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Judge Reyna (00:06):

We have a full morning of arguments before the court this morning. We have four cases that are docketed for argument. First case is Phigenix Inc. Versus Genentech, Inc. Mr. Thompson, you reserved four minutes of your time for rebuttal, correct?

Benjamin Thompson (00:28):

Yes, your honor.

Judge Reyna (00:29):

And Ms. Maynard, you reserved three minutes of 15 minutes—three minutes for the cross appeal.

Deanne Maynard (00:37):

Yes, your honor. Thank you.

Judge Reyna (00:38):

Okay, you may proceed.

Benjamin Thompson (00:45):

May it please the court. Good morning. Ben Thompson from Fish & Richardson for Phigenix. Phigenix's appeal concerns two summary judgment grounds the below court entered adverse to Phigenix. I'd like to begin with the court's judgment stemming from its decision to strike Phigenix's expert infringement report. Now, Phigenix's expert's opinion—it was not a new theory. At most, it was a subset, or targeting a subset of the theories plainly disclosed in Phigenix's infringement contentions. The infringement contentions expressly accused [inaudible] usage in patients that had been pre-treated with two chemotherapy agents trastuzumab and taxane—try that again, trastuzumab and taxane. The expert's infringement theory accused the same treatment—treatment with Kadcyla following pre-treatment with these two other chemotherapy agents.

Judge Stoll (01:45):

Why is it that you narrowed your infringement contentions?

Benjamin Thompson (01:51):

So my firm was not involved in that specific time in this case. We came along after the infringement contentions—sorry—after the motions for summary judgment were ordered. It was Phigenix's position that there was no narrowing. The theory with the whole time was administration of Kadcyla following treatment with trastuzumab and a taxane is the infringement. And that's what the infringement contentions say. They don't mention other compounds, granted the infringement contentions didn't say and nothing else. They also did not say at least trastuzumab in a taxane.

Judge Stoll (02:24):

What is the percentage of patient population that would receive the drug with just those two other drugs? I think I read somewhere—I'm not expressing myself well, but I think I read somewhere that the narrowed—if you don't mind me using that phrase, but the narrower infringement contentions would only cover 4% of the people who take this medication. Is that an accurate statement?

Benjamin Thompson (02:51):

I believe that was the prognostication that Phigenix's expert made based on the data before him. Yes, it would be a small percentage. However, we're willing to adopt the assumption that Phigenix's expert was proceeding on a narrower subset.

Judge Reyna (03:09):

Were you arguing that adding the limitation and nothing else that that's not—that did not develop a new theory or infringement?

Benjamin Thompson (03:15):

We're willing to assume that it is a narrower theory than what was disclosed infringement contentions, and even adopting that assumption that Phigenix's 'expert was pursuing this narrower theory against a subclass of the patients that would be encompassed by Phigenix's infringement contentions, the district court, nevertheless abused this discretion. And, and I'll tell you why. The district court found that disclosing the broader contention of administering Kadcyla to all patients meeting the criteria required by the Kadcyla label, meaning at least trastuzumab and taxane before Kadcyla, does not adequately disclose a narrower theory of administering Kadcyla to a specific subpopulation of patients, but we believe that's factually inaccurate. By definition, if I say my infringement contentions, I'm accusing A, B, C, and D, these classes of patients, and my expert proceeds only on subclass of patients, A. Nevertheless, the defendant was on notice of that theory.

Judge Stoll (04:10):

You think that it's sufficient that the subclass was identified every time. I mean, in every infringement contentions, it doesn't matter so long as at least some—subclass is identified, even if it's 96%—that are only 4% are the ones that are actually accused of infringement?

Benjamin Thompson (04:28):

I'm not willing, in case I have to come back here later and argue something different, I'm not willing to say every time. But in this case, we can't forget that the infringement contention specifically said packs two is inhibited when you give Kadcyla following pretreatment with trastuzumab and taxane. It wasn't this hidden sub class that was not articulated in the infringement contentions. It was the only combination of drugs that was specifically identified in the infringement contentions.

Judge Reyna (04:55):

Despite the degree of narrowness that we're talking about here, it is the addition of a needle limitation. And that limitation was not included in your infringement contentions.

Benjamin Thompson (05:07):

I respectfully disagree. The infringement contentions say what they say. It's Kadcyla following pre-treatment with trastuzumab and taxane—

Judge Reyna (05:09):

[Inaudible] and nothing else.

Benjamin Thompson (05:12):

Correct. But even if they could be read to include that out our subclass, again, there's no—there's no real prejudice to Genentech when they're on notice that Phigenix's infringement contentions are also targeting the infringing subclass.

Judge Bryson (05:32):

It's a negative limitation really, is what it is, right?

Benjamin Thompson (05:34):

Correct. But if I'm, if I'm in Genentech shoes and I know that there's this broader class of patients who are accused of infringement, I have to infringement theories for all of the various subclasses. This is not the same as a new infringement theory, where you're ambushing someone late in litigation with new infringement theories that they were not aware of. And the—what made this error worse is when the court applies case law directed only to new infringement theories, not narrower theories. And there's no dispute that the court relied only on case law concerning new theories. The district court, not the district court and not Genentech has anyone identified a case where a district court properly struck an infringement theory for being narrower than what was in the in the infringement contentions.

Judge Reyna (06:20):

It was struck because of the prejudice that it caused to the defendant. This is after the fact discovery had close. I believe Genentech had even conducted some experimentation to prove its case. And all of that kind of went into the waste basket didn't it?

Benjamin Thompson (06:37):

It did not. If Genentech was conducting experiments to disprove infringement, it should have conducted experiments to disprove infringement with respect to the entire class of patients accused in the infringement contentions. If it didn't do that, that was Genentech's mistake.

Judge Stoll (06:51):

What about the abuse of discretion standard that we have to apply? How do you see that the district court abused his discretions, obviously very deferential standard?

Benjamin Thompson (07:03):

Yes, it is your honor. First reaching the factual mistake that the broader contentions don't disclose the narrower contention. That was an error that led the court to apply an absent case law. And given the time I have, I'd like to shift over to the inducement issue if I may quickly. The district court also found that there was not sufficient evidence of Genentech's intent to prescribe Kadcyla to this subset of patients. The Kadcyla label plainly indicates it should be administered to patients pretreated with trastuzumab and taxane. And that is the specific combination that is accused in this case. Further Genentech admitted that it expects Kadcyla to be administered in accordance with these instructions. That was in response to an RFA at appendix 729. The district court even found that the Kadcyla label instructs physicians to administer Kadcyla to all patients that have previously received trastuzumab in a taxane. That's in the district court's opinion at appendix 12. Given the express instructions on the Kadcyla label, in combination with Genentech admission, that it's encouraging Kadcyla's administration in accordance with that label. Those two things alone should have provided sufficient circumstantial evidence on the intent element of inducement to get past summary judgment.

Benjamin Thompson (08:30):

Now where things went awry here is the, court looked past the instructions on the, the Kadcyla label and proceeded to apply case law concerning off-label administration or off-label prescription of drugs. And

although the court said, “that’s a distinction without a difference,” that that’s not actually true. In these on-label cases, such as the Santa Fe case, you can infer the drug maker’s intent purely by the instructions on the label. And, and that’s where we are here. The Kadcyla label, we can look at it. It’s at appendix 2252. Specifically says, “here’s Kadcyla you should give it to patients that have been previously treated trastuzumab and taxane.” That’s the infringement theory. That’s what the label says you should do.

Judge Stoll (09:15):

Do you think the Sanofi case makes it so the district court aired in relying on the non-substantial non-infringing uses?

Benjamin Thompson (09:25):

Exactly your honor. Because in off-label cases where you don’t have a label that specifically instructs infringement, you start to look other places to try and infer the drug maker’s intent because you don’t have the label to point to. And in that situation, like Judge Freeman did at the district court, she looked at the prevalence of the drugs used in the specific infringing scenario and other factors that were not appropriate to look at when you’re in a situation in an on-label case. And Sanofi actually says that says, “well, even if there are substantial non infringing uses, or there’s a low prevalence of the specific infringing subclass, that’s immaterial when the intent can be inferred from the drug label itself.

Benjamin Thompson (10:16):

Now Genentech’s response to the Sanofi case is that the Sanofi case is not applicable because that case involved instructions—sorry, that case involved instructions that were encompass the infringing use. Well, I had to disagree with Genentech where it says there’s a complete absence of any language encouraging Kadcyla use among the infringing class. That’s in Genentech’s brief that there is a complete absence of any language encouraging Kadcyl’s use among the infringing class. The Kadcyl label itself, specifically encourages the infringing use among the subclass. It says, “give Kadcyla after pretreatment with trastuzumab and taxane.” That was more than enough circumstantial evidence to find intent to get beyond summary judgment in this case. I’ll reserve the rest of my time for rebuttal.

Judge Reyna (11:11):

Thank you. Counsel Maynard.

Deanne Maynard (11:21):

Good morning, your honors, and may it please the court. Dean Maynard on behalf of Genentech, the district court acted well within its broad discretion in striking Phigenix’s late disclosed theory here, and that’s all the court would need to decide to affirm this case. The district court also correctly granted summary judgment of non-infringement. And on top of that, this patent does nothing but express a plan and a hope to look for something that might work with breast conditions. And it’s therefore invalid for three different reasons.

Judge Bryson (11:48):

That’s your cross appeal?

Deanne Maynard (11:49):

That’s our cross appealing.

Judge Bryson (11:53):

I don’t know whether it’s appropriate to deal with the cross appeal now or whether we should wait until let’s wait, but I do have a question for you on the cross appeal side.

Deanne Maynard (12:01):

Okay. Thank you. Just Judge Bryson. So I looked to start with the striking of the expert, because obviously gets a very deferential standard of a review from this court, which defers to a district court's both application and understanding of their local rules and their understanding what was going on in their courtroom. This district court had presided over this case for several years. At the time she struck this expert, she'd heard a tutorial, a claim construction hearing, she'd heard argument on Rule 11, she'd heard argument on two summary judgment motions. And she recognized that this was a marked change in the infringement theory and correctly so, and that it would prejudice us. And I can explain how,

Judge Stoll (12:40):

Where, where did yeah. Where is the prejudice?

Deanne Maynard (12:41):

The prejudice it's both in the invalidity and infringement Judge Stoll. So, this was before the infringement contingents basically were based on the Kadcyla label.

Deanne Maynard (12:53):

If you're taking in accordance with the Kadcyla label, then somehow that triggers this inference upon inference upon inference that infringes these patent claims. And throughout the litigation pre-suit to complaint 11 motion, everything. Genentech's position had been if your theory is right, if the giving Kadcyla to patients according to the label, i.e., to those who have had trastuzumab and taxane before they get Kadcyla triggers this inference upon inference upon inference that is your infringement theory. Then Genentech's own clinical trials anticipate your patent claim, inherent anticipation. What infringes infringes now, anticipates before. And that was Genentech's constant reframe. And the district court was aware of that. Our expert in infringement contentions—our expert on invalidity in his report relies on their infringement contentions. At page A190 expressly says, "I'm assuming your infringement contention theory." At A192, our expert lays out a comparison between the—there's a chart at the bottom of A192 that lays out the compares like the—what Genentech studied versus, and the label versus their contingent their infringement contentions.

Deanne Maynard (14:23):

And so, and the district court found that only after the court rejected their priority date claim to 2005, did they change their theory. And that debunks any notion they did and changed their theory. They did change their theory.

Judge Stoll (14:38):

It's about three months between the time that the court issued its order on the priority date and the time that the expert made their position clear in a deposition?

Deanne Maynard (14:48):

She issued her opinion on February 24th of 2017. The expert change announced—we found out about the change theory and the expert's deposition on May 31st, 2017. That was after the close of fact discovery, after export reports and rebuttal reports had been exchanged, and in the midst of expert depositions. And the district court found that that was the cause and effect. That they changed it, and they didn't tell anybody either. So they didn't comply with the local rules in trying to change it. And they knew how to comply with the local rules, because previously in the case, they had moved them in their infringement contingent after they did testing.

Judge Bryson (15:21):

Do you think there's a distinction between narrowing your theory of infringement and adding a negative

limitation, or is that, do you think just a semantic distinction?

Deanne Maynard (15:36):

No, I think it's critical, and it's what matters here. And, so to the infringement theory, what they did here was add a negative limitation. Yeah. And the upshot of that was—before it had been the entire Kadcyla population infringes, when you give Kadcyla, according to the label. Now it's affirmatively at least 95% of the patient population does not infringe. And this supposed subpopulation, which at best is less than 5% if it exists at all does—is the infringing population. Now Genentech does need to do different studies and different because we need, and we need to do discovery from them. Why now do you think—what's different? What's different about a patient who only receives trastuzumab and taxane and nothing else that makes them infringing when you don't think a patient who has received other chemotherapy agents infringes? We need to know from them why that's different. And now the 95% is effectively a control group, right? They say it doesn't infringe. We would need to test that. And we had no reason. So he says we should have tested the whole—we had no reason to test any subpopulation—they had never. And, and why, if, even if we thought they were breaking it up into subpopulations, which ones would we have chosen gender, age, you know, prior other conditions, health factors.

Judge Bryson (16:52):

Suppose that I'm struggling to try to distinguish between the narrowing that one would regard as being sort of in the ordinary course of things. You drop a few claims or you drop out several patents. Those are narrowing that no one would even blink an eye at. That's happens all the time. It's perfectly fine, versus the kind of prejudicial negative limitation or other changes that you're saying really do change the whole ball game in a potentially prejudicial way. I mean, if I added that we–our claims only extend to people with gray eyes, let's say. I mean, that's not technical a negative limitation, but it is a, a strong restriction of the class of potential infringing conduct in a way that I suppose, would you say that something like that had the potential for prejudice in it?

Deanne Maynard (17:51):

It could.

Judge Bryson (17:52):

For the same reason that you're saying?

Deanne Maynard (17:53):

It could. And let me try another way to explain why this is prejudicial here. All along their—we were taking their infringement theory, their broad infringement theory that the whole Kadcyla patient population infringes as a concession, that any art that covered that population would therefore anticipate if it predated the patent.

Deanne Maynard (18:11):

Yeah.

Deanne Maynard (18:12):

They took away that concession, that would change the—you know, how we would frame our inability defenses. They also then added a concession, which is 95% of your patient population does not infringe. And the district court entered summary judgment on that. And they haven't appealed that that's at A4 and A21. So now they're conceding something different. They've taken away the concession we were relying on for our invalidity case. So we need to retool our invalidity defenses.

Deanne Maynard (18:38):

And they're adding a concession that we didn't know about that now we need to figure out, well, "why is it you think those people don't infringe and what is it about your claims and the Kadcyla drug that makes it act differently in these two sets of populations"? And so whatever may be in the case, in other cases, and, you know, you can think of all different kinds of hypothetical—this case. It was prejudicial. The district court, who was very familiar with this case and the theories the parties had advanced in it, recognized it was a change, recognized that prejudice Genentech, recognize that in laying prejudice aside that, you know, separate and apart, the district court concluded, they violated the local rules by not moving to amend at which would've required them to show diligence in doing so, like they'd done that they moved timely, and she concluded they hadn't moved timely.

Deanne Maynard (19:25):

She concluded that if they wanted to change their opinion after her February order, they needed to do so right away. And I said, as your honor mentioned, they late waited until May. And they didn't exactly directly tell us. We had to confirm with them that their expert had meant to change their theory. And she said that prejudice Genentech, it was too far along. The case trial was set for November of that year. Trial was set for months away. And the judge said, in her order, that their failure to comply with the local rules had affected her ability to potentially accommodate the schedule. I could—if I could shift, I'm happy to ask, answer more questions about like shift to inducement for just a second.

Judge Stoll (20:00):

Could you, you just talk about the Sanofi case?

Deanne Maynard (20:03):

Yes.

Judge Stoll (20:03):

Okay.

Deanne Maynard (20:03):

Yes, your honor. Be glad to, so this is different than the Sanofi case because in the Sanofi case, this court recognized that the label there expressly called out the sub class that was infringing. It's—this is diff—this case is a different in two ways from Sanofi.

Deanne Maynard (20:16):

Yeah. This case in some ways, not like anything you've ever had. Because what they're claiming is that this the label, which says, "gives to somebody who's had trastuzumab and taxane saying it's totally silent as to two things in a way that is different from Sanofi. It's completely silent. Absolutely. Nothing about encouraging, actively promoting inhibiting Pax2, or expressing [inaudible], which is what their claims cover. So most of your cases, there's no there's no space or leap of faith between, well, "are you or are you not encouraging giving this drug to somebody who has the hospitalization risk factors that are covered in the claims"? The question in Sanofi was, you know, did, "does the label do that"? And this court said, yes, it does. Because it says, give the drug. And then the only example of people who would give the drug for that purpose were in the Athena trial, which was there and it laid out the factors. That's not this case. There's nothing in this case that directly, you know, where the, the label here is silent. Both as to the claims, it says nothing to disclaim. And it's also silent as to this supposed subclass. There's no active inducement with respect to those who have received and nothing else. And then, unlike Sanofi as well, the district court concluded that this is a hidden non-compliant subclass at best with the standard of care. And in Sanofi the facts were the opposite that it was a, you know, a vast majority of people—

Judge Bryson (21:41):

Do, do you think that the same analysis would apply it again to go back to my example with gray eyes? If the additional limitation were people give this drug only to people with gray eyes, that's the infringement contention, and the label says nothing about gray eyes. It just says, "give the drug to people who satisfy the two pre-precursor drug requirement."

Deanne Maynard (22:06):

Well, I think the label—

Judge Bryson (22:08):

Would there be inducement in that case, because the theory would be, of course, that, of course you would've expected the gray-eyed people would be among the category of people that would take it since you didn't have any indication that it would be limited to people with particular color-eyes.

Deanne Maynard (22:21):

Under the Supreme court's case law and this court's case law, I don't think you could infer from a label that was silent about gray eyes, the level of promotion and encouragement that would be required to allow a case based solely on the label as this one is. And in here, there's the added fact that they don't dispute that at best, you know, this supposed subclass is less than 5%. It's a very small—the vast majority of the patients, and that's backed up. They would be receiving a contrary to the standard of care. The ASCO standard of care is that you should receive a third agent Perjeta.

Judge Bryson (22:59):

Would, would your answer be different if it was the class that was identified was not 5%, but was 95%?

Deanne Maynard (23:06):

It would be perhaps a harder case, your honor, but no, I think the label would still be silent. The label is silent. And again, the golf here between what the label says at all and what the claims cover. So, you know, and that's what the—there's that you get into the willful blindness here. There's no evidence that Genentech knew that encouraging anybody to take Kadcyla was causing the expression of PAX, the inhibition of Pact 1 and expression of [inaudible]1B.

Judge Stoll (23:36):

Do you think, um, willful blindness has any application at all to intent? I mean, the Supreme Court talks about it in terms of knowledge in global tech, but not intent. And from the criminal law, from which it drives, it's really talking about knowledge, not intent. So do you think willful blindness has a place when we're analyzing intent?

Deanne Maynard (23:55):

Well, I think, you know, one can like break it down into sort of too many buckets that, to not matter. The question is, do we meet the statute which requires active inducement. And you have to have this specific intent to promote or encourage someone to infringe the claims, not just take an act. And when you—when you look at here, there's no—we had no knowledge that giving Kadcyla to anyone, much less, this subpopulation that they've come up with very late, late, late into to the case was infringing their patent claims.

Judge Bryson (24:29):

Could I ask you about the cross appeal?

Deanne Maynard (24:30):

Yes, please.

Judge Bryson (24:31):

I'm wondering why we have jurisdiction over the cross appeal. Now you've correctly, I think, identified this as a cross-appeal case, perhaps in an excess of caution. But in any event, but the problem I see is that this is the denial of summary judgment, which normally we don't have jurisdiction to review. So why is it that we have jurisdiction to review the denial of summary judgment, which is in the posture of a cross appeal, not in the posture of defending a judgment on an alternative ground, because it seems to me, and I'm, we have a couple of cases that talk about this. It seems to me that there's no jurisdiction in that setting unless I'm missing something.

Deanne Maynard (25:15):

Well, so we did not raise a counterclaim. This is a just a defense in this case. And so it is an affirmative.

Judge Bryson (25:24):

Go ahead.

Deanne Maynard (25:24):

So I think you're appellate jurisdiction, Judge Bryson, stems from the 1291 judgment on non-infringement that's the judgment is properly in this court. They, and, and if, but—

Judge Bryson (25:35):

Are you suggesting we have pendant appellate jurisdiction here over the cross appeal?

Deanne Maynard (25:39):

No, no, I'm suggesting that—so, the there's only one claim here in this case, theirs. We did not make a declaratory judgment—

Judge Bryson (25:47):

Okay. Well maybe let me make myself clear on the thing that is bothering me .

Deanne Maynard (25:49):

Okay.

Judge Bryson (25:49):

Either it's not a cross appeal, which I thought was where you were kind of going, or it is a cross appeal. If it is a cross appeal, it does seem to me that you have to satisfy all the requirements for jurisdiction for an appeal, which would mean that you couldn't appeal from the denial of summary judgment. If it's not a cross appeal, i.e., for some reason, such as that you didn't file a counterclaim, but rather you filed the defense and therefore you couldn't—your judgment isn't going be broader than a simply a non-infringement judgment. Then it seems to me have to deal with the problem that the judgment, if it's predicated on your defense of invalidity, it actually is broader in its effect on the plaintiffs, right? Because in a later proceeding, for example, the collateral estoppel effect of a judgment on—that it's predicated on in validity, would bar them in a way that a judgment predicated on non-infringement would not. So it seems to me that suggests that it does have to be a cross appeal. And if so, where do we have jurisdiction?

Deanne Maynard (26:55):

Well, so I think you have jurisdiction over the case. The only claim in the case is their claim. The only claim

in the case, that's their claim for infringement. The judgment on that claim was entered in our favor on grounds that we don't infringe, and that they have no evidence of infringement. And that that's the 1291 judgment, that judgment's on appeal. We noted. I think the two—I think there are two separate issues. I agree with your analysis completely, but I think except the conclusion, which is—

Speaker 1 (27:19):

<Laughs>

Deanne Maynard (27:19):

I think there's two there's—but I think because I think the questions are separate. Do you have appellate jurisdiction over the judgment? Yes. I think you do under 1291. The only claim is their claim. Judgment is entered. There's a final judgment in this case. That case is properly in this court. If we want to defend the judgment of non-infringement on the alternative grounds, that the claims are invalid, because that would—I think you could conclude two things because that it can't be that you can't reach it because it's an alternative ground to the judgment that's properly before you.

Deanne Maynard (27:50):

So I think you could conclude one of two things: we didn't need to cross appeal. And we did so out of an abundance of caution, and we wrote our opening brief within the word limits of a regular brief in case you decided we were mistaken, and then you can strike our reply brief. And I still hope you would address the invalidity because these issues are important, but, or you can conclude that you have jurisdiction appellate jurisdiction over the whole case. And we properly noted a cross appeal because as you note, ruling affirming in the alternative ground on invalidity would lessen their rights and enhance ours. And so we've properly given, you know, noted and appeals on that basis.

Judge Bryson (28:27):

Sounds like what you're saying is there's pendant appellate jurisdiction.

Deanne Maynard (28:30):

Okay. Well, yeah. I'm happy for you to label it that way.

Judge Bryson (28:34):

Well except that we have cases that say that you can't use appellate, pendant appellate jurisdiction in this setting.

Deanne Maynard (28:38):

Well, but this is an affirm—this is an alternative ground, right? To affirm the only claim in the case and the only judgment in the case. So—

Judge Bryson (28:48):

But it's an alternative ground, which you are required to bring as a cross appeal by hypothesis [inaudible].

Deanne Maynard (28:55):

I that, right. And, and I think that unlike in Cardinal chemical, unlike if we had brought a declaratory counterclaim, this court's not like required to reach our invalidity claim. And so you could like, as if I had appealed a claim construction issue, for example, in the midst of their appeal, for which there was also—that's an example for which there's also no, you know, separate appealable— I couldn't appeal a claim construction issue, but I can raise it in my red brief as an alternative ground.

Judge Bryson (29:21):

So this is a conditional cross appeal in your view?

Deanne Maynard (29:26):

No, because I think a conditional cross appeal, it has a different meaning. I think it's—

Judge Bryson (29:33):

Well, in other words, if we rule in your favor on the issue on which you're appellee, are you saying we nonetheless should deal with a cross appeal?

Deanne Maynard (29:41):

I think you don't have to—

Judge Bryson (29:44):

Well, do you want us to?

Deanne Maynard (29:44):

And I think we would like you to hold these patents invalid because just as a public service. Like these patents are just merely a plan to hunt for something. They lack utility. They aren't enabled. They are hugely broad. They don't specify any compounds—that if you just look at the indirect inhibition and they tell no one how to do it, and they don't certainly don't sow possession of the broad breadth of their claims.

Judge Reyna (30:06):

So if we rule in favor of the appellee, you withdraw the—what you've called your cross claim?

Deanne Maynard (30:11):

Well, so if you—I think you can affirm. I think it's up to the court's discretion whether to go on and decide the invalidity, if you affirm the judgment on either of the grounds given by the district court.

Judge Bryson (30:22):

In the course of your research on this you, you do cite the [inaudible] case, which seemed to me to be appropriate. Did you run across the advanced software design corporation?

Deanne Maynard (30:34):

That standing here that I don't recall.

Judge Bryson (30:37):

Alright, and SIMCon against Mycron. Those are two cases that deal with this problem. Now, advanced software is like this case with one exception, which is an exception you've pointed out. That it had a counterclaim in it. So I'm—other than that—it's a cookie cutter of this case. So, I'm wondering is that enough to convert this from a case in which, as in the advanced software case, we dismissed the cross appeal into a case in which we don't?

Deanne Maynard (31:07):

I think that—

Judge Bryson (31:09):

Your suggestion earlier was yes, that's an important factor.

Deanne Maynard (31:11):

I think yes. I think it is an important factor because I think the only claim in this case, there was final judgment under 1291, and that case is properly before the court. And we have noted a cross appeal out of an us of caution in case you perceived that ruling for us on this alternative ground to get to the same judgment of non-infringement would enhance our rights or lessen theirs. But I don't think you need separate appellate jurisdiction over that cross appeal, given that there's only one claim in the case and the final judgments under 1291. But I'd be happy to submit a letter on those cases if you would like, your honor. I think—have I run over my time?

Judge Reyna (31:47):

Yes, you've run well over your time.

Deanne Maynard (31:47):

I apologize time. Thank you. Judging Reyna. We would request that you affirm.

Judge Bryson (32:00):

Hello, again.

Benjamin Thompson (32:00):

Hello.

Judge Bryson (32:00):

Do you have anything to say on the on the viability of the cross appeal?

Benjamin Thompson (32:08):

I do not. I trust this panel will make the right decision. We're willing to talk about the invalidity issues.

Judge Bryson (32:14):

You may have too much confidence in us <laughs>.

Benjamin Thompson (32:19):

I would like to talk about a couple of things Ms. Maynard raised. One of them was there's this narrative about how this alleged change or narrowing of Phigenix's infringement theory stem from the court's decision on a priority date issue. As Ms. Maynard recognized that decision came down in February of 2017. the month before that in open court, Phigenix's former council made it clear that the infringement theory concerned a combination of trastuzumab and taxane with Kadcyla and nothing else. And that is at appendix page 429 and 430. Specifically, there was discussion of some potential, potentially invalidating prior art. And Phigenix's council said that, well, "this previously clinical trial, they're being given a much different cocktail here. That's not just trastuzumab and taxane." In the end, I think that Phigenix agrees with the district court's initial impression of this issue, which the judge announced at a hearing on these motions and that's at appendix 349. The district court said "I'm loathed to strike the infringement contention because the way it's worded. I don't think it needs to say trastuzumab and taxane and nothing else when it says trastuzumab and taxane." That's what the contention is. And just to be clear, [inaudible] is a brand of trastuzumab.

Benjamin Thompson (33:51):

On the prejudice issue, Genentech recognizes that the district court did find there could be some prejudice, however, the actual prejudices were never really explained. Again, if the infringement contentions say "I'm targeting people with gray eyes, blue eyes, and green eyes," and then later the expert says, "well, sorry, I

can't support those theories on the latter two." The defense still has to prepare its non-infringement position with respect to the gray eyes—

Judge Stoll (34:20):

What about what we heard from Ms. Maynard about how the—with the broader infringement contentions, there was some ability to rely on those for proving validity or in validity in this case?

Benjamin Thompson (34:36):

And, theoretically speaking, there could be a case where the infringement theory is narrowed and necessarily the claim interpretations that the plaintiff is adopting have narrowed, and some piece of prior art that would have applied to the broader theory doesn't apply. However, I haven't seen from Genentech any specific prior art that falls into that bucket.

Judge Stoll (34:57):

I think their position is that they were practicing the prior art. And, so they were practicing the part that was then not included in the more narrowed infringement contentions.

Benjamin Thompson (35:10):

Again, I didn't see that argument being made in the briefing or any specific instance of a piece of prior art.

Judge Stoll (35:15):

But if that were the case, would that be prejudice then?

Benjamin Thompson (35:19):

It could be. And on the abuse of discretion point, applying an opposite law, I believe this court has told us, is an abusive discretion. I will hit the validity issues with the time I have remaining. Some common themes across the validity issues is that invalidity has to be shown by clear and convincing evidence. These specific invalidity issues we're dealing with in Genetech's cross appeal are highly factual in nature. Utility is a question of fact, written description is a question of fact, and enablement is a question of law. But the real dispute here pertained to whether there was undue experimentation, which is also a factual inquiry. On enablement, the real question came down to was any experimentation required undo? And there was no real quantifying evidence or evidence quantifying the amount of this experimentation that would've been required.

Benjamin Thompson (36:15):

Phigenix's expert analyzed the wands factors and said, "no, undo experimentation." Genentech expert says, "well, it looks like the number of compounds you'd have to identify would be enormous." I don't know what enormous means. The district court didn't either. This case is not like the YF case, where there was evidence showing that the experimentation would've had to been performed on tens of thousands of compounds. Each of which would've taken weeks to assay; that's a lifetime of undue experimentation. We don't have any such quantifying evidence here. On written description, Phigenix presented expert testimony on the issue, extensive expert analysis saying the person of ordinary skill in the art would've understood that the inventor was in possession of the invention. Genentech countered that with attorney argument only. And for utility, this court has told us that utility is not a high bar. There's no debate that the patent discloses utility with respect to prostate cancer Phigenix's expert provided testimony, indicating that you could correlate those findings and understanding with respect to prostate cancer over to breast cancer, showing the utility there. And I believe I'm out of time.

Judge Reyna (37:26):

Thank you.

Benjamin Thompson (37:27):

Thank you.

Judge Reyna (37:32):

I'm going to give you back your three minutes.

Deanne Maynard (37:38):

Thank you, Judge Reyna. I really appreciate that. And I'll limit my comments to the cross appeal. This patent, as I indicated in my opening remarks, really just sets forth a plan to hunt for something that may or may not work with breast cancer. Every working example is about prostate cancer and there's nothing—and so basically for the same reasons, it lacks utility. It's not enabled. And it lacks written description. I'm happy to focus on any one of those theories, if your honors would like. But as far as utility, our expert gave unrebutted testimony that a person of skill in the art would not just infer from the fact the prostate working examples that they would work with breast cancer. And the patent only says what could be done, what might be done?

Deanne Maynard (38:38):

The examples beginning with example,12 will be determined, you know, might be considered. The district court held that there was nevertheless a dispute of fact because there was—she felt like there was analytical reasoning. The patent to go from the one to the other, but as this court held in Rasmuson and Jansen, mere analytical reasoning is not enough unless a person of skill in the art would consider it to be obviously correct. And, as I said, there's unrebutted testimony from our expert at appendix 168 paragraph one and appendix 2300 to 2301 that an expert wouldn't expect it to work. In terms of enablement, that's a question of law. And this court can decide here. The claims are extremely broad. It's a method of treating compositions that are defined only by their function. So, and under the claim construction order, it doesn't encompass just things that directly affect Pax2, or [inaudible], but also anything that indirectly affects the pathways upstream from them in such a way that it affects them.

Deanne Maynard (39:42):

And that—it's undisputed is an enormous subset. And they say, "well, it would be routine." All they say is "well, it would be routine to task." But one, all they say is it would be routine to test for Pax2, but there's not a single example of a class of compounds or any compound within then that you could use to treat breast conditions. So at column eight through column 12, there's just a laundry list of large molecules in small molecules in. But they point to nothing in the patent, and nothing in the patent teaches anything about treating, which you even an example of something that treats breast conditions or breast cancer. And then there's no examples of how to affect [inaudible], which the claims cover as well. Instead, they focus on, well it'll be routine to test for what affects Pax2. But even under YF, the enormous number of compounds that would need to be treated, especially given their infringement theory.

Deanne Maynard (40:35):

Now that it matters what you've had before. So not only do you have to figure out which compounds are in this set, you have to figure out like, and under what conditions would it matter? And nothing in the patent teaches someone of skill in the art how to do that. Written description. It's a similar problem, you know—they say it's a question of fact, but under this court's decision in Rochester, a patent can validate itself. And, and that's the situation here as a matter of law. And I think the shortest path from the specification here to invalidity on written description is the claim to the indirect inhibitors. So as I said—

Judge Reyna (41:10):

Can you conclude your—

Deanne Maynard (41:10):

Oh, yes. So, sorry. I apologize. Thank you Judge Reyna for your patience. And we request that you affirm the judgment.

Judge Reyna (41:16):

We thank the parties for their arguments.