IN THE CIRCUIT COURT OF THE STATE OF OREGON

FOR THE COUNTY OF MULTNOMAH

SUZANNE M. LUKAS-WERNER, and SCOTT WERNER, wife and husband,	)	
Plaintiff,	)	
vs.	)	No. 1009-13177
NOVO NORDISK, A/S, a Denmark corporation, et al; NOVO NORDISK, INC.; A DELAWARE CORPORATION; BRECKENRIDGE PHARMACEUTICAL, INC., a Delaware corporation; and KRISTINA HARP, M.D., an Oregon citizen,	)	
Defendant.	)	

TRANSCRIPT OF PROCEEDINGS

BE IT REMEMBERED that the above-entitled matter came on regularly for Motions before the Honorable Janice R. Wilson, Judge of the Circuit Court of the County of Multnomah, State of Oregon, on May 11th, 2012.

APPEARANCES:

MR. MICHAEL WILLIAMS & MS. LESLIE O'LEARY, MR. STEVEN SEAL, Attorneys for Plaintiffs;

MR. PATRICK LYSAUGHT AND MS. MARY-ANNE RAYBURN, Attorneys for Defendant Novo Nordisk;

Estelle T. Keating
1021 S.W. Fourth, Room 420
Portland, Oregon 97204

MAY 11th, 2012; 2:10 P.M.

P R O C E E D I N G S

THE COURT: Thank you very much. Good afternoon. Please be seated.

This is the time set for a hearing in Suzanne Lukas-Werner, et al, versus Novo Nordisk, et al, case number 1009-13177. And I believe we have for this afternoon oral argument on defendant Novo Nordisk, Inc.'s Motion to Dismiss the Innovator Liability Claims and, in the alternative, Motion to Strike. And we have a bunch of other scheduling things to discuss.

So, I read all of your materials, motion, response and reply -- small sense of deja vu. I'm ready to hear argument on the Motion to Dismiss.

Mr. Lysaught?

MR. LYSAUGHT: May it please the Court, we are here on the Motion to Dismiss Plaintiffs's Innovator Liability Claim, which arose and is part of Plaintiff's Third Amended Complaint. It arose as a result of plaintiff's decision to voluntarily dismiss Breckenridge, who is a manufacturer of a generic version of Activella, 17 Beta Estradial and NETA.

The question is, first of all, whether or not the dismissal of Breckenridge was necessary under the *Mensing* decision. Our position is that it was not, that

there are other viable claims that could have been asserted and followed up on by the plaintiffs. In fact, virtually every claim that they make against us, other than labeling, could have been asserted against Breckenridge, including claims involving mixing, advertising, marketing, et cetera.

They decided without investigation, without discovery, to go ahead and dismiss Breckenridge. And they also decided to do it with prejudice.

As a lawyer, who practiced for a few years, although we always want a dismissal with prejudice, we certainly always take one without prejudice.

So the question is why did plaintiffs do it with prejudice under the circumstances? And I can only assume that it was a strategic decision by plaintiff's counsel to basically put themselves in the position that they are in today, so that they can come to this Court and say, "Well, Your Honor, if you don't grant our motion, if you don't allow us to pursue innovator liability, we have no way to pursue a claim as it relates to the 14 months that she took the Breckenridge product. And yet, in fact, they could have and would have had they followed through and done investigation, had they recognized, for example, that the products, in fact, are not identical. The bioidentical standard with regard to FDA for approval

under an ANDA process of generic version is bioequivalency for blood only. It does not relate to whether or not, as an example, it's bioequivalent in various tissue within the body, including breast tissue. So they completely and totally failed to follow up.

They are arguing against an overwhelming number of cases that have concluded that there is no such thing as an innovator liability claim, including two Federal Court decisions in Oregon applying Oregon law, concluding that such a claim does not exist. They argue that this Court should essentially ignore all of that law, ignore all of those decisions and look to two things. One is the *Conte* decision in California. The other is the *Kellogg* decision in Vermont.

The *Conte* decision is an intermediate Appellate Court decision. In our view, the *O'Neil* decision, which was issued by the California Supreme Court, swallows *Conte* up and spits it out. The reason it does is because it recognizes that there is, in fact, no basis to impose liability on a third party based upon any theory that would apply to a manufacturer of another product.

THE COURT: Why -- why did the California Supreme Court not take review of *Conte*?

MR. LYSAUGHT: I can only speculate, but my speculation is, having looked at and read lots of cases in

California and elsewhere and analyzed what the California Supreme Court does, is they look for the right vehicle. If they took *Conte*, it was a very limited case with very limited applicability. We're talking about strictly and solely the situation that we have here, which is a generic drug and the original manufacturer of that very same product. If they announced a rule in that case, it would have very limited application. This rule makes clear that we're not going to impose liability in many different circumstances, including those that would apply to *Conte*.

And the thing that they made clear and what all of the analysis has failed to address here and in *Kellogg* is the actual physical damage -- assuming that there was any -- in this case or in *Kellogg* or in *Conte* was done by someone else's product, not by Activella, in this instance, or the original version of Regulin in those two instances.

And that's a critical component. Because if you look at traditional product liability law, if you analyze it, understand it, there are two requirements. One is that the manufactured or distributed by the party against whom you are pursuing a claim, and second that the physical injury is caused by that product.

The theory can be failure to warn or inadequate warning, but still the injury must, in fact, be the result

of interaction with that product. Here it is not. *Conte* it was not. *Kellogg* it was not. It turns traditional product liability concepts on their head, and it does so for no basis at all.

THE COURT: Well, I understand the plaintiffs say, "Stop talking about product liability. That doesn't matter here." They are stating a claim of negligence. It happens to be concerning the properties of a product, but -- but that, you know, you don't get sort of some protection by trying to sweep it under the umbrella of product liability law.

MR. LYSAUGHT: He is, in fact, following the lead of the *Conte* decision and the *Kellogg* decision, which again didn't address this issue of physical harm in terms of how is it that we can somehow ignore that part of the requirement, even if we're looking at negligence, even if we're looking at negligence.

If I am someone and I give bad advice to somebody, but they ignore my advice and do something that I have advised them to do but for another reason -- let's assume somebody is an investor in a club. I have advised them to go ahead and purchase stock. They ignore my advice, but the club of which they are a member purchases the stock, they can't sue me. He can't sue me because they didn't do it. That was a decision made by somebody

else for another reason.

The same is here, too. There is no nexus between alleged negligent conduct and the injury. The injury physically was caused, the nexal cause was something else, negligence or not.

Moreover, the -- as the *Fazzolari* decision doesn't replace product liability concepts or laws. And, in fact, if you look at the case of *Griffith versus Blatt*, an Oregon Supreme Court case, 2002, that clearly isn't focused on this issue, but it's a Supreme Court of Oregon talking about strict products liability and negligent products liability in the same context.

And they say this -- this is page 1262. The cite is, if I can find it, 334 Oregon 456. Plaintiffs -- and I quote. "Plaintiff's strict liability and negligence claims both constitute a, quote, product liability civil action, end quote. ORS 30.920 provides the elements of a strict liability claim. Number one, one who sells or leases any product in a defective condition unreasonably dangerous to the user or consumer or to the property of the user-consumer is subject to liability for physical harm or damage to property caused by that condition if, A, the seller or lessor is engaged in the business of selling or leasing such product."

So, the Oregon Supreme Court in the context of

looking how negligence and products liability are, in fact, part of the statutory construct under Oregon law, treats them the same. And they are the same.

And our position is there is no such innovator liability claim under Oregon law. There never has been.

We cite another case in our brief that basically stands for the proposition that the *Fazzolari* decision doesn't apply to products liability claims. And it's *Waddill versus Anchor Hocking*. And, again, it's a recognition by the courts of this State that product liability analysis is different from pure negligence and foreseeability analysis under Fazzoli. And the reason --

THE COURT: *Fazzolari*.

MR. LYSAUGHT: *Fazzolari*. I'm sorry. *Fazzolari*.

THE COURT: I should add that to my list of things you have to be able to say if you are admitted.

MR. LYSAUGHT: It's getting longer and longer, Your Honor.

The reason is because the construct of a product liability case, whether it's negligence or strict liability, depends upon the relationship -- the relationship between a manufacturer, distributor or lessor in Oregon and the user of the product. And that's where the duty arises. And that's the way in which the law

recognizes the duty, whether negligence or strict liability, and that's the basis upon which liability would be imposed.

But, again, if you look at Oregon law, California law or even Vermont law, what's missing here is the fact that the injury, itself, is not the result of Activella. It's not the result of exposure to Activella. It would be the result of exposure to a completely different product manufactured by somebody else, provided by somebody else to this particular individual, plaintiff Susan Lukas-Werner. And if there is an injury, it was that product, not ours. And that is one issue that no one can deny, and there is nothing in the law that suggests that you can make a quantum leap beyond the issue of negligence and beyond the issue of anything and have damages resulting from something that actually didn't physically harm the plaintiff.

Thank you, Your Honor.

THE COURT: Thank you.

Ms. O'Leary, Mr. Williams, Mr. Seal, who's up?

MR. WILLIAMS: Let me try to take those in reverse order. Your Honor, first, the codification of product liability law, which Mr. Lysaught quoted at 30.920 subsection four of that very statute says, "Nothing in this section shall be construed to limit the liabilities

of seller under principles of common law negligence. Therefore, it's clear that the common law of negligence is what is at stake here. It doesn't turn on the statutory interpretation of the strict liability codification.

And I think under the common law of negligence of Oregon, this is actually not a tough call. It's certainly a new call. There is no ruling from an Oregon State judge on this yet that we know of, but *Fazzolari* says if there is a duty and if it is foreseeable -- reasonably foreseeable -- then a negligent action can obtain.

Here there's a duty to have an accurate label from FDA regulations. *Fazzolari*, itself, says that if the injury is so foreseeable that it's pretty obvious, even that can give rise to the extent of the duty, because you know someone is out there that could be hurt by your misconduct. And clearly the product at issue here is the wording of the label. It's the description of the overall risks and benefits of the combination of estradiol and NETA.

Breckenridge had a copy of that label. It was clearly foreseeable to Novo Nordisk that physicians and patients would rely on its label because it was required that the other -- that the generic drug have that label. And, therefore, I think it's a pretty simple -- it's a

pretty simple conclusion here.

Now, Mr. Lysaught argues that you have to have the physical contact of the drug to the injury. That's not true. *Oksenholt* was a physician suing for damages caused by the ingestion of the drug by his patient. The physician in *Oksenholt* did not ingest the drug. He just relied on the warning label. And it was -- and therefore, as long as you have got reliance on the warning label in Oregon, you don't have to actually ingest the drug if the warning label's inadequacies caused the injury. And I think it's that simple.

For Mr. Lysaught to suggest that we should have fought some -- I don't know what cause of action we could have against Breckenridge other than a failure to warn claim. We're not contending there was something wrong with the chemicals here. It's a question of describing adequately the risks and benefits of the drug, which was all Novo Nordisk's language. And that's why her doctor and Ms. Lukas-Werner relied on it. They relied on Novo Nordisk's language.

THE COURT: In the reply memoranda, defendants talk about *Oksenholt* and say that plaintiff's reliance on that case is misplaced because it was from 1982, and that relied not on common law negligence and foreseeability analysis in Oregon, but pre-*Buckman* Oregon law, that said

you could have a civil claim for violation of FDA regulations. Do you want to address that point?

MR. WILLIAMS: Sure. We have been through this in the pharmaceutical litigation now over and over and over again. And, basically, what the law is is that violation of a FDA regulation is evidence of negligence of a manufacturer. We're not trying to prove the FDA would have taken a different action. That's what Buckman was about. Buckman was a claim that there was fraud on the FDA and that if they had told the FDA the truth, the FDA would have taken a different action. That's not what's at issue here.

We're claiming that it was the label, itself, that's inadequate, and it is there -- they have to comply with FDA law. And the jury is allowed to hear what FDA law requires of a drug manufacturer. And that gives you one of the ways *Fazzolari* can create a duty is statutory violation, because it gives you a standard of care. But that doesn't violate the Buckman decision at all.

THE COURT: One could read plaintiff's argument to suggest that in Oregon post-*Fazzolari* -- we all learned how to pronounce *Fazzolari* when that came out, believe you me, that, you know, there was originally this thinking that, "My gosh, it looked like *Fazzolari* did away with concept of duty in Oregon negligence cases. There wasn't

any such thing. You didn't worry about duty anymore, unless it was a duty created by something else or some other relationship. Otherwise, it was basically kind of flip things around, duty flowed from foreseeability.

It kind of looks that's what plaintiff's argument is here, the duty to provide an adequate warning to users of generics is imposed on the innovator because of the foreseeability that patients or their prescribing physicians -- I'm not answering that question now about learned intermediaries, but would -- in fact must -- they will, because they must, rely on the labeling developed by the innovator.

But we also know since *Fazzolari* -- *Fazzolari* didn't actually stand for that necessarily or at least the Supreme Court has told us since, "Oh, no, no, actually it's a little more confined than that."

But tell me what -- what -- why I'm misreading that argument. Let me restate it, because that was a really long, convoluted sentence. It appears that plaintiff's argument at one level may simply be in Oregon, if it's foreseeable that someone will be harmed by a negligent misrepresentation, foreseeability is all we need. If you want to talk about duty, duty arises out of the foreseeability, and there can be liability.

MR. WILLIAMS: Well, I think that the clearest

source of duty here is from the FDA statutes that require them to have an accurate label and to know enough about their drug to be able to describe the risks and benefits adequately.

THE COURT: "Their own drug," isn't that the key? Their own drug?

MR. WILLIAMS: Their own label, right. But their own label must be the label for the generic, too. That -- that's the requirement of FDA law also.

So the FDA regulations create a duty to make sure the generic labels are correct, because the generic labels have to be the same as their labels.

THE COURT: So, FDA regulations, especially now the Supreme Court has elaborated this in *Mensing* -- FDA regulations create a duty of any drug -- innovator. Drug manufacturer, the one who develops the original labeling to any prescriber or consumer -- again, I'm not deciding that question right now -- of not only that manufacturer's product, but any generic version that any other manufacturer might ever make in the future.

MR. WILLIAMS: And the reason is because the generic must by law be identical. It must have the same label and it must have the same constituents, same doses.

THE COURT: Now, let me ask a question about that. I know we talked about this before, but I have got

to wrap my mind around this one again. Isn't it that it must be identical if the manufacturer of the generic wants to avoid going through the whole NDA process, et cetera, et cetera. If they wanted to make something, manufacture and sell a product that looked to be virtually identical to that other product, which is no longer protected by a patent and they didn't want to, I'll call it, ride the coattails of the -- I'll call it the innovator, the innovator's original labeling, they could go through their own process, couldn't they, NDA, with the FDA and put all the warnings they thought were necessary and appropriate and so on, so forth? It's only if they want to ride the coattails that they are forbidden from altering the language of the label; isn't that right?

MR. WILLIAMS: Yes, that's true.

THE COURT: Okay. So it's not that -- it's not actually technically correct that the manufacturer of a generic is required to use the innovator's label. It's only if they want to avoid -- avoid having to jump through all those loop holes, which I'm sure are time consuming and expensive, that they have to, you know, follow the -- dotted I's and crossed T's and not change it.

MR. WILLIAMS: That's absolutely true. If they wanted to go through the entire NDA process themselves for the same doses, the same drugs, they could do it. I mean,

I don't know -- to me that's kind of a fantasy world because no company is going to do that when they can sell the generic without going to that expense and risk.

I don't see how that cuts off the -- it certainly doesn't cut off the foreseeability that physicians and patients are going to rely on the innovator's label when they take a generic drug. I think foreseeability here is easy. I mean, that's not a problem. It's the question of whether there is some duty. And I think the whole scheme of innovator and generic drug manufacturing creates that duty.

THE COURT: And if we do have to go back and find a duty and the source of that duty is the -- I'm still stuck. How are you saying anything other than the duty arises out of the foreseeability of another manufacturer's use of the same label under the FDA regulations? Because it's not a duty that arises out of the relationship between the manufacturer of a product and the ultimate consumer or prescriber of that product. Otherwise, you get stuck.

MR. WILLIAMS: Ms. O'Leary has some points about some amendments to the FDA regulations that she wants to explain to you, if that's all right.

THE COURT: Sure. Thank you.

MS. O'LEARY: Sorry, Your Honor. I just wanted

to clarify. Before the *Mensing* decision came out, there was a lot of -- well, the cases were split. There was a split in the circuits, and there were some courts that said m"His is ridiculous. Any type of generic manufacturer has an independent duty to update the label and to, you know, monitor its drug and do all this stuff."

And then along comes the *Mensing* decision by the Supreme Court, and the Supreme Court announced that these amendments to the FDA regulations concerning generic drugs does not confer that duty on these generic manufacturers. It is and has been the duty of the innovator, the brand-name manufacturer, who is the original NDA holder, to be the one responsible for updating the label and making sure that they keep their label current.

I mean, for those on the other side of the argument, everybody thought this is absurd because, you know, their drug is off patents. They don't really care what happens. They are not making all that money on it anymore. It's the generics. But, surprisingly, the Supreme Court articulated this different position, said, "Yes, we know it doesn't make sense, but you know if congress wants to fix that, they are going to have to fix it. In the meantime, it's the brand name manufacturer that continues to hold that duty to keep the label current based on the latest science."

So, here we have the innovator here, and Novo Nordisk, whatever entity it is, still has that duty. That duty arises under the federal regulations as confirmed by the Supreme Court.

So the duty that it has and arguably has had ever since these amendments came to pass, provide the foreseeability of Novo Nordisk to -- you know, to know that down the road there are going to be other generic companies that are going to be relying on this label. And whether it likes it or not, it has the responsibility to keep monitoring its product, keep monitoring the science, keep doing studies to make sure that its label is still accurate, because other generic manufacturers are going to be relying on it. In fact, they have to rely on it.

As you pointed out, Your Honor, if they want to -- if they want to come up with a different label, then they have to go through a more rigorous process. They have to go out there and they have to do the studies and they have to provide the studies to the FDA.

But even when you read *Mensing*, you are left with this kind of funny but -- I mean, that's what the court said, is that well, you know, you can do that, but -- but the FDA -- I think even in the amicus briefs the FDA said, "Oh, well, it's not up to them. It's up to the NDA holder to do all that."

So -- but if they wanted -- if they wanted to do that, I suppose they would have to go through a brand new process, where they would have to have all those clinical studies to support the safety of their claims.

THE COURT: Remind me, does *Mensing* say what happens if the original developer of the drug, the NDA holder, is gone, out of business? Not is not -- you know, things out of patent or they are not even making it anymore, they just don't exist?

MS. O'LEARY: I'm not sure whether they have dealt with that bankruptcy of a company that just vanished.

I know that the amicus petitioners did point out the whole absurdity of it. It would leave people without a remedy, as it did with this particular person, you know, Ms. Mensing, or there are other people.

In fact, there was an example in the newspaper -- I don't know if you remember the *Wyeth v. Levine* case where that was Wyeth's drug. It was an injectable drug. And due to a failure to warn, it led to the plaintiff -- the doctors not knowing that you are not supposed to inject it that way, and the plaintiff had her arm amputated.

So this went up to the Supreme Court, and the Supreme Court said, "Well, the manufacturer has a duty to

warn, duty to update the label when it learns of new and important risks." And along comes, you know, the generic manufacturer of the same drug a few years later, the same thing happens. The woman has the same injury, the same amputation, but she doesn't have a cause of action against that generic manufacturer, even though that generic manufacturer's label was just the same as the other one was. These happened at the same time. No claim, no liability, no remedy.

So, it's an absurd result, but that's what the Supreme Court said the law is. And that's why all of a sudden now we're starting to see cases such as *Conte*, there are cases all over where I think that at some point the same issue is going to come up. Somebody has got to be held responsible. And the Supreme Court said that it's the brand name manufacturer. The brand name manufacturer still has that duty to warn and update the label even though that manufacturer may not be actively marketing it. That's the way it is until the legislature changes it.

THE COURT: Okay. Thank you.

And had you concluded your argument, Mr. Williams?

MR. WILLIAMS: I have, Your Honor.

THE COURT: Go ahead, Mr. Lysaught.

MR. LYSAUGHT: Just a couple of points. First

of all, in *Mensing*, the U.S. Supreme Court did not consider the issue of liability of the NDA holder. And while there is some discussion in there about various issues, one of the things that's very clear is despite a statement in their brief, it's completely and totally wrong that the -- the generic manufacturer has no duties with regard to safety. They have a responsibility to collect adverse events, report them to the FDA like any other pharmaceutical company. The difference is what the Court pointed out here, and this is why we say, among other things, they have a cause of action either based upon the fact that they decided to take a shortcut and take a free ride on somebody else's coattails, or, you know, their theory that, you know -- their big theory, at least as I understand it, is this: That we should have used oral micronized progestin instead of NETA. Would they not have a cause of action against a generic company who chose to copy what they alleged is a bad drug?

How about failure to exercise due diligence when you decided what drug to copy? Or what about you could have done your own test or that you could have discovered all these things that we said, and you could have developed a different drug? You could have gone through the ANDA process. You could have developed your own innovative product, including oral micronized progestin

and some, as of yet, unidentified estrogen or they can pick an estrogen.

The idea that they don't have a cause of action, that these people are left without a remedy, is completely and utterly wrong.

They argue for this broad, broad, broad application of *Fazzolari*, that it creates virtually unlimited liability based on foreseeability. Isn't it foreseeable if you are a generic manufacturer and you develop a drug that is allegedly defective and dangerous and you had all the options in the world, number one, not do a generic at all or, number two, do another generic or, number three, do something different and actually be an innovator, why wouldn't those theories be recognizable under Oregon law?

Mensing doesn't say anything at all. It is a very limited holding.

What it says is -- and all it says -- is a plaintiff cannot under state tort law assert a failure to warn claim based upon the language in the product label, itself. That's it. Every other conceivable --

THE COURT: You make it sound like it's such a small thing, Mr. Lysaught.

MR. LYSAUGHT: Well, it probably could be at some point in time.

But in any event, the critical part, at least as I read *Mensing*, is that on remand, the Eighth Circuit where *Mensing* originally arose, they reentered their dismissal of the original NDA holder as well.

So this idea that something in *Mensing* says, oh, it's really the innovator who is on the hook, it's the NDA holder that's on the hook is simply wrong, and again the idea that these people are left without an identifiable cause of action is wrong as well. That's what I said. I mean, they came in. They made a strategic decision to do this. They did it with prejudice so that they could come into this court and argue, "Gee, poor us. We have no place else to go." They did. They chose to do what they did.

But, moreover and critically, the Court, I think, is correct in the sense that *Fazzolari* isn't this -- there is no duty. And, in fact, the Supreme Court decision of Oregon in the *Griffith* case is post-*Fazzolari*. So it's pretty clear that people sitting on the Supreme Court of this State think that the requirements of the Product Liability Act, even if you are asserting a negligence claim, apply as well. Because that's exactly what it says. It says you have to be a manufacturer, seller or lessor of the product. And that is standard product liability law.

That is -- you know, he talked about the subsection in the Oregon statute. But that's what the product law has always been. Whether it was pursued under a negligence standard or a strict liability standard or a warranty standard, you don't get to recover against somebody whose product you didn't use.

And, again, he stood up and talked about the -- he said, I quote, "The label is the product." The label is not the product. Okay. I have got a defective label. It is the worst label that's ever been written with respect to whatever product it is. But you don't use the product and you are not exposed to it. Have you been injured? Can you recover? Have you been damaged? The answer is no.

And that's exactly the situation we have here. Whatever the label says, it could have been different for a lot of different reasons had the generic manufacturer chosen to do something different.

But the label is not the cause of injury. The physical cause of injury is the product. And there is nothing in the product liability law of Oregon or any other state that removes the requirement that that physical damage has to be caused by the product.

And, again, the label is not a product. It's not what you bought and it's not what you paid for, and

there is no liability.

THE COURT: Well, this is really interesting. I think plaintiff's argument has a lot of appeal, but that's not my job here today. I am required to attempt to predict -- and I need a much bigger crystal ball than I am using -- what the Oregon Supreme Court would do with this theory. And my best prediction is that the Oregon Supreme Court would not recognize the innovator liability theory in these circumstances.

Frankly, I was thinking I don't really care about defendant's arguments about what causes of action the plaintiffs might have still brought against Breckenridge. That's not the question before me. The question is does this particular pleading state a cause of action under the Oregon common law, regardless of what other things might have been there and weren't there.

The only reason I think there is any place for that argument in this motion, actually, is thinking that the Oregon Supreme Court, when it takes this issue up, will look at Article I, Section 10 of the Oregon Constitution and look at the *Mensing* case and say where that provision in our constitution says every man(sic) shall have a remedy by due course of law for injury done him(sic), and his person, property or reputation, would they say that in light of the U.S. Supreme Court's ruling

in *Mensing* there has to be innovator liability for that remedies clause to be given effect and meaning? And they would look and say, "Well, even if it's not that particular remedy, are there others and so on." So, you know, I'm not ignoring that argument completely, but I think it's really tangential to the core issue here.

And I do not think the Oregon Supreme Court would conclude that the innovator, the original manufacturer of a drug responsible for its labeling, has a duty arising out of the FDA regulations to the consumers or prescribers of all generic versions of its drug.

And the plaintiffs acknowledge that foreseeability alone won't get them there. That really is kind of what it amounts to, because the regs don't permit the manufacturer of a generic that doesn't want to go through the labeling process to do anything other than use the innovator's labeling. That makes the harm foreseeable to the innovator.

I don't think we can get there from here. So I'm granting the defendant's motion. I do it reluctantly, but I'm granting it.

Okay. Scheduling: There is sort of the big scheduling issue raised by plaintiff's motion to reset the trial date and related deadlines, to which defendants have not had an opportunity to respond. But I wonder if

STATE OF OREGON)
) ss.
County of Multnomah)

I, Estelle T. Keating, Official Court Reporter of the Circuit Court of the State of Oregon, Eleventh Judicial District, certify that I reported in stenotype the foregoing proceedings in the above-entitled case.

I further certify that my stenotype notes were reduced to transcript form by Computer-Aided Transcription under my direction.

And I further certify that pages 1 through 36 contain a full, true, and accurate record of my stenotype notes.

Dated this 11th day of May, 2012, at Portland, Oregon.

/s/ *_Estelle T. Keating_*
Estelle T. Keating