoon, everyone. We are here resuming the hearings in the Zantac Products Liability Litigation, MDL number 2924. We are continuing with some additional questions and answers with respect to the generic Defendants' Rule 12 Motion to Dismiss on the ground of preemption and incorporated memorandum of law, and that is ar Docket Entry 3105.

I will ask all counsel who are arguing that motion and engaging in the question and answer to put your video and audio on.

Good afternoon, everyone, I hope you are all well. I hope you had a really restful, relaxing weekend and you are back. So, just to follow up -- and I do appreciate your making yourselves available for a followup day of questions with respect to the motion.

Mr. Keller, on behalf of the Plaintiffs, you said on Friday that shorter expiration dates would warn Plaintiffs "not to consume a product" after a certain date.

The risk that you have alleged in the complaint, though, is a cancer risk, and you allege that all generic manufacturers knew of the cancer risk.

How is the duty, a duty to provide an adequate warning of a products risk or danger satisfied by an expiration date when the risk is a cancer risk? Isn't the warning that the state law requires different than a warning not to consume the

product?

MR. KELLER: Ashley Keller for the Plaintiffs, your Honor, and as Ms. Stipes is probably aware, I am the only one speaking for Plaintiff, so if I forget to reintroduce myself, it is Ashley Keller every time on behalf of the Plaintiffs.

No, is the answer to your Honor's question. The duty would be fully satisfied because a manufacturer, behaving as a reasonably prudent manufacturer would, must have an accurate expiration date.

When you think about expiration dates for drug products, or for any other product, there is typically not a warning that provides an explanation to consumers as to why the expiration date is set as it is.

Milk is the most common example, and it is an example we use in our papers. When a dairy farmer puts the expiration date on a carton of milk, it doesn't further explain if you take it after this date the milk might be sour, the following bacteria are likely to grow in the milk which would be dangerous to you once ingested into your stomach. It simply says this is the expiration date for the milk, and that tells a reasonably prudent consumer don't take the product after this date.

So, that is what we are alleging with respect to the expiration date theory of negligence. It is true that separately, under state law and behaving as a reasonably

prudent manufacturer would, state law would impose a duty also to warn about cancer risk, but only the brands could satisfy that duty. We fully acknowledge that the generics could not.

But the expiration date does provide an important warning to consumers, it is an important warning that state law demanded the generics provide, and it is a state law duty we allege they breached.

THE COURT: You allege the same state law that you argue imposes one duty on the brand and a separate and/or different duty as to the generic.

How do you support a proposition that a duty under a state law, a state law duty can require one thing of one type of manufacturer, and that very same state law duty requires something that is different from a different manufacturer?

MR. KELLER: That is a very good question.

THE COURT: Same law, same duty.

MR. KELLER: A couple of different points because this is a really important area to focus on. First, we allege the duty to have an accurate expiration date for both types of manufacturer Defendants, so it is not just the generics.

THE COURT: I acknowledge that, yes.

MR. KELLER: Second, and I think this is the actual heart of your question, and it goes back to something we were talking about on Friday, the duty under most states' law stated at a very high level of generality -- let's take negligence,

for example -- is behave as a reasonably prudent manufacturer would under the circumstances. That is going to impose a lot of sub duties.

During my relaxing weekend, I spent some time on WestLaw just to confirm that what I said to your Honor on Friday was accurate, and it was. It is totally commonplace in jury instructions for judges to say the Plaintiffs have alleged five theories of negligence, or sometimes the law refers to that as five specifications of negligence. That is just an older term for the same concept, five theories of negligence.

And it is really five theories of breach, they did one, two, three, four, and five, and the instructions will typically say you only have to find one breach in order to find that the Plaintiff can recover and that the Defendant is liable. The Plaintiffs don't have to run the table, they only need to win one.

The law of the state is the same for all Defendants. Brands and generics both have a duty under Alabama law, for example, to add a cancer warning. The issue is, Federal preemption says generics can't do that. The duty of sameness articulated in Mensing says that specification of negligence, that theory of negligence, though it exists under state law, cannot be applied because of Article VI, clause 2 of the supremacy clause to the generics.

So, while the law of Alabama is the same for both

generics and brands, we acknowledge that that particular theory can't be asserted legally against the generics. In my research on WestLaw once again confirming our conversation from Friday where I said to your Honor, look at Bates where limiting instructions are articulated as a basis to ensure there is no prejudice and that generics wouldn't be held liable for a preempted theory, that is also completely commonplace.

I am happy that I predicted off the cuff the actual practice for State Court jury instructions. Juries are regularly instructed, the state law requires these five things, but because of Federal preemption, the following two things are off the board. I am instructing you as a matter of law, ladies and gentlemen of the jury, you cannot return a verdict for Plaintiff on theories A and B, it has to be the other theories.

I know that was a long-winded answer to your question, but we don't think there is any difference in state law between the brands and the generics, but because of Federal law, we have a narrower path that we have to walk against the generic manufacturers.

THE COURT: Okay. I understand what you are saying as to the brands and the generics.

You began your analysis with, to some extent, let's look at Federal law, let's look at Federal preemption, it tells us what one of the manufacturers can't do. So, it sounds like in a way you are then asking the Court to redefine what the

duty is based on what the manufacturer can't do because of Federal preemption, as opposed to beginning with looking at the duty that the state law requires and asking, can the manufacturer, in this case the generic, fulfill the duty, and in answering that question one would look to the Federal law to see whether any aspect of the Federal law preempts the state law duty.

So, it is kind of what do you look at first, and I am interested in what -- I will hear from the Defense on this as well, but it is sort of the analysis that one undertakes in going through impossibility preemption. The Mensing Court, for example, looked at the duty first to provide a safe label, and then considered that in the context of the Federal regulatory scheme as it applies to generics.

Now, it is true that the Court explored different avenues, notifying the FDA, could dear doctor letters suffice, but the Court began by looking at what is the duty.

In fact, the Court was so clear about it, in fact, I think the Court even used the word "clear", but at one point the Court says, "To summarize, the relevant state and Federal requirements are these, state tort law places a duty directly on all drug manufacturers to adequately and safely label their products."

Taking Mensing and Demahey's allegations as true, state law imposed on the manufacturers a duty to attach a safer

label to their generic product, in this case, for purposes of spelling it is M-E-T-O-C-L-O-P-R-A-M-I-D-E.

Another part of the opinion, "We find impossibility here. It was not unlawful under Federal law for the manufacturers to do what state law required of them, and even if they had fulfilled their Federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law."

And the Court acknowledged that the brand and generic manufacturers had different Federal drug labeling duties, and that is based on the statutory scheme. The brands are responsible for accuracy and adequacy, the manufacturers have the duty of sameness.

Let me just see if there was one other provision.

Similarly, in that complaint in Mensing, the Court acknowledged that the Plaintiffs pled that the manufacturers knew or should have known that their labels did not adequately warn of that risk. As we know from your complaint, the Plaintiffs' complaint, the knowledge that the generics are said to have, or alleged to have is are the same, you can correct me if I am wrong, as the knowledge that the brands are alleged to have.

So, as in Mensing, the generics in our case allegedly have the very same knowledge about the risk of the product, of the drug, the inadequacy of the warning, and the Court

acknowledging that the duty is to ensure an adequate and safe label. So --

MR. KELLER: Yes, your Honor.

THE COURT: -- consistent with the preemption analysis in Mensing, how do we get to where your argument lies?

MR. KELLER: Very good, your Honor. We completely agree with the Supreme Court's decision in Mensing.

First, I want to talk about the knowledge allegations. You are not wrong, we do allege that the generic manufacturers had the same knowledge as the brand manufacturers, and if they didn't, they should have had that knowledge. They are charged as being experts in the field.

Knowledge is not one of the requirements to which the Supreme Court referred in Mensing. Knowledge is not the breach of duty. Knowledge is relevant to the elements of our claims. You can't change an expiration date or have reasonably prudent storage and transport conditions, or an appropriate packaging protocol if you don't know how your product works.

So, our knowledge allegations, we think, are very appropriately included in the complaint, but that is not what Mensing or preemption is referring to.

We also agree with Mensing that you start with the duty under state law. You start with -- to quote the language that your Honor just referenced -- the requirements, but state law imposes multiple different requirements on manufacturers of

products, a requirement to have an accurate expiration date, the breach of which would be a breach of duty under, for example, negligence where the elements are duty, breach, causation and damages, a requirement to properly store and transport your drug, a requirement to put it in proper packaging, and yes, a requirement to warn about cancer.

All of those are requirements, you start with those, then you look at Federal law and say which of these requirements are impossible to square with the Federal regulatory landscape. For the brands, none of those requirements are impossible to square with the Federal regulatory landscape, so all of them can proceed.

For the generics, the cancer warning, that requirement is impossible to square with the duty of sameness, but the expiration date requirement isn't. In fact, the very same regulation that Mensing is talking about is the one that articulates that expiration dates are an exception to the duty of sameness.

So, we completely agree you start with the duty or the requirement. I think those are synonyms for the same concept. But you do it at a granular level, and the reason you do it at a granular level, or provision-by-provision, to quote the Eleventh Circuit in Paco (phon), is because we are not redefining any of the elements of the cause of action.

As I just referenced before, jury instructions in

State Court routinely say if you have breached any of your duties that are imposed by the common law of negligence, any one breach is enough to support a Plaintiff verdict.

So, they can't point to the fact that they were unable to meet the requirement to add a cancer warning to say that is a get out of jail free card for breaching the requirement to have an accurate expiration date. Any breach of duty under the common law is enough to return a negligence verdict for the Plaintiff.

THE COURT: Well, with the negligent failure to warn, for example Alabama, paragraph 1180 -- our light just went off in this courtroom.

MR. KELLER: I can still see you, your Honor.

THE COURT: We had to move to a different courtroom today because somebody is using our other one.

Under Alabama law, a manufacturer has a duty of reasonable care to provide an adequate warning to consumers of a product's danger when used in its intended manner.

How are you arguing that changing an expiration date fulfills the generic manufacturers' duty of reasonable care to provide an adequate warning to consumers of a product's danger when you have acknowledged at the hearing on Friday that the expiration date isn't a warning of a product's danger, it is, at best, a warning not to consume?

MR. KELLER: I respectfully disagree with your Honor's

characterization. I do think it is a warning of the product's danger. It is not a specific danger.

THE COURT: That is not what you said on -- I don't believe that is what you said at the hearing on Friday.

MR. KELLER: I do have the transcript from Friday, but I don't have that exchange. If I was imprecise, let me try and be more precise.

I do not think it is a specific warning of cancer, it obviously isn't that, but I do think it is a warning of danger. It is saying there is a risk if you consume it after this date. It is not telling you what the risk is, it is not being specific.

I think if you took a survey, which is obviously not the subject of a 12(b)(6), it is a fact question, almost every consumer would say they don't consume products past their expiration date, they would know to stop taking it because something could go wrong. They can't articulate that something and that is not required. The common law is usually operating at a pretty high level of generality.

So, I do think that an expiration date is a warning of danger. It is not as specific as we would like and the brands have a duty to be more specific, and they can comply with that requirement under both state and Federal law.

I think an expiration date would go a long way to alerting generic consumers of the dangers associated with

Ranitidine, and the fact that the word "cancer" doesn't appear with the dating digits is neither here nor there for purposes of the state requirement at issue in these counts.

Your Honor, if I could just add, even if you didn't consider it a warning of danger, it would be very easy to say, under the reasonably prudent man or woman standard, a manufacturer obviously has a duty to have an accurate expiration date. If they are putting an expiration date on the product, it has to be accurate.

So, I think it counts as a warning, the expiration date, but even if you didn't, the expiration date would still support a breach of a state requirement that isn't preempted or inconsistent with Federal law.

THE COURT: Well, at page 40 of the transcript from the Friday hearing you say, "As I said before, I don't think that an expiration date is itself a warning about cancer, it is a warning when a consumer should not continue to take the product."

MR. KELLER: And I stand by that. I hope there wasn't an inconsistency, but I think that is what I said this afternoon as well.

THE COURT: You went on to say, "But the expiration date itself is just a warning to a consumer not to consume a product."

MR. KELLER: Correct.

THE COURT: That goes back to my question of how, then, does a generic meet the duty under Alabama law to provide an adequate warning to consumers of a product's danger?

MR. KELLER: I think, even though it is not providing a cancer warning, it is not using the word "cancer," it is alerting consumers that there is danger if they consume it after the proper expiration date.

So, though it is not as specific a warning as would be possible under state law, it is still a warning of danger, and a reasonable manufacturer would provide a reasonable expiration date, and we, I think, plead the allegations that, if accepted as true, demonstrate the generics didn't do that.

THE COURT: So, is it your position that a shorter expiration date would satisfy the state law duty to warn?

MR. KELLER: Yes, your Honor.

THE COURT: And from the Defense, would an expiration date satisfy the state law duty to warn; and if yes, why? If no, why?

MR. YOO: Thank you, your Honor, Thomas Yoo for the generics.

An expiration date would not satisfy the alleged state law duty to warn. As the Court has already pointed out, the duty, as articulated by the Plaintiffs and as referenced in the authority submitted by the Plaintiffs, is a broad duty to act reasonably to provide an adequate warning of the risk of the

product's danger.

Here, that alleged risk is cancer and exposure to NDMA, and notwithstanding the exchange with the Court just now, I think the Plaintiffs are quite clear in both their papers and statements on the record during the hearing that they concede an expiration date is not a cancer warning.

Again, not to sound repetitive, but the touchstone is not what could a Defendant have done to mitigate some of the risk, it is what must a Defendant have done to avoid liability altogether.

So, an expiration date, a new a set of four to six digits, is not a cancer warning, I think the Plaintiffs concede that, nor is there any plausible way to see how a new set of digits would warn consumers about the alleged risk of cancer from using Ranitidine.

In this sense, I don't think it is very different from the milk analogy in that when we look at an expiration date on a carton of milk, people think different things. Some people may think it may result in something like an upset stomach, but no one looking at a set of dates would assume that there was a clinical risk of a serious adverse event associated with the expiration date.

Same thing with Ranitidine. Absent instructions and an actual clinical warning about the risk of cancer, no consumer, or even physician, would look at an expiration date

and assume that if they don't use it before the expiration period, that the patient is going to be exposed to a risk of cancer.

I think the Plaintiffs' amended complaints bear that out where they make it quite explicit that the alleged duty on the generics is to not only provide an expiration date, a different expiration date, but to provide instructions and a warning of cancer such that consumers and physicians are made aware of this alleged risk of cancer that the generics supposedly have known all along and failed to disclose.

So, an expiration date is absolutely not a cancer warning and would not be sufficient to satisfy the state law duty.

I would also add, your Honor, that the allegation regarding an expiration date is fundamentally irreconcilable with the Plaintiffs' claim as to why Ranitidine is defective.

An expiration date would not matter at all but for the Plaintiffs' allegation that Ranitidine degrades into NDMA, and does so not only under normal storage conditions, but simply by being ingested and digested in the human body.

So, it matters not that the Plaintiffs say they believe a better expiration period would have been two months because they are still alleging that that Ranitidine still degrades into NDMA when consumed.

THE COURT: Let me ask you a question. What do you

think provides the contours of the duty imposed upon the manufacturer, the generic manufacturer in this instance -- when you are talking about negligence, negligence failure to warn or general negligence, it is very broad. There are probably many things that a manufacturer can do just in any ordinary business. A storekeeper could do many things in the store to keep the store safe.

How do you suggest that the analysis is to be undertaken to determine the breadth of obligations that the generic manufacturer has under a -- whether it be a general negligence theory or a negligent failure to warn?

Is it every single thing that could possibly be done, and if a generic manufacturer couldn't do but one of those things, it couldn't comply with state law duty because one of those things, perhaps, is preempted? Or do you go about defining the contours of the analysis for what a duty is, and therefore what obligations a generic manufacturer has, in a different way?

MR. YOO: I assume that is for me, your Honor?

THE COURT: Yes.

MR. YOO: Thank you, Thomas Yoo again for the generics.

I think the analysis is much more straightforward than that, as the Supreme Court instructs in Bartlett and did in the Mensing decision, and that is to look at what it is the

generics would have to do in order to avoid liability altogether.

If that, according to the Plaintiffs, one thing, you look at one thing. If it is three things, then you would have to satisfy all three things. If any one of the three things is not possible because of the strictures of Federal law, then the entire claim is preempted.

THE COURT: Okay. So, if Plaintiffs are saying that they are alleging that the manufacturers only had to do three things to ensure that the product was safe, three things that they could do, does that define the duty for the generics?

MR. YOO: Well, your Honor, instead of looking at it purely abstractly, what the Plaintiffs have alleged here is that there are things that the generics could have done to reduce any additive risk related to a container or an expiration date.

But what they continue to embrace is the primary allegation that all of those things are relevant because of the inherent defect of Ranitidine.

And so, when those things matter, according to the Plaintiffs, because all Ranitidine is defective and all Ranitidine, no matter how you handle it, and as soon as you put it in your body turns into a carcinogen, then you would have to take care of all of those issues in order to avoid liability.

That is the point that we are trying to make, your

Honor, and that is why all of these claims are preempted under Mensing and Bartlett.

This is not a case of simply some handling practice resulting in some risk that otherwise Plaintiffs say would not be present.

This is the Plaintiff saying there is a unique molecule here that becomes a carcinogen in the body, and everyone who handled it, made it, sold it is liable, including the generics, and on top of that, we think there are a couple of additional things that we can pin on the generics. It doesn't matter whether those additional things could have been satisfied or not when doing those things wouldn't allow the generics to avoid liability.

The Plaintiffs would not concede, your Honor, that a Ranitidine product manufactured by a generic with a two-month expiration date would not degrade into NDMA in the human body. To the contrary, they say the opposite.

So, it is still has in tow as a necessary part of the claim the design of the product, and ultimately, the lack of a cancer warning, and that is what makes this preempted.

THE COURT: If they were at trial and they were limited to arguing the manufacturers were -- the generic manufacturers were negligent, and the only way in which they were negligent was failing to have a proper expiration date, and ladies and gentlemen, as you can see, the evidence shows

that the expiration date can cause someone to ingest more NDMA than they otherwise would and that then causes cancer, and the jury instruction is the standard jury instruction on negligence, negligent failure to warn, ladies and gentlemen, if you find that the generic manufacturer expiration date that was on the label caused the Plaintiffs to ingest more NDMA and that caused cancer, then you may find the generic manufacturer negligent.

So, the Ranitidine molecular composition isn't being argued as the basis for negligence, design isn't being argued, the cancer warning. It is, ladies and gentlemen, in order to find the generic manufacture negligent, or having negligently failed to warn, you may do so only if you find that the expiration date was inappropriate, was too long.

MR. YOO: Thank you, your Honor, Thomas Yoo again for the generics.

That would not be their argument, your Honor, because the argument would have to be, you would find the generics negligent because of an incorrect expiration date because Ranitidine is a drug that forms NDMA, because Ranitidine happens to be a molecule that degrades into the components of NDMA and forms NDMA in the body.

That is just the nature of Ranitidine as the Plaintiffs allege. So, the generics would still be penalized for making the drug they were required to make under the ANDA

approved by the FDA.

Put another way, your Honor, in your discussion with Mr. Keller, I believe he articulated what the Plaintiffs view of the duty is on the generics as what a reasonably prudent manufacturer would have done, but the second half of that equation is, given that Ranitidine degrades into NDMA, and there is an increased risk of cancer.

And there is a reason, your Honor, why in the decade of jurisprudence since Mensing no Court has recognized an expiration date exception or a container exception to Mensing preemption because Plaintiffs, at the pleading stage, could easily add such allegation to any pharmaceutical product liability case.

Whether it is tardive dyskinesia in Mensing or myocardial infarction and stroke or a birth defect, they could take some alleged inherent clinical risk of a drug, and then in order to bring in the generics industry, add a cause of action that says at the pleading stage, we believe that an incorrect expiration date or the failure to use blister packs may have contributed to this risk.

That is not how the law works, and no Court has done that.

THE COURT: I am not sure these arguments have been made before. I don't disagree that there have been no cases that we could find where, since Mensing, a claim has been made

that survived preemption against a generic, but then again, I also haven't seen a case, and no one has brought to my attention, where such arguments are being made or such theories of liability are being put forth.

Let me continue, and if there is anything to add, I will allow the parties to do so.

I asked the question would a shorter expiration date satisfy a state law duty to warn. The Plaintiffs said yes, Defense said no. I want to complete the question as to the other two claims.

For the Plaintiff, would changing the product container satisfy the state law duty of reasonable care; yes or no?

MR. KELLER: Yes.

THE COURT: From the Defense?

MR. YOO: No, your Honor, for the same reasons we have discussed.

THE COURT: I am assuming the same answer for would changing the storage and transportation conditions satisfy the state law duty of reasonable care. From the Plaintiff?

MR. KELLER: Yes, your Honor.

THE COURT: From the Defense.

MR. YOO: No, your Honor, for the same reasons.

THE COURT: Plaintiffs, if a shorter expiration date helps, but doesn't fully satisfy the state law duty, wouldn't

the entire state law cause of action, a cause of action for failure to warn, be preempted?

MR. KELLER: I am sorry, your Honor, could you repeat your question? I want to make sure I heard it right.

THE COURT: If a shorter expiration date helps, but doesn't fully satisfy the state law duty, wouldn't the entire state law cause of action, that is the cause of action for failure to warn, be preempted?

MR. KELLER: No, your Honor, it wouldn't be preempted. It might fail under state causation principles, which would be something the Court could address when the question of fact and causation was presented.

Many states have complicated causation law, particularly in the area of exposure to carcinogens, and so it is possible under many state laws that if it would have helped and reduced the amount of NDMA exposure below a certain level, even if there was still a lot of NDMA that the Plaintiff was exposed to, causation could be legally established.

That is a tricky question on causation. I don't think it is tricky on preemption because, as your Honor previously remarked, preemption is about comparing duties or requirements, and if the duty that we are alleging they breached is to have a proper expiration date, and the premise of your Honor's question is the expiration date they actually had was improper because a shorter one would have helped, then we have already

established a breach of duty, and that is the only focus of the preemption inquiry.

THE COURT: Where do you allege in the complaint, just an example of either the expiration date or the container or the storage and transportation, that that failure to have a proper expiration date or a proper storage condition or a proper container caused, not contributed to, or didn't mitigate, or didn't in some way impact the volume of consumption, and therefore the harm, but actually was the cause of the ingestion of NDMA and/or the cause -- that led to the cause of cancer?

I know you said it on Friday, you used the word legally sufficient. Where in your complaint do you allege that for any one of those claims?

MR. KELLER: Sure, your Honor. The complaint is actually replete with those allegations. We have always been picking on Alabama because they have the perils of being first in the alphabet.

Since I have it handy, paragraph 1182, for example: Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did and would not have been harmed by NDMA.

That is the factual allegation that we are making and you can see that throughout the sub counts. There is a

causation type paragraph associated with all of the expiration date claims and all of the packaging claims and all of the storage and transport claims. Ultimately, of course, we will have to prove that, but for purposes of a 12(b)(6), that factual allegation has to be accepted as true.

THE COURT: Thank you.

MR. YOO: Your Honor, would you like me to respond on that point?

THE COURT: Sure.

MR. YOO: Thank you. Thomas Yoo for the generics.

The Plaintiffs actually not only have not alleged that changing the expiration date or using a different container would have allowed the generics to avoid liability or prevented a harm; to the contrary, they lumped those things into all of the other things we have been talking about premised on the inherent risk of Ranitidine to turn into NDMA.

The amended personal injury complaint at paragraphs, for example, 951, 1167, 1753 allege that the Defendants knew or should have known that Ranitidine posed a great risk of harm and they failed to exercise reasonable care to warn of the risks associated with the use and exposure to Ranitidine-containing products.

The dangerous propensities of Ranitidine products and the carcinogenic characteristics of NDMA as described above were known to the manufacturer Defendants, but were not known

to end users and consumers such as Plaintiffs.

That is mostly a direct quote, your Honor, I have some ellipsis in my notes, so I think I left out a few phrases. But further in the amended personal injury complaint at paragraphs 959, 1175, and 11 -- excuse me, 1761, Plaintiffs go on to allege, had the manufacturer Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with the Ranitidine products, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication.

This is not tethered to a different set of digits that comprise the expiration date, this is talking about a change to the clinical warning in the FDA approved label.

As to negligent containers, nowhere do the Plaintiffs say simply changing the containers would have prevented all harm or allow the generics to avoid liability. To the contrary, in the amended personal injury complaint at paragraphs 1992 and 1997, for example, Plaintiffs talk about a different container would have reduced the amount of NDMA consumed by the Plaintiffs.

At paragraphs 2001, 2005, 2009, and others, the Plaintiffs allege the manufacturers breached the duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-containing products.

But again, your Honor, the test is not what could a

generic have done to minimize the risk or lower the risk; it is what would it have had to do to avoid liability altogether.

THE COURT: Okay, let me ask Mr. Keller about that because I had seen that in the complaint, and I know Mr. Keller has just pointed me to 1182 paragraph as it relates to the expiration date, and he is relying upon, presumably, similar type paragraphs for each of the states as it relates to the allegation of the causation between expiration date and harm by NDMA.

But with respect to container and storage and transportation, would you acknowledge that that is the nature of the allegation of causation, if you will, that it is a causation that relates to minimizing NDMA with respect to container and/or reducing the amount?

I don't know whether it is the same for storage and transportation. Maybe I cut Mr. Yoo off too quickly if you were going to also point out that similar language is used with respect to storage and transportation.

MR. KELLER: So, your Honor, we -- sorry.

THE COURT: Let me just get clarity. Is that where you were going, Mr. Yoo, that that same language is used with storage and transportation?

MR. YOO: Your Honor, I believe the allegations in the complaint as a whole would hold that to be true. I don't have specific language quoted in front of me with regard to storage

and transportation.

I think, as the Court pointed out earlier, the storage and transport allegations do include very broad and general allegations regarding a duty to ensure that the products are not unreasonably dangerous.

So, again, there is nothing in there I could say that -- where the Plaintiffs have said a different storage and transport method or better adherence to the labeled transport and storage conditions would ensure that the Plaintiffs were not exposed to a risk of cancer. They don't say that.

THE COURT: Mr. Keller.

MR. KELLER: Thank you, your Honor.

A couple of points to unpack here. We are not alleging that the Defendants had a duty to get NDMA levels down to zero. As they re so wont to point out, bacon and beer have NDMA in it at some level just given the nature of the molecule that couldn't have been completely eliminated, but that is not the relevant test for causation.

So, for product containers, look at, for example, paragraphs 2001 and 2002, again for Alabama, each manufacturer Defendant breached its duty by failing to utilize containers that would minimize, not eliminate, but minimize the NDMA produced in its Ranitidine-containing products.

Then to paragraph 2002, as a direct and proximate result of this failure, excessive levels of NDMA built up in

the Ranitidine-containing products each manufacturer Defendant sold. These high levels of NDMA caused Plaintiffs' injury.

So, we are not accusing the Defendants of breaching a duty to get the exposure to nothing; we are accusing them of breaching duties that allowed a level of exposure that was high enough to be a legally sufficient cause of the Plaintiffs' injuries.

We are well before the point where we need to point out what that particular level is. At some point in the future your Honor is going to hear plenty about that from the experts in Daubert.

I just want to pause on this point because Mr. Yoo -- I applaud him for taking his position to its logical conclusion and reiterating that if there is any breach of any state law duty that they couldn't satisfy, there has to be preemption.

I just want to point out for the Court, and I say this with a little trepidation because I know that it has sweeping ramifications, that argument would apply to the brands, too, and the brands couldn't redesign the molecule either. We all agree that, under Federal law, they couldn't redesign the molecule post FDA approval.

Mr. Yoo was referring to the last complaint where we talked about how Ranitidine was inherently defective. We excised those allegations because we took your Honor's misbranding decision seriously, and he wants to go back to

those allegations, but regardless, to the extent that the argument is you couldn't comply with all of your state law duties, and therefore every state law duty is preempted, the brands should be out of this case, too, because under design defect law you have a duty to reasonably design your molecule and redesign your molecule --

THE COURT: But isn't one way to do that, to fully comply, is to change the label, is to make the label safe, and they can do that?

MR. KELLER: No, your Honor, it would not fully comply. Many states would say you also have to redesign this molecule. Even adding a warning doesn't fully eliminate all of the risks associated with the product, and there is a different design that you could offer to make it safer. You have to do that, too.

Nobody disputes that the brands can't do that, and the brands don't try and to dismiss our repleaded design defect claims, even though they couldn't comply with that redesign theory. That should tell you something about Mr. Yoo's argument. He does go to his logical conclusions, but that is not how preemption works.

THE COURT: Doesn't the restatement say if you can't change the design, then do it through the label?

MR. KELLER: If you can't change the design as a matter of state law, it is not talking about Federal

preemption. They could certainly change the design as a matter of state law, they could tinker with the molecule all they wanted.

MR. YOO: Your Honor, may I provide a brief response?

THE COURT: Yes.

MR. YOO: Thank you. Thomas Yoo for the generics.

I am not looking at the prior complaint, I am looking at the amended complaints where the Plaintiffs allege in the amended personal injury complaint at paragraphs 343, 1957, 1989, the Ranitidine molecule itself contains the constituent molecules to form NDMA.

Paragraphs 6, 346, 935, 1150, 1737, that the Ranitidine molecule internally degrades to form NDMA.

Paragraphs 953, 1169, 1755, the medical monitoring complaint at paragraph 871, for example, that at all relevant times the Ranitidine-containing products were defective at the time they left Defendants' control.

Amended personal injury complaint paragraph four, there is no recommended daily dose of NDMA. The ideal level of exposure is zero.

The consumer economic loss complaint, paragraph 341, the medical monitoring complaint paragraph 209, NDMA is a genotoxic which interacts with DNA and may subsequently induce mutations. Genotoxins are not considered to have a safe threshold due to their ability to alter DNA.

It goes on and on and on, your Honor. There is nothing has been excised out. As I said on Friday, your Honor, I don't think this is an exaggeration, the Plaintiffs have doubled down on the notion that NDMA -- excuse me, Ranitidine is inherently defective because it turns into NDMA during normal conditions and when ingested and digested in the human body.

THE COURT: Okay, thank you.

This is a question for Plaintiffs. On page 20 of your opposition you offer "as a judicial admission that the only inaccurate warning complained of by Counts 3, 4, and 7 of the AMPIC is the expiration date."

The judicial admission is not part of the complaint. How is the complaint, standing on its own, clear as to what these counts are based upon? Are they clear or are you relying upon your judicial admission to make clear that which you did not believe is clear in your complaint?

MR. KELLER: To be clear in my answer, your Honor, we think the complaint is crystal clear, and admittedly that language from our opposition is some frustration. We think the generics are deliberately confusing the issues.

The title of these counts, which are extremely granular because, again, we wanted to provide a lot of specificity in light of the Court's prior shotgun pleading order, all specifically say, for example, negligence, failure

to warn consumers through proper expiration dates, and then each of the sub counts goes through -- states what the particular jurisdiction's law is at a high level, and then more granularly says that the exposure to NDMA caused by the expiration dates is what caused the Plaintiff's injury.

So, we don't think the judicial admission is necessary at all. We offered it as sort of an exasperated final -- if we have done anything unclear, let this brief serve as a public document for us to say we really, really mean it, we are only talking about these particular theories of breach, expiration date, product containers, storage and transport.

So, I think the amended master personal injury complaint is more than adequate on that score. We don't need the judicial admission. We sort of viewed that as gilding the lily if absolutely necessary.

THE COURT: So, paragraph 1168 that is incorporated into your sub counts for negligence, failure to warn, that, among other things, alleges "manufacturer Defendants failed to warn and have wrongfully concealed information concerning the dangerous levels of NDMA in Ranitidine-containing products, and further, have made false and/or misleading statements concerning the safety of Ranitidine," that stands on its own?

MR. KELLER: In context, your Honor, with the rest of the allegations and recalling that we make these claims against both categories of Defendants, yes, I still think the generic

manufacturers know exactly what we are accusing them of in these counts.

It is true that they had all sorts of knowledge, and as we have discussed before, knowledge is relevant to whether we can establish a breach of duty.

I don't think that isolating paragraph 1168 robs the generics of notice of what these claims are really driving at.

THE COURT: Maybe, then, the way for me to understand this is that this paragraph, for example, tells me the Plaintiffs are alleging that in fact the generic Defendants, which is encompassed -- they are encompassed with the manufacturer Defendants. I believe that is how you have defined manufacturer Defendants.

MR. KELLER: Yes.

THE COURT: That the generic Defendants in fact had a duty to warn, that they wrongfully concealed information concerning the dangerous level of NDMA, they made false and/or misleading statements concerning the safety of Ranitidine, and they failed to warn about all of those things, and they had a duty to do all of those things, but Federal preemption law says they couldn't do some of those things.

They had the duty, but, under Federal law, they couldn't do some of those things, so, they had to do this thing. Is that --

MR. KELLER: Yes, your Honor, just like State Courts

announcing the common law start with the broadest statement of duties and then get to the specific, that is what happened here. We talk about the general things that reasonably prudent manufacturers are charged with doing, and then we get to the very specific thing that they could have done under state law and Federal law and we don't allege against them the things that admittedly they could not do consistent with Federal law.

THE COURT: But that they had a state law duty to do.

MR. KELLER: Yes. We cannot run from the fact that, under state law, they had a duty, for example, to add a cancer warning.

THE COURT: Okay.

Question for Plaintiffs. The generic manufacturer Defendants argue on page 31 of their Motion to Dismiss that AMPIC Count 14, the count for unjust enrichment, is a derivative claim that cannot survive absent a substantive state law claim.

I don't think the Plaintiffs responded to that argument in their opposition. Do you agree that Count 14 is a derivative claim that must be dismissed if all other claims against the generic manufacturer Defendants in the AMPIC are dismissed?

If you don't agree, please explain.

MR. KELLER: Especially in the context of this preemptive argument, your Honor, yes, I agree with that,

meaning I agree the Defendants are correct, that if you dismiss all of the other claims against them, the unjust enrichment claim can't stand on its own.

THE COURT: All right. Can you stand by for just a few minutes? I am going to just take a few minutes, make sure I review my notes so I don't have to bring you back again, and maybe you can give thought to whether there is anything you wanted to say that you didn't feel you were able to, maybe I cut you off. Maybe ten minutes or so?

MR. KELLER: Of course, your Honor.

THE COURT: Okay. Thank you.

(Thereupon, a brief recess was taken.)

THE COURT: Okay, counsel can rejoin if you are there. All right. All accounted for.

So, this is a question for Defense. It is a little bit following up from Mr. Keller's -- one of his comments toward the end about sort of the implications of maybe taking the Defendants' argument to a certain point, so to some extent, I am following up on that.

I think I'm understanding the Defendants' position to be that the generics on the negligence claims have immunity from any liability on these negligence claims, in some respects because of the way the complaint is pled, the allegations are set forth with respect to Ranitidine and its composition and how it acts with heat in the stomach, etc.

I guess I would like to understand, if that is your position, that there is sort of is a degree of immunity because of preemption as to all of these negligence claims for the reasons that I think I have understood you to say, which are based on how this particular drug case is pled, the particulars of this case of Zantac and NDMA and what it is and how it acts as alleged.

If I have understood that correctly, I am trying to think through -- if you are able to comment on the implications for such a finding of immunity as to negligence claims in other cases. In other words, are there boundaries to such immunity as it relates to negligence claims being brought against a generic manufacturer?

MR. YOO: Your Honor, Thomas Yoo for the generics.

I think in this case, and in other cases like it, which, frankly, I think are most pharmaceutical product liability cases, where the alleged injury and risk are inherent clinical risks associated with the drug for whatever reason, generics are preempted.

I don't know that I have looked at it as some type of immunity, per se, but I understand what the Court is asking. I think it is for this reason that you don't see any cases that are excepted from Mensing and Bartlett based on a container theory or an expiration date theory or something else that the Plaintiffs say is ancillary to their claims.

To the contrary, under Guarino and Savarez (phon), and other cases that have been cited to the Court since the first round of Motions to Dismiss, Courts have routinely looked at creative theories, alternative wording for the claims, and in the words of the Guarino Court in the Eleventh Circuit, the Courts have looked at it as just another garb that the Plaintiffs are trying to dress up, what is inherently a case about an inherent clinical risk of the drug itself.

When that is the case, as it is here, the claims are preempted, and that certainly applies to negligence.

THE COURT: So, then, potentially read into your answer, putting it in the context of my question, arguably, then, a boundary as to whether it is immunity or preemption might be a complaint that is not based on all -- in the drug context, is not based on, to use your words, inherent clinical risks of the drug itself.

MR. YOO: I think conceptually, theoretically, your Honor, that is correct. So, as applied to this case, if the Plaintiffs are not saying that Ranitidine is inherently defective, if the Plaintiffs are not saying that Ranitidine degrades into NDMA, if the Plaintiffs are not saying that Ranitidine turns into NDMA in the digestive system, and they wanted to bring an entirely separate lawsuit based on something specific to an expiration date, we would have to look at those allegations.

But it is not what has been pled here today or what this MDL was slated to be, which is, again, what they have embraced to this day, which is it has to do with the molecular structure of Ranitidine and what happens in the body under normal conditions.

THE COURT: Okay. While you have the mike, so to speak, because I am going to be concluding now, were there any final comments that you or your colleagues wanted to make? Then I will turn to Mr. Keller.

MR. YOO: No, your Honor, we don't have any further comments. Thank you very much.

THE COURT: Something like beating a dead horse, we have arrived there? Okay. And Mr. Keller?

MR. KELLER: I'm sorry, your Honor, I have to talk just one or two more times, but I will take less than 90 seconds.

First, let's go back to expiration dates and the sort of warning they provide. We talked about milk. My kids drink Horizon milk. If the expiration date on their carton of milk was improperly stated as two months when manufacturer should have known it was four weeks, and they drank it at six weeks and got sick, even though the expiration date doesn't say anything about why they got sick or the bacteria that was forming, it provides no further information, if we were just talking about milk, I don't think anybody would dispute there

is a state cause of action there for negligence, and so I think the same thing applies here.

THE COURT: Isn't milk safe, though, when it is made, and isn't the allegation in this complaint that Zantac isn't safe even when it is made?

MR. KELLER: Milk by its inherent nature degrades over time. I think that that is inherent in the design of milk, and the same thing applies to Ranitidine, it degrades over time, which is actually a good segue to the final point that I --

THE COURT: Just so I am sure I understand, isn't it Plaintiffs' allegation not only that Ranitidine degrades over time, but from the very, very inception, just the way it is chemically made up, it is just dangerous right from the get-go, right from the get-go?

MR. KELLER: Right from the get-go, your Honor, milk is going to start to degrade. Ranitidine degrades into NDMA, which is more dangerous than the things milk degrades into, but we don't dispute that some background level of exposure to NDMA is okay. People are allowed to eat bacon and drink beer.

We are not suggesting that Ranitidine, because it has a propensity to degrade right from the get-go, is necessarily problematic, and the FDA approved it, but I do want to focus on this point because --

THE COURT: But I thought the Plaintiffs' allegations included that if the FDA knew some of the things that it should

have known had the Defendants been forthcoming with studies and whatnot, it wouldn't have been approved, it shouldn't have been approved, it couldn't have been approved. Isn't that the Plaintiffs' position?

MR. KELLER: Ranitidine has been recalled and so we do look at --

THE COURT: From the outset though.

MR. KELLER: We are not alleging a fraud on the FDA theory against anyone, not the brands or the generics. So, I want to make that point crystal clear.

THE COURT: Is it the Plaintiffs' position that the drug should not have been approved, and would not have been approved had the FDA been aware of all of the information that the Defendants allegedly knew, but didn't conceal -- or didn't reveal, that they did conceal?

MR. KELLER: We have not taken a position on whether FDA would have approved the product. We are only bringing theories against the Defendants based on what they could have done, and FDA yanking it or not approving it at inception is not one of those theories.

The inherent propensity of Ranitidine to degrade -- I heard my friend, Mr. Yoo, bring this up a couple of times, so this is a point to close with -- that is precisely why the theories that we allege against the generics here, which you don't typically see against generics, are viable.

It is true that there are no cases that say that expiration date theories can go forward, and there are no cases that say they can't. Your Honor has to decide that question of first impression based on the law and the well-pleaded allegations, but I pretty strongly disagree with Mr. Yoo's slippery slope fear that this is going to open the floodgates to people bringing expiration date claims against the generics.

Take any other pharmaceutical MDL, take Truvada, for example, where the allegation is that an HIV drug causes osteoporosis, and the users weren't warned of that. The expiration date has nothing to do with it. It is not a function of the molecule degrading over time that causes the bone problems with Truvada, it is just that is how the drug works.

Maybe it would have been still a good risk/reward for someone HIV positive to take it and to absorb the risk of their bones thinning out, but they weren't warned of that.

You couldn't plead an expiration date claim or a packaging claim against the generics in that MDL, or just about any other. It is precisely the unique facts of how Ranitidine turns into NDMA over time that allows the theories we have pled against the generics to be viable.

This is not going to be open season on generic manufacturers in the future because most drugs don't look like Ranitidine. They should not get off Scott free in this MDL

because of the unique facts and circumstances of this case where we have pled requirements under state law consistent with Federal law just because they are used to getting out in other cases.

THE COURT: Mr. Keller, I want to go back to something you said.

I am sure you are familiar with your paragraphs 407, 408, 1519, for example. Do they not allege studies from 1981, Dr. Silvio de Flora publishing results of experiments in the Lancet showing Ranitidine produced NDMA in combination with gastric fluid and nitrates? This study put all future manufacturers of Ranitidine on notice of the risk of consuming Ranitidine in combination with high nitrate foods.

MR. KELLER: Yes, your Honor, they do say that. If what your Honor is getting at is, how is that consistent with our theory or us not taking a position on whether FDA would have approved Ranitidine, it is still consistent.

The FDA might have approved it with a different label that said only take this product for two weeks, or four weeks, and don't take it with high nitrite food, but that is not the same thing as saying the FDA would have never approved it at all.

THE COURT: Is the Plaintiffs' position, through its allegations in the complaint, that Ranitidine was always misbranded?

MR. KELLER: I do not believe that is our position in the amended complaint, your Honor. In fact, we have made no misbranding allegations other than with respect to the over-the-counter sales of Ranitidine and the economic loss Plaintiffs in the class action complaint.

The amended master personal injury complaint does not contain any allegations of misbranding, and none of our theories rest on misbranding.

THE COURT: Was that the position, then, in the prior complaint, that Ranitidine was always misbranded, but that is not the allegation in this complaint?

MR. KELLER: In our prior original complaint, your Honor, which again, just to be clear, is not the operative pleading, but to directly answer your question, we did make a misbranding allegation in the previous round.

I don't think we locked ourselves in to when Ranitidine became misbranded, and so I don't think that we took a position on whether it was right away, or if new science had to come out since the original FDA approval that would have subsequently made the drug misbranded because the label became false or misleading in any particular.

So, yes, we alleged misbranding previously, but I don't think we took a position on timing.

THE COURT: What about in this complaint, what is the timing of the allegation as to when Ranitidine, or the drug

became misbranded?

MR. KELLER: To be clear, your Honor, when you say this complaint, I assume you mean the amended consumer economic loss complaint? Because in the amended master personal injury complaint we do not allege misbranding at all.

For the economic loss complaint, I still do not believe we have taken a position on when temporally the label became false or misleading in any particular. That is a fact question that we are still exploring through discovery.

THE COURT: But, while you may not use the word misbrand in the AMPIC, you, yourself, have said that it is not about the label, it is not about what you call something. Many state laws have different variations of sort of the same concept.

You are alleging other types of causes of action that directly and indirectly suggest that the product, at a minimum, was mislabeled. If it is mislabeled, would you say that that meets the definition of misbranding?

MR. KELLER: Yes.

THE COURT: Okay. So, even though you might not have used the word misbranded, aren't you making those types of allegations in the AMPIC?

MR. KELLER: We do allege that the label, particularly against the brands, needed to have different warnings, and with respect to the generic manufacturers, needed to have an

accurate expiration date. That is the, I believe, only labeling-based theory we allege against the generics.

You are also correct that I pointed out from Bates that the substance of the duties is what matters, not the naming convention, but even in substance, when it comes to the labels we have not pinned down a particular time when we allege the label should have had different information on it. That is still a factual issue for discovery.

So, we are not yet locked into starting at this date in 1980, whatever, the label should have changed.

THE COURT: Okay. All right. Thank you so much, nice seeing everyone again. I don't have any more questions.

MR. KELLER: Thank you, your Honor.

THE COURT: I appreciate it very much, have a nice rest of the day.

MR. KELLER: You as well.

MR. YOO: You, too.

(Thereupon, the hearing was concluded.)

* * *

I certify that the foregoing is a correct transcript from the record of proceedings in the above matter.

Date: June 11, 2021

/s/ Pauline A. Stipes, Official Federal Reporter

Signature of Court Reporter