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# Transcript of Oral Argument

**Case:** Regeneron -v- Mylan

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

**Petitioner Fresenius Ex. 1008, 0001**

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| <p>1<br/>2<br/>3<br/>4<br/>5<br/>6<br/>7<br/>8<br/>9 Regeneron Pharmaceuticals, Inc. v.<br/>10 Mylan Pharmaceuticals Inc.<br/>11<br/>12 Court of Appeals for the Federal Circuit<br/>13<br/>14<br/>15<br/>16<br/>17<br/>18<br/>19<br/>20<br/>21<br/>22<br/>23 Job No.: 585226<br/>24 Pages: 1 - 69<br/>25 Transcribed by: Christian Naaden</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p>1 FEMALE 2: Correct.<br/>2 JUDGE 2: Right? On the same page you say<br/>3 the AsoPha -- DropGenetics prior art anti-VEGF<br/>4 intravitreal form- -- formulation Lucentis not<br/>5 Regeneron's?<br/>6 FEMALE 2: Correct.<br/>7 JUDGE 2: Is that correct?<br/>8 FEMALE 2: Yes. So the -- we -- the --<br/>9 we're differentiating between the active<br/>10 ingredient, which is the anti-VEGF and the<br/>11 formulation that you actually carry the drug in,<br/>12 which is the formulation. So all of the formulation<br/>13 ingredients are all of the ones that are under the<br/>14 anti-VEGF drug descriptor.<br/>15 So histidine is the same for Lucentis and<br/>16 ours [ph], trehalose is the same for Lucentis and<br/>17 ours, polysorbate is the same for Lucentis and ours<br/>18 and then water. So all -- so those five -- those<br/>19 ingredients, they're under anti-VEGF. Those are the<br/>20 formulation ingredients. So the drug is the anti-<br/>21 VEGF compound.<br/>22 So Lucentis is the anti-VEGF drug compound<br/>23 then VISMED and the Espholi and Eylea have the<br/>24 anti-drug -- the anti-VEGF drug called the<br/>25 Aflibercept. However, if you look at the</p> |
| <p>1 PROCEEDINGS<br/>2 JUDGE 1: The next case for argument is<br/>3 24-2002, Regeneron Pharmaceuticals v. Mylan.<br/>4 FEMALE 2: Good morning, Your Honor. May I<br/>5 please report the Amazaki [ph] for Biocon Mylan<br/>6 defendant's appellant? May I proceed?<br/>7 JUDGE 1: Yes, please. Good morning.<br/>8 FEMALE 2: Thank you. Thank you. The<br/>9 district court's infringement validity and remedy<br/>10 judgments for the Bio- --<br/>11 JUDGE 2: Counsel, let me ask you a<br/>12 housekeeping question.<br/>13 FEMALE 2: Sure.<br/>14 JUDGE 2: Page 7 of your lieu brief --<br/>15 FEMALE 2: Yes.<br/>16 JUDGE 2: -- there's a chart. I'd like you<br/>17 to turn to it.<br/>18 FEMALE 2: Yes.<br/>19 JUDGE 2: Uh, the chart shows that<br/>20 Lucentis says anti-VEGF rends this amount of money.<br/>21 Right?<br/>22 FEMALE 2: Yes. [Inaudible].<br/>23 JUDGE 2: It then shows that both the<br/>24 YESA- -- YESAFILI and Eylea have anti-VEGF<br/>25 Aflibercept.</p> | <p>1 formulation ingredients -- and that's what the 865<br/>2 Pad was about, it's directed to pharmaceutical<br/>3 formulations -- our pharmaceutical formulation is<br/>4 actually different from the commercially marketed<br/>5 product.<br/>6 We use a histidine buffer, they use sodium<br/>7 phosphate buffer. We use trehalose as a -- a sugar<br/>8 stabilizer, --<br/>9 JUDGE 2: Mm-hmm<br/>10 FEMALE 2: -- they use sucrose,<br/>11 polysorbate, yes, in water, obviously, those are<br/>12 all the same, but Regeneron also adds a salt that's<br/>13 called sodium chloride. So they are not identical<br/>14 formulations.<br/>15 JUDGE 1: Okay. There are a lot of issues<br/>16 in this case and we've --<br/>17 FEMALE 2: Correct.<br/>18 JUDGE 1: -- got a 300-page district court<br/>19 opinion.<br/>20 FEMALE 2: We do.<br/>21 JUDGE 1: So it's kind of hard to tackle<br/>22 and -- but let -- so let me just ask you some<br/>23 scattered questions.<br/>24 FEMALE 2: Sure.<br/>25 JUDGE 1: I mean, my question is about</p>                                                                                                                                                           |

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| <p>5</p> <p>1 obviousness and then about anticipation.<br/> 2 FEMALE 2: Okay.<br/> 3 JUDGE 1: But what obviousness combination<br/> 4 are you appealing? Is it Dixelone [ph] or is it<br/> 5 Frazier, and Gutter, whatever the other one is?<br/> 6 FEMALE 2: Yeah, both. So there were --<br/> 7 there were two issues. So first we said that --<br/> 8 that the claims were obvious in view of Dixelone<br/> 9 because Dix is the one that basically has Eylea<br/> 10 formulation and really the only difference is the<br/> 11 dose amount in terms of a range where it says --<br/> 12 what Regeneron calls its species.<br/> 13 Then we also had what we are referring to<br/> 14 as the description of Aflibercept that were in the<br/> 15 prior art, which was the frazion [ph] reference in<br/> 16 combination with what we're calling the Lucentis<br/> 17 prior art and that's comprised of two main<br/> 18 references, one of which is the drill reference,<br/> 19 the other of which is called the shans [ph]<br/> 20 reference.<br/> 21 But both of those references we're<br/> 22 essentially discussing this -- this type of<br/> 23 Lucentis formulation here where it's an<br/> 24 intravitreal formulation, it was actually used in<br/> 25 the eye and, you know, had the -- the anti-VEGF</p> | <p>7</p> <p>1 that?<br/> 2 FEMALE 2: Sure. And I think you see that<br/> 3 in cases such as ClearValue --<br/> 4 JUDGE 1: Yeah. It's hard though, because<br/> 5 we have -- I don't think we found the case. You've<br/> 6 got cases with one range and the other probably<br/> 7 [inaudible] has--<br/> 8 FEMALE 2: Right.<br/> 9 JUDGE 1: -- one range and the Pam [ph]<br/> 10 has another. You've got one where the prior art has<br/> 11 one and the other -- but I -- I haven't found a<br/> 12 case, which is our case, which is the prior art has<br/> 13 the range and the patent has just one.<br/> 14 FEMALE 2: Right. Well, I -- I think that<br/> 15 one of the close ones that would come up with be<br/> 16 the Purdue Pharma v. Epic. In that instance had a<br/> 17 situation where it -- it's similar to what<br/> 18 Regeneron is arguing here in the sense here that<br/> 19 you had a broad description for the drug compound<br/> 20 to be -- that was prior art that was for analgesic<br/> 21 treating pain.<br/> 22 And then this report said it was<br/> 23 anticipatory to have a formulation that was<br/> 24 directed to opioids and opioids and analgesics. And<br/> 25 the reason why is because opioids were obviously</p>                                                                                    |
| <p>6</p> <p>1 drugs in it. So one of the --<br/> 2 MALE 2: How do you pronounce that anti-<br/> 3 VEGF drug [inaudible]?<br/> 4 FEMALE 2: So Ranibizumab is --<br/> 5 MALE 2: Can we just all it the R drug?<br/> 6 FEMALE 2: We can absolutely call it the R<br/> 7 drug and then the other one, the A drug, is<br/> 8 Aflibercept.<br/> 9 MALE 2: Aflibercept.<br/> 10 FEMALE 2: Yeah.<br/> 11 MALE 2: And that's an important one. We<br/> 12 should say Aflibercept.<br/> 13 JUDGE 1: Well, let me take -- take you<br/> 14 back to the list --<br/> 15 FEMALE 2: Sure.<br/> 16 JUDGE 1: -- up to the anticipation.<br/> 17 FEMALE 2: Sure.<br/> 18 JUDGE 1: I mean, the two issues that are<br/> 19 not disturbing to me but that raised some questions<br/> 20 are this criticality and the anticipation of 40 vs.<br/> 21 10 to 50 --<br/> 22 FEMALE 2: Correct.<br/> 23 JUDGE 1: -- and then the teaching away<br/> 24 with the district court bond. So what is your view<br/> 25 of our case law and what it compels with respect to</p>                                                                                                                                                                                                                                                                      | <p>8</p> <p>1 anal- -- were -- were known and established to<br/> 2 those who weren't very skilled in the art, in -- in<br/> 3 the background knowledge as drugs that were used as<br/> 4 analgesics to treat pain.<br/> 5 And in that instance you didn't even have<br/> 6 the prior art reference mentioning opioids<br/> 7 specifically but again, it was understood in the<br/> 8 sense of what does a person of ordinary skill in<br/> 9 the art when they see the reference actually<br/> 10 understand it to be not just reaching in terms of<br/> 11 specific examples but also what is the nature of<br/> 12 the enabling disclosure.<br/> 13 And I think that's one of the [inaudible]<br/> 14 where the district court fell down here, because<br/> 15 the district court was very much focused on, well,<br/> 16 you don't have an example that was actually put to<br/> 17 intravitreal use in Dix.<br/> 18 The problem with that though is if -- and<br/> 19 -- and, Your Honor, to get to your point in terms<br/> 20 of the chart on Page 7, if we were to look at the<br/> 21 Eylea formulation and we look at the formulations<br/> 22 that are in the examples in Dix, you have those<br/> 23 identical ingredients there and instances and the<br/> 24 same amounts.<br/> 25 So the only distinction in terms of what</p> |

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| <p>9</p> <p>1 was there was a drug amount 10 to 50 versus they</p> <p>2 had limited their claims here to 40. And when you</p> <p>3 have an enabling disclosure, and in fact, when the</p> <p>4 865 patent itself says that not only that</p> <p>5 particular drug range in Dix but an even broader</p> <p>6 range from 1 to 100 is also going to work to give</p> <p>7 you these stable --</p> <p>8 JUDGE 2: I'm sorry to interrupt. I'm a</p> <p>9 little confused. I would have expected you to have</p> <p>10 said the word criticality by now.</p> <p>11 FEMALE 2: Sure.</p> <p>12 JUDGE 2: And you didn't say it so and now</p> <p>13 --</p> <p>14 FEMALE 2: Well, and that's what I --</p> <p>15 JUDGE 2: -- we- -- went off on Purdue</p> <p>16 Pharma and then went to some other territory, and</p> <p>17 my understanding was the focus of your briefing was</p> <p>18 -- if it was the patent on the [inaudible] to show</p> <p>19 that the 40mg per milliliter formulation was</p> <p>20 critical.</p> <p>21 FEMALE 2: Right. Because that gets to the</p> <p>22 genus species issues when to --</p> <p>23 JUDGE 2: And -- and -- and then</p> <p>24 obviously, the district court found otherwise and</p> <p>25 now we have to sort out what does our range case</p> | <p>11</p> <p>1 look at subsequent cases though that had been</p> <p>2 interpreted and applied at [inaudible] such as the</p> <p>3 ClearValue Polymers case, the -- the critical issue</p> <p>4 that -- in terms of why were we concerned that that</p> <p>5 genus and Atofina was so big is because it was not</p> <p>6 actually describing and enabling what came later in</p> <p>7 the claim species so much so that hit actually did</p> <p>8 operate in a different way, and I think that in the</p> <p>9 ClearValue case they make that clear that when they</p> <p>10 are discussing Atofina they said yeah but in</p> <p>11 Atofina, that species that was selected</p> <p>12 fundamentally worked in a different way. So that's</p> <p>13 news.</p> <p>14 JUDGE 2: A- -- and just getting getting</p> <p>15 to just both initial question cases like, I don't</p> <p>16 know, INEOS and ClearValue, etc., there seem to be</p> <p>17 a claimed range inside of a broader prior art</p> <p>18 range. Right?</p> <p>19 FEMALE 2: Sure.</p> <p>20 JUDGE 2: And here we have not a claimed</p> <p>21 range but a claimed point. And then the question is</p> <p>22 well, when we look at INEOS or ClearVa- -- Value or</p> <p>23 anything else I can get my hands on, I don't see</p> <p>24 that specific fact pattern.</p> <p>25 A prior art range and then a claimed point</p> |
| <p>10</p> <p>1 law really say --</p> <p>2 FEMALE 2: Right.</p> <p>3 JUDGE 2: -- and -- and demand in terms of</p> <p>4 making an anticipation case.</p> <p>5 FEMALE 2: Right. And -- and you're</p> <p>6 exactly right Judge [inaudible]. I think the</p> <p>7 district -- this is where the reas- -- one of the</p> <p>8 reasons why the district court went astray as well,</p> <p>9 to me when you're looking at criticality issues,</p> <p>10 you're looking at what is claimed as compared to --</p> <p>11 JUDGE 2: Well, the first question is --</p> <p>12 FEMALE 2: -- what is the next prior art</p> <p>13 range.</p> <p>14 JUDGE 2: -- the first -- first question</p> <p>15 is before we try to assess what does criticality</p> <p>16 mean is do we even look to criticality in the first</p> <p>17 place.</p> <p>18 FEMALE 2: Right.</p> <p>19 JUDGE 2: And so, the district court said</p> <p>20 no. In this context, we don't because there's a</p> <p>21 case called Atofina that says you just look at</p> <p>22 something as a genus. And then if I concluded that</p> <p>23 the genus was too big then I don't have to go any</p> <p>24 further, there's no anticipation.</p> <p>25 FEMALE 2: Right. But I think that if you</p>                               | <p>12</p> <p>1 inside of that range, do we think about that fact</p> <p>2 pattern the same or differently from the claimed</p> <p>3 range inside of a prior art range?</p> <p>4 FEMALE 2: Right. And that's why we went</p> <p>5 back to some of the -- the early -- you know, the</p> <p>6 earlier classic cases such as Peter and Rusheg</p> <p>7 [ph]. And I think there again, when you look at</p> <p>8 what those clients are talking about when they're</p> <p>9 saying, you know, it -- it really gets back to, and</p> <p>10 I think the crazies was, was it really described</p> <p>11 for purposes of Section 102B.</p> <p>12 So I think here when you have a situation</p> <p>13 where we have with Dix and with the formulations</p> <p>14 here, you have the same ingredients, the same drug</p> <p>15 involve, and you've got a range of 10 to 50 to</p> <p>16 select this [inaudible] so to speak.</p> <p>17 JUDGE 2: You're -- you're -- you're --</p> <p>18 you're getting back to the facts. I -- I'm -- I'm -</p> <p>19 -</p> <p>20 FEMALE 2: Well, the -- but pri- --</p> <p>21 JUDGE 2: -- I'm -- I'm thinking about the</p> <p>22 law.</p> <p>23 FEMALE 2: Right. But I think from the</p> <p>24 legal perspective, I think you make the -- you --</p> <p>25 you just get back to what was described in the</p>                                               |

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| <p>13</p> <p>1 nabel [ph]. So for example, you know, do we have<br/>2 any blaze marks that sufficiently direct a person<br/>3 of ordinary skill of the art towards a particular<br/>4 issue.<br/>5 That -- yeah, maybe if you've got a genus<br/>6 that's got, you know, 10 billion compound<br/>7 possibilities in it and now I'm going to select the<br/>8 single compound species. Maybe that's not going to<br/>9 be good enough.<br/>10 However, if you've had a situation where<br/>11 you've already got an existing range and he<br/>12 district court here actually made findings that,<br/>13 you know, you -- that a -- that a person of<br/>14 ordinary skill in the art would certainly be able<br/>15 to make the full scope of what's within this range,<br/>16 and it's the composition and you haven't<br/>17 articulated any new use or any particular way in<br/>18 which this composition will be used [inaudible].<br/>19 JUDGE 2: But if it's not that specific<br/>20 number the patent has a possibility of blindness.<br/>21 FEMALE 2: No. See, that's -- that's one<br/>22 of the issues with the district court actually got<br/>23 the test wrong because when you're going to talk<br/>24 about criticality, it has to be criticality against<br/>25 what the prior art range was. So show me the 40 the</p> | <p>15</p> <p>1 about 40 that worked better or differently as<br/>2 compared to --<br/>3 JUDGE 2: Can you give me an example? I<br/>4 mean, I -- I --<br/>5 FEMALE 2: -- everything else in the range<br/>6 of 10 to 50. So -- and -- and I could --<br/>7 JUDGE 2: When you say better -- I -- I am<br/>8 just trying to get an understanding what you think.<br/>9 FEMALE 2: Sure. One -- one that meets<br/>10 this court's standards, for example, a difference<br/>11 of degree and not in kind or a new established<br/>12 utility or something that actually a person of<br/>13 [inaudible] skilled art wouldn't have been enabled<br/>14 to do with this composition that they already had<br/>15 in Dix. And that's where I think we get to the<br/>16 fundamental problem here is that particularly once<br/>17 the district court said that these claims that --<br/>18 JUDGE 2: Getting to some of the other<br/>19 issues on 102, it seems --<br/>20 FEMALE 2: Sure.<br/>21 JUDGE 2: -- like the district court<br/>22 identified other reasons for why there is a lack of<br/>23 anticipation with the [inaudible] reference aside<br/>24 from this 40 and 50 business.<br/>25 FEMALE 2: Sure. Well, the only other one</p>                                |
| <p>14</p> <p>1 species somehow performs differently than 10 to 50.<br/>2 And he didn't make that finding. He said,<br/>3 "Oh, well let me look at how it's go- -- how I<br/>4 think it might compare based on how a Ranibizumad<br/>5 drug compare and how a Ranibizumad drug perform<br/>6 [inaudible].<br/>7 JUDGE 2: Isn't also your view that the<br/>8 burden is placed on the wrong side in terms of<br/>9 establishing criticality?<br/>10 FEMALE 2: Yeah, I think Regeneron had to<br/>11 first come forward with some type of demonstration<br/>12 that there was criticality and moreover, to get to<br/>13 your point, tied to some teaching in their<br/>14 specification that -- so that the public is<br/>15 actually getting the benefit of a quid pro qual<br/>16 [ph].<br/>17 JUDGE 2: Well, let's assume for the<br/>18 moment that we don't have to believe that expressed<br/>19 disclosure and specification.<br/>20 FEMALE 2: Okay.<br/>21 JUDGE 2: But I am trying to understand<br/>22 what in your view should Regeneron have done to<br/>23 establish criticality?<br/>24 FEMALE 2: I think Regeneron should have<br/>25 shown that there was something unique and special</p>                                                                                                                                  | <p>16</p> <p>1 that he really focused on is he said, 'Well, I<br/>2 don't see that you have an actual example of 40 mg<br/>3 per milligrams per ML being put through<br/>4 intravitreal use in Dix.<br/>5 However, -- and -- and you said that --<br/>6 that -- that when Dix was talking about use of VEGF<br/>7 fusion protein that that wasn't specific enough to<br/>8 get you to Sequence I.D. No. 4 that's like<br/>9 [inaudible] in the faint [ph].<br/>10 The problem; however, is that when you --<br/>11 is -- is that that is a very myopic view. It's not<br/>12 actually looking at the specification as a whole,<br/>13 because in the specification as a whole, number of<br/>14 Dix's examples use Sequence I.D. No. 4.<br/>15 In the preferences that Dix expressed for<br/>16 his preferences for the VEGF antagonist. He said,<br/>17 "I prefer, you know, more prefera- -- preferably<br/>18 Sequence I.D. Numbers 2 and 4 more preferably<br/>19 Sequece I.D. Number 4. Well, that's a laze [ph]<br/>20 mark to that. So if -- if --<br/>21 JUDGE 1: You want to check if that was a<br/>22 test or anything? Do you know what it was?<br/>23 MALE 3: I don't [inaudible].<br/>24 JUDGE 1: Okay. Why don't you just go ask<br/>25 Lathea [ph].</p> |

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| <p>17</p> <p>1 JUDGE 2: Let's pretend that's a false<br/>2 alarm. What about --<br/>3 JUDGE 1: Did he say it was okay?<br/>4 MALE 3: She's -- she's checking.<br/>5 JUDGE 1: Okay. Thank you. Go ahead.<br/>6 JUDGE 2: What about the 98 percent<br/>7 stability limitation? I think there was a finding<br/>8 that [inaudible] even if Dix discloses the 40 mg<br/>9 [inaudible] there is -- there is nothing in Dix<br/>10 that necessarily leads to that particular<br/>11 formulation that would get you this particular --<br/>12 particularized stability of limitation on the<br/>13 client [inaudible].<br/>14 FEMALE 2: Sure. And I think there again,<br/>15 the district court was not focused on Dels Dix [ph]<br/>16 having enabling disclosure. And here again, that's<br/>17 why I think the ClearValue Polymers case, you know,<br/>18 is quite relevant because in Clear- -- in that case<br/>19 they had the 150 or less, they only had an example<br/>20 of 60 to 70 but nevertheless, 50 was sufficiently<br/>21 enabled. Here, Dix had a 25 mgs.<br/>22 MALE 3: [Inaudible].<br/>23 JUDGE 1: We're good?<br/>24 FEMALE 3: Yes.<br/>25 JUDGE 1: Thank you.</p>                                                | <p>19</p> <p>1 I mean, I -- I thought I saw something<br/>2 where an expert said maybe most likely you would<br/>3 get 98 percent but then to me that doesn't quite<br/>4 tie things off for a -- a true anticipation.<br/>5 FEMALE 2: Right. Well, but I guess the<br/>6 issue is, Your Honor, again, these are formulation<br/>7 claims.<br/>8 And Regeneron to justify enablement they -<br/>9 - and the district court made findings, I'll have<br/>10 to a specific page, where he said, well, you know<br/>11 once you have a stable example to follow and you<br/>12 have an ingredient list, then of course, you can<br/>13 make all of these other formulations stable because<br/>14 that's just the routine experimentation.<br/>15 And furthermore, even in the 865 patent<br/>16 itself, it concedes that -- and this at Column 2,<br/>17 lines 53 to 57 -- they say that an even broader set<br/>18 of stable liquid formulations are going to have 40<br/>19 to 50, which includes Dix's number and area going<br/>20 to be able to be the stable looking formulations of<br/>21 the invention.<br/>22 It actually does happen, and [inaudible]<br/>23 these prior art references are also under this<br/>24 court case while presumed enabling for the full<br/>25 scope of what they disclosed. Regeneron is the one</p> |
| <p>18</p> <p>1 FEMALE 2: Dix had an ex- -- a specific<br/>2 example with Aflibercept, all the same ingredients<br/>3 as Elyea that was 98 percent stable or more at 25<br/>4 mg per ML. He had another one at 50 mg per ML also<br/>5 more than 98 percent stable. So there again is<br/>6 where I get into so okay --<br/>7 JUDGE 2: So did you have, I don't now,<br/>8 expert testimony or somebody say, yes, definitely,<br/>9 you can take it to the bank if you did a 40 mg<br/>10 version of Dix, you would get the 98 percent<br/>11 stability?<br/>12 FEMALE 2: Yes. And in fact, how do we<br/>13 know that you actually do get 98 percent stability?<br/>14 Because that's what the Eylea formulation is, it's<br/>15 got all of those ingredients.<br/>16 JUDGE 2: Well, I -- I agree with that but<br/>17 we're -- we're -- we're look -- working backwards<br/>18 with a Dix --<br/>19 FEMALE 2: Right.<br/>20 JUDGE 2: -- formulation, a Dix disclosure<br/>21 and then trying to figure out whether Dix discloses<br/>22 this claimed embodiment. And at least on this 98<br/>23 percent number if there's something you can show me<br/>24 in the record where there's testimony evidence,<br/>25 something.</p> | <p>20</p> <p>1 -- is the party that should have had the burden to<br/>2 come forward to say well, if -- if somehow there's<br/>3 a way in which you practice this, that does not<br/>4 actually lead to stability, but they couldn't do<br/>5 that here because the very argument that they made<br/>6 to justify enablement is that once you've got an<br/>7 example to follow and they use 40 and 50 mg<br/>8 examples, here Dix has 25 and 50 mg examples, then<br/>9 you are sure you have enough to get your stable<br/>10 formulation. So if it's --<br/>11 JUDGE 2: I just want to make it clear<br/>12 right now I'm not worried about 112 considerations<br/>13 or anything like that.<br/>14 FEMALE 2: Okay.<br/>15 JUDGE 2: I'm only concerned about<br/>16 [inaudible] 102 and whether this one reference has<br/>17 everything that's in the claim and that's all I<br/>18 need to know, why should I feel comfortable in<br/>19 flipping the district court for making an<br/>20 unreasonable finding that Dix does not disclose the<br/>21 98 percent limitation, even if it discloses the 30<br/>22 mg of milliliter limit.<br/>23 FEMALE 2: Right. Because Dix actually<br/>24 made the 50 mg formulation 98 percent stable. He<br/>25 made a less concentrated version 98 percent stable.</p>                           |

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| <p>21</p> <p>1 And this court has never held that you have to have<br/>2 an actual practice example in the specification in<br/>3 order to anticipate. You needed the enabling<br/>4 disclosure.<br/>5 That's the critical issue, and Dix gave<br/>6 the person of ordinary skill in the art the<br/>7 enabling disclosure for 40. And if I may, I would -<br/>8 - if I -- if can talk, I don't know if [inaudible].<br/>9 JUDGE 1: I -- I want -- I want to take it<br/>10 back to criticality. Did you have something else on<br/>11 the screen?<br/>12 FEMALE 2: No, no, go ahead.<br/>13 JUDGE 1: I -- I just have one quick<br/>14 question.<br/>15 FEMALE 2: I -- I just know I'm in my --<br/>16 my time, Your Honor. So I --<br/>17 JUDGE 1: No. I -- I know. No.<br/>18 FEMALE 2: Yeah.<br/>19 JUDGE 1: We'll still be here.<br/>20 JUDGE 2: We're going to be here a while.<br/>21 FEMALE 2: Okay.<br/>22 JUDGE 1: Did -- back to criticality --<br/>23 FEMALE 2: Right.<br/>24 JUDGE 1: And then I'll discuss with your<br/>25 friend why I think the district court's findings</p>                                                                                                                                                                                                                                                                                                     | <p>23</p> <p>1 JUDGE 2: And 8 -- and -- 8159 district<br/>2 court makes a finding that this 40 mg per ML<br/>3 limitations hit some kind of sweet spot maximizing<br/>4 [inaudible] life of the Aflibercept and the<br/>5 [inaudible] at the same time minimizing toxicity<br/>6 stability concerns.<br/>7 FEMALE 2: Right. And --<br/>8 JUDGE 2: And so the question in my mind<br/>9 is, is that enough to show this something -- this<br/>10 establishes that this particular volume 40 is<br/>11 critical to the operability of this drug product.<br/>12 FEMALE 2: Right. It's not, Your Honor,<br/>13 because first, if you actually go look at the<br/>14 citations that the district court offered to cite<br/>15 it, those citations don't actually say that.<br/>16 Second, because Regeneron here is trying to say<br/>17 there's something special about 40, well, you're<br/>18 going to get those same results if you're at 41,<br/>19 you're going to get those same results if you're at<br/>20 39.<br/>21 JUDGE 2: How do we know that?<br/>22 FEMALE 2: Well, we know that because<br/>23 there is -- there -- the -- the --<br/>24 JUDGE 2: What's the testimony to that<br/>25 effect to that effect?</p>                                                                         |
| <p>22</p> <p>1 may have put the burden -- wrong burden and ask the<br/>2 wrong question. But did Regeneron put up any<br/>3 evidence to show criticality?<br/>4 FEMALE 2: Within the range of what was<br/>5 already disclosed by Dix, no. All of the<br/>6 criticality evidence and this is reflected in the<br/>7 district court's findings, was focused on, well,<br/>8 here is how Aflibercept performs relative to<br/>9 Ranibizumab because of this inflammation risk. And<br/>10 because of that, that -- that to me is exactly the<br/>11 problem here, is that these are composition claims.<br/>12 The district court construed the claims<br/>13 that's suitable for intravitreal administration. It<br/>14 only meant you need to have, Judge Wall [ph], the -<br/>15 - the list of ingredients on Claim 7 that had<br/>16 previously been used in intravitreal formulations<br/>17 or in an another example. We have that in Dix.<br/>18 So if -- if we look at this court's cases,<br/>19 usually when you're assessing criticality, it's --<br/>20 is this -- are seeing some unusual property as<br/>21 compared to the genus? And that's what we don't<br/>22 have here. We don't have any evidence showing that<br/>23 40 mg for ML within the scope of the 865 claims is<br/>24 always going to out perform the Dix formulations<br/>25 and they're not going to get there.</p> | <p>24</p> <p>1 FEMALE 2: Well, because the testimony --<br/>2 JUDGE 2: That's Mr. Trout [ph], no?<br/>3 FEMALE 2: Sure. The testimony here is<br/>4 that in -- in all -- all that he say -- all the<br/>5 district court is saying is they chose the 40 mg<br/>6 concentration to minimize -- to maximize the half<br/>7 life of Aflibercept in the eye.<br/>8 Well, Aflibercept, that's the molecule and<br/>9 then that was already known in the prior art that<br/>10 half life had already been established. That's in<br/>11 the [Holesh ?] publication. So the -- the more<br/>12 potenc- -- the higher potency of Aflibercept and<br/>13 its expected half life in the eye, that was already<br/>14 background knowledge to one our very skilled in the<br/>15 art.<br/>16 So when it comes to them minimizing<br/>17 toxicity and stability concerns, this is where I<br/>18 get to, and to Judge [inaudible], your point, is<br/>19 that Regeneron never came forward to say there's<br/>20 anything different.<br/>21 They don't say it in their own<br/>22 specification there's anything different about 40.<br/>23 The -- the test- -- I can certainly get you the<br/>24 testimony where the named inventors and Dr. Trout<br/>25 all agreed that in the spec- -- in the 865 patent</p> |

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| <p>25</p> <p>1 specification, they say nothing about the -- these<br/>2 formu- -- this -- these formulations are going to<br/>3 have a better half life if there's some kind of<br/>4 superior technology or outcome that's going to<br/>5 result from this as against the broader range that<br/>6 was dis- -- you know, originally disclosed and<br/>7 planned and then the specification itself that it<br/>8 admits it's going be a stable intravitreal<br/>9 formulation suitable for injection.<br/>10 And furthermore, none of those particular<br/>11 elements actually made their way into the claims.<br/>12 So if we're going to look at the scope of what has<br/>13 actually been claimed here, these particular<br/>14 efficacy elements are not there, and Regeneron in<br/>15 their briefing ad- -- was quite adamant that these<br/>16 claims should not be construed as requiring anyone<br/>17 or any composition to meet any efficacy standards.<br/>18 I think if we were to go back to this<br/>19 court's recent decision Janson Betheva [ph], which<br/>20 we cited in our brief, 97F4. I'm not sure what pin<br/>21 cite is.<br/>22 You know, this court was very clear that<br/>23 when it comes to doing these types of comparative<br/>24 analysis if it involves an element that's not<br/>25 actually in the claims, you should be very</p> | <p>27</p> <p>1 JUDGE 1: You -- I think -- tell me if I'm<br/>2 wrong, district court said you don't need to show<br/>3 criticality because of the size. We [inaudible]. So<br/>4 let me first ask you about the size.<br/>5 Two different -- even if we read Atofina<br/>6 is -- is -- is our court has not subsequently read<br/>7 it, but in any event, the size is different and<br/>8 it's much larger in Atofina than it is here. So I<br/>9 don't know how slum dunk, full stop, the size there<br/>10 dictates the size here.<br/>11 The other question I had about size so you<br/>12 can respond together, is that your expert talked<br/>13 about, yeah, there are a million things in this<br/>14 because we're down to the tenth and the hundredths<br/>15 but there was no -- but there was no -- nothing I<br/>16 could find in the records you can show me where<br/>17 that's the way -- those are the kinds of<br/>18 calculations are used with respect to these drugs.<br/>19 I mean, it seems to me as in Atofina we<br/>20 had degrees of 100, 200 dig- -- integers and not,<br/>21 you know, e- -- expanding the scope into the<br/>22 hundredths or even the thousands, then you can have<br/>23 millions no matter what the scope. So if you could<br/>24 respond to that first step before we get to<br/>25 criticality.</p> |
| <p>26</p> <p>1 concerned -- you -- you -- you shouldn't be<br/>2 considering that as somehow establishing unaccepted<br/>3 results or anything along those lines.<br/>4 JUDGE 1: Okay. We will restore some<br/>5 rebuttal time [inaudible].<br/>6 FEMALE 2: Your Honor, I did want to<br/>7 emphasize as well if I could, I don't know, on the<br/>8 non-infringement issue.<br/>9 JUDGE 1: No. We're not going to. We don't<br/>10 have time.<br/>11 FEMALE 2: Okay. Okay.<br/>12 JUDGE 1: We -- we haven't [inaudible] for<br/>13 that, no. We're running out of time.<br/>14 FEMALE 2: That's fine. Thank you, Your<br/>15 Honor.<br/>16 JUDGE 1: Good morning.<br/>17 MR. TRASK: Good morning. May it please<br/>18 the Court. Andrew Trask for Regeneron. My friend on<br/>19 the other side focused her remarks on 102 and --<br/>20 and briefly on 103, so I'll do the same unless the<br/>21 court has other questions.<br/>22 JUDGE 1: Can we start on 102?<br/>23 MR. TRASK: Yes.<br/>24 JUDGE 1: And can we start on criticality?<br/>25 MR. TRASK: Yes.</p>                                                                                                                                                                                                                                                                                                  | <p>28</p> <p>1 MR. TRASK: Yes, Your Honor. Happy to. So<br/>2 on the size of the genus here there is two<br/>3 important considerations. One is that there was<br/>4 testimony from both sides experts that this was not<br/>5 a small range, so we have the testi- --<br/>6 JUDGE 1: Well, not a small -- where does<br/>7 that get us? Not a small range.<br/>8 MR. TRASK: Right. So that -- part of --<br/>9 part of the analysis here is as -- as the<br/>10 [inaudible] case explained, the perspective of the<br/>11 person of our very skill in the art and how they<br/>12 would view the size of the range is an important<br/>13 consideration in these overlapping ranges cases.<br/>14 And so, that's where that testimony goes is to that<br/>15 factor under the Azrem [ph] case in this case.<br/>16 Both sides experts acknowledge this was a<br/>17 large range. Dr. Raveno [ph], Mylan's expert<br/>18 pointed out that it encompassed digits to the<br/>19 tenths and hundredths place, which the district<br/>20 court found that encompassed hundreds or<br/>21 potentially thousands of discreet values.<br/>22 JUDGE 2: So both experts agreed to that?<br/>23 MR. TRASK: The --<br/>24 JUDGE 2: You look at the range? You don't<br/>25 just look at whole numbers but you go all the way</p>                                 |

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| <p style="text-align: right;">29</p> <p>1 down to the tenths or even the hundredths?</p> <p>2 MR. TRASK: Dr. Raveno, Mylan's expert,</p> <p>3 testified on cross examination that range -- range</p> <p>4 encompass not just whole values but also digits to</p> <p>5 the tenths and the hundredths place. This is at --</p> <p>6 the district court acknowledges -- made its</p> <p>7 findings at A157. Dr. Raveno's testimony was at</p> <p>8 A9496 through 99 and that precise point, Your</p> <p>9 Honor.</p> <p>10 And then, Dr. Trout, Regeneron's expert,</p> <p>11 also testified expressly that this was not a small</p> <p>12 range in the eyes of the [inaudible] that said</p> <p>13 A10448. So -- so that goes to the size of the</p> <p>14 range, but there's an even more fundamental issue</p> <p>15 here that distinguishes this case from some of the</p> <p>16 other overlapping ranges cases of this court.</p> <p>17 So in the -- in the Atofina case, the</p> <p>18 ClearValue case, the Aldrin case and others, the</p> <p>19 difference between the prior art and the claims</p> <p>20 invention was the identity of the range. Right?</p> <p>21 There was -- in -- in Atofina it was a range of</p> <p>22 degrees Celsius disclosed and a range of de- --</p> <p>23 degrees Celsius claimed.</p> <p>24 ClearValue with a PPM range disclosed, a</p> <p>25 PPM range claimed and so on. Here, there's a</p> | <p style="text-align: right;">31</p> <p>1 4,000?</p> <p>2 MR. TRASK: The -- the upper bound on the</p> <p>3 number of fusion proteins encompassed by this class</p> <p>4 was not the subject of precise of testimony, but</p> <p>5 the testimony was clear and it was agreed by both</p> <p>6 sides and the district court found at A157 --</p> <p>7 JUDGE 1: Can you -- 157?</p> <p>8 MR. TRASK: Yeah. That -- that the 10 to</p> <p>9 50 range in the prior art was not linked to</p> <p>10 Aflibercept -- Aflibercept specialty. And because</p> <p>11 of that, what we have here a genus on top of a</p> <p>12 genus. So we have a genus of fusion proteins and a</p> <p>13 genus of concentrations of fusion proteins. And so</p> <p>14 this is unlike --</p> <p>15 JUDGE 2: But the D- -- I'm just confused</p> <p>16 because the Dix reference only called out to</p> <p>17 species, right?</p> <p>18 MR. TRASK: The -- the disclosure said the</p> <p>19 -- the Dix reference the -- apologies -- the -- the</p> <p>20 passage of the Dix reference that we're referring</p> <p>21 to here is at Column 2, Lines 21 to 23. And this</p> <p>22 disclosure of the 10 to -- 10 to 50 range refers to</p> <p>23 this genus of fusion proteins, and it describes how</p> <p>24 they're made up.</p> <p>25 They have receptor regions, they have a</p>                                                                                                                                       |
| <p style="text-align: right;">30</p> <p>1 different scenario. There's agreement by the</p> <p>2 experts that the range in the prior art of 10 to 50</p> <p>3 mg to milliliter was not specific to the claimed</p> <p>4 protein, it was not [inaudible] as a range of 10 to</p> <p>5 50 mg per milliliter of Aflibercept. It was</p> <p>6 disclosed as a range of a genus of fu- -- of fusion</p> <p>7 proteins. This is --</p> <p>8 JUDGE 2: Genus of what, two?</p> <p>9 MR. TRASK: More than two, Your Honor. So,</p> <p>10 Mylan's own expert agreed with this point. He</p> <p>11 testified it was a classic protein, sets at A9497.</p> <p>12 And what the Dix reference says expressly</p> <p>13 at A12593 is that it is a -- this 10 to 50 range</p> <p>14 corresponds to a genus of "VEGF specifically fusion</p> <p>15 proteins," and there were two proteins called out</p> <p>16 specifically by their amino acid sequence --</p> <p>17 sequences in the Dix specification. But there are</p> <p>18 other proteins within this class of fusion proteins</p> <p>19 that apply to this range.</p> <p>20 JUDGE 2: How do we know that?</p> <p>21 MR. TRASK: Dr. Raveno testified to it at</p> <p>22 A9496 through 99. And Dr. Trout testified to the</p> <p>23 same at 10 -- sorry, A10449.</p> <p>24 JUDGE 2: Well, what did they say? Did</p> <p>25 they say it was four fusion proteins, 14, 400,</p>                    | <p style="text-align: right;">32</p> <p>1 constant region, so it's describing this genus as</p> <p>2 more than just the two discreet disclosed amino</p> <p>3 acid sequences but rather this genus of -- of</p> <p>4 proteins that contain these different structural</p> <p>5 features.</p> <p>6 So that's clear from the Dix reference. It</p> <p>7 was agreed upon by the -- by the -- both experts on</p> <p>8 both sides and it was found by the district court</p> <p>9 without -- we would submit clear error. So this is</p> <p>10 -- this is a different scenario from the other</p> <p>11 overlapping range cases where you have the same</p> <p>12 parameter in the prior art and in the claim range.</p> <p>13 JUDGE 2: But if we were to just put that</p> <p>14 to the side for a moment then if we would have read</p> <p>15 INEOS and ClearValue and especially the way they</p> <p>16 explained the meaning of Atofina, then would you</p> <p>17 agree that putting this one factor to the side that</p> <p>18 when we have something like this 40 mg per</p> <p>19 milliliter inside the range in the prior art of 10</p> <p>20 to 50, then it's incumbent upon the patent owner to</p> <p>21 show or demonstrate some kind of criticality?</p> <p>22 MR. TRASK: So I acknowledge that those</p> <p>23 cases involve criticality in the context of</p> <p>24 overlapping ranges, of course. Criticality was not</p> <p>25 required here, as the district court correctly</p> |

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| <p style="text-align: right;">33</p> <p>1 found for several reasons. One, there were other --</p> <p>2 JUDGE 2: I -- let --</p> <p>3 MR. TRASK: Yes.</p> <p>4 JUDGE 2: -- I'm just trying to understand</p> <p>5 our case law.</p> <p>6 MR. TRASK: Yes.</p> <p>7 JUDGE 2: That- -- that's what our case</p> <p>8 law calls for.</p> <p>9 MR. TRASK: That's --</p> <p>10 JUDGE 2: Right?</p> <p>11 MR. TRASK: -- so what the ca- -- case law</p> <p>12 calls for, and I think what you're referring to,</p> <p>13 Judge, Chen [ph], is that upon a showing of prima</p> <p>14 facie anticipation, the burden shifts to the</p> <p>15 patentee to show criticality. So the threshold</p> <p>16 question is, did --</p> <p>17 JUDGE 2: If the range overlaps with the</p> <p>18 prior art range then it's incumbent upon the patent</p> <p>19 owner to show criticality for its claimed branch.</p> <p>20 Is that --</p> <p>21 MR. TRASK: But --</p> <p>22 JUDGE 2: Is that a correct understanding</p> <p>23 our case law?</p> <p>24 MR. TRASK: -- that -- that's not my</p> <p>25 reading of the case law precisely. I think it --</p>                                                                                                                                                                                                                                                                      | <p style="text-align: right;">35</p> <p>1 deciding whether the burden shifts to the -- to the</p> <p>2 patentee. And -- and all of -- you know, as -- as I</p> <p>3 think, Your Honor pointed out early --</p> <p>4 JUDGE 2: So I -- as I understand your</p> <p>5 argument, you've got roadblocks that's setting up</p> <p>6 before we have to worry about criticality. One is</p> <p>7 we're dealing with, as you would call it, a class</p> <p>8 of VEGF antagonists and two, the size of the prior</p> <p>9 art ra- -- range is just too big.</p> <p>10 MR. TRASK: That's -- that's right.</p> <p>11 There's also -- there's no -- but I -- I would say</p> <p>12 those are the main -- those are the main</p> <p>13 considerations. That's right.</p> <p>14 JUDGE 1: Okay. But don't the [inaudible]</p> <p>15 could also say even if there were criticality and</p> <p>16 go a -- go ahead and -- and analyze criticality?</p> <p>17 MR. TRASK: That's correct, Judge</p> <p>18 [inaudible]. So --</p> <p>19 JUDGE 1: Okay.</p> <p>20 MR. TRASK: -- we -- we stand by the</p> <p>21 district court's finding that there was no need to</p> <p>22 show criticality, but even if there were a need to</p> <p>23 find criticality, the district court made a ample</p> <p>24 findings on the record here regarding criticality.</p> <p>25 So --</p>            |
| <p style="text-align: right;">34</p> <p>1 JUDGE 2: Okay then, what is it?</p> <p>2 MR. TRASK: It's -- if there's a prima</p> <p>3 facie case of anticipation, it's not simply the</p> <p>4 case of whether the range is overlapped but as</p> <p>5 Azrem explained, for example, what is the size of</p> <p>6 the genus in the eyes or the posep [ph]. That's a -</p> <p>7 - that's an important consideration as the court</p> <p>8 precedent says.</p> <p>9 And so the -- the question of whether that</p> <p>10 threshold has been crossed and whether a prima</p> <p>11 facie anticipation case has been made out -- needs</p> <p>12 to consider the size of the range, the -- you know,</p> <p>13 whether there's an overlapping genus as we</p> <p>14 discussed a moment ago. All of those factor into</p> <p>15 whether a prima facie anticipate --</p> <p>16 JUDGE 2: The genus for -- for ClearValue</p> <p>17 talk about the size of the prior art range? It's --</p> <p>18 MR. TRASK: I don't -- yeah, ClearValue</p> <p>19 talked about the relative size of the prior art</p> <p>20 genus. I -- I'm sorry, the -- I think -- I -- I</p> <p>21 don't know the answer to that question off the top</p> <p>22 of my head, Your Honor, but --</p> <p>23 JUDGE 2: I mean, I -- I --</p> <p>24 MR. TRASK: The -- the ortherem [ph] case</p> <p>25 certainly discusses that as a factor in -- in</p> | <p style="text-align: right;">36</p> <p>1 JUDGE 2: It seems peculiar though to try</p> <p>2 to do a comparison with the claimed embodiment</p> <p>3 against this [inaudible], you know, for teaching</p> <p>4 the way and unexpected results because as I</p> <p>5 understood, I mean, there's not a lot of case law</p> <p>6 on criticality but it seems like the thrust of the</p> <p>7 thinking of -- for criticality is comparing what</p> <p>8 you've claimed against other embodiments that come</p> <p>9 within the prior art range.</p> <p>10 MR. TRASK: So the district court didn't</p> <p>11 li- --</p> <p>12 JUDGE 2: And so that's the type of apples</p> <p>13 to apples analysis you have to do another apples to</p> <p>14 analysis comparing your drug to some other drug.</p> <p>15 MR. TRASK: So there was no dispute here</p> <p>16 that the Gadrell [ph] reference, which is the one</p> <p>17 that discloses the R drug, was the closes prior art</p> <p>18 here.</p> <p>19 And so, in our view, it was appropriate</p> <p>20 for the district court court to draw upon those</p> <p>21 comparisons. But there were also comparisons that</p> <p>22 were specific to Aflibercept. So I would direct</p> <p>23 Your Honor's attention to the the courts findings</p> <p>24 at A159.</p> <p>25 These are the findings of criticality that</p> |

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| <p>37</p> <p>1 I think Judge Chen, you pointed to earlier and the<br/>2 district court's opinion.<br/>3 JUDGE 2: I didn't really see a comparison<br/>4 between here is why 40 is special.<br/>5 MR. TRASK: Right.<br/>6 JUDGE 2: Because look what happens when<br/>7 you do 45 or 35.<br/>8 MR. TRASK: Right. Let- -- let me address<br/>9 that because I do think that there's a -- a -- a --<br/>10 a direct linkage between the claims of 40 mg per<br/>11 milliliter and the critical- -- criticality<br/>12 findings on Page A159.<br/>13 And so, the district court on A159 cited<br/>14 several witnesses testimony.<br/>15 JUDGE 1: Well, first she says no record<br/>16 evidence shows that these desirable benefits of the<br/>17 claimed invention would have obtain at other<br/>18 concentrations between 10 and 40. Right? That's<br/>19 what she says in the middle of 159.<br/>20 MR. TRASK: That's correct, Your Honor.<br/>21 JUDGE 1: And accordingly, even antici- --<br/>22 an- -- anticipation were required we're showing<br/>23 criticality. Undisputed evidence at trial<br/>24 demonstrates that the 40 concentration is critical<br/>25 to the benefits. Is that the right standard?</p>                                                                                                                   | <p>39</p> <p>1 Graham.<br/>2 And what that test- -- what that cited<br/>3 testimony says is -- first of all, Dr. Furfine,<br/>4 this is at A9075, said that if you double the<br/>5 concentration of Aflibercept, you get an extra half<br/>6 life. So -- so the concentration of Aflibercept and<br/>7 the formulation is tied directly to the --<br/>8 JUDGE 2: Everybody knew that though,<br/>9 right?<br/>10 MR. TRASK: That's not right. That -- that<br/>11 -- the district --<br/>12 JUDGE 2: Everybody knew that if you<br/>13 increase the concentration you're going to improve<br/>14 the half life.<br/>15 MR. TRASK: That's -- that's not --<br/>16 there's no finding to that effect. That's<br/>17 [inaudible] and that assume some kind of a<br/>18 constant, like a linear increase in<br/>19 pharmacogenetics of which there was no -- no<br/>20 finding if that would have been the case here.<br/>21 Thi- -- this was found by the district<br/>22 court to be a key insight of the inventors in<br/>23 developing this formulation. So --<br/>24 JUDGE 2: When you say key insight, what<br/>25 is the key insight particular? Not that drive up</p>                                                                                          |
| <p>38</p> <p>1 Firstly, I think she put the burden on -- let me<br/>2 just throw this out -- she put -- arguably, she put<br/>3 the burden on them, not on you. Is that right?<br/>4 And the inquiry doesn't seem to me, is<br/>5 whether the 40 mg concentration is desirable but<br/>6 whether it's critical to the operability of the<br/>7 claimed invention. In other words, the claimed<br/>8 invention is critical only if it can be shown that<br/>9 the claimed invention only works for 40 mg and not<br/>10 for others.<br/>11 So I don't understand how her analysis of<br/>12 the evidence jives with what I understand to be the<br/>13 criti- -- criticality analysis.<br/>14 MR. TRASK: Understood, Your Honor. Let me<br/>15 explain that. So on that same page and in fact, the<br/>16 sentence before the one that Your Honor just<br/>17 quoted, the district court Judge Kleeh found that<br/>18 the testimony at trial demonstrated that the<br/>19 inventors specifically chose the 40 mg per<br/>20 milliliter concentration to maximize the half life<br/>21 of Aflibercept in the eye while minimizing toxicity<br/>22 and stability concerns.<br/>23 And what the district court is citing<br/>24 there are -- is the testimony of the two of the<br/>25 inventors of the 865 patent, Dr. Furfine and Dr.</p> | <p>40</p> <p>1 concentration would drive up half life if it's a<br/>2 coordination.<br/>3 MR. TRASK: The -- the finding was that<br/>4 the -- the concentration is directly tied to the<br/>5 half life such -- such as if you double the<br/>6 concentration you get an extra half life coupled<br/>7 with the additional testimony cited by Dr. Kle- --<br/>8 excuse, cited by Judge Kleeh that -- on that same<br/>9 page of Dr. Graham.<br/>10 Dr. Graham testified that the propensity<br/>11 for aggregation is -- and this is -- sorry, this is<br/>12 at A10040 -- that the pro- -- propensity for<br/>13 aggregation of Aflibercept, increases as the square<br/>14 of the concentration. And so, aggregation as well,<br/>15 which was acknowledged by experts at trial from<br/>16 both sides was a extremely phenomenon for this<br/>17 drug, --<br/>18 JUDGE 2: Mm-hmm.<br/>19 MR. TRASK: -- which is injected into the<br/>20 eyeball. And so, what the inventors found was that<br/>21 the -- the propensity for aggregation increases the<br/>22 square of the concentration, again, supporting<br/>23 Judge Kleeh's finding that they minimize toxicity<br/>24 and stability concerns by using this particular<br/>25 concentration. And so --</p> |

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| <p style="text-align: right;">41</p> <p>1 JUDGE 2: I guess the question I -- that<br/> 2 still remains is that the prior art room, which is<br/> 3 10 to 50, you've claimed 40, and I -- and I don't<br/> 4 see anything in the record that indicates here is<br/> 5 why 40 did something different and therefore,<br/> 6 critical to the operability of our clean drug --<br/> 7 drug product compared to other things that are not<br/> 8 prior art knowledge. And I thought that that is the<br/> 9 nature of the criticality analysis.<br/> 10 I mean, can we agree on that, that we have<br/> 11 to look at the performance of the operability of<br/> 12 the claimed embodiment against other things that<br/> 13 are in the prior art range?<br/> 14 MR. TRASK: I think that's a fair<br/> 15 characterization of the criticality inquiry. Azrem,<br/> 16 for example, says ask whether the claimed value is<br/> 17 central to the invention. I think the -- and -- and<br/> 18 whether the invention would operate differently at<br/> 19 various points within the range.<br/> 20 JUDGE 2: Okay. So that -- I think that's<br/> 21 what I'm wondering if whether there's a gap in this<br/> 22 record or in this case when it comes to the<br/> 23 analysis on criticality.<br/> 24 MR. TRASK: So I don't think there's a<br/> 25 gap, Your Honor, for -- for a couple of reasons.</p>               | <p style="text-align: right;">43</p> <p>1 it shows that the 40 mg per milliliter<br/> 2 concentration claimed and all of the asserted<br/> 3 claims is critical to the invention and<br/> 4 distinguished the invention from the closest prior<br/> 5 art, which the parties agreed was the draw<br/> 6 reference of which -- which referenced the -- the R<br/> 7 drug that Your Honor mentioned.<br/> 8 So the -- the other thing I point out is<br/> 9 that the -- the testimony from Dr. Furfine, one of<br/> 10 the inventors that connected the concentration 40<br/> 11 mg per milliliter with the half life of Aflibercept<br/> 12 was un rebutted.<br/> 13 The district court found that A200 and<br/> 14 there was no challenge by Mylan to that -- to that<br/> 15 finding a trial and certainly unappeal. And so,<br/> 16 there's -- there's multiple ways in which the<br/> 17 district court found criticality, but connections<br/> 18 with Aflibercept itself with -- through the<br/> 19 testimony of Dr. Furfine and Dr. Graham as well as<br/> 20 to the comparisons of the closest prior art in the<br/> 21 [inaudible].<br/> 22 JUDGE 2: You're getting away from the<br/> 23 Dixelanta two, you're not relying on the preamble,<br/> 24 are you? Of the -- for use in intra- --<br/> 25 intravitreal administration compared to the cancer</p> |
| <p style="text-align: right;">42</p> <p>1 One is the testimony concerning the precise<br/> 2 concentration, selected by the inventors as found<br/> 3 by the District Board in A159, which balance the --<br/> 4 the half life with concerns regarding safety and<br/> 5 efficacy as well as the district court's findings<br/> 6 regarding unexpected results.<br/> 7 And so, these findings are at A198 and the<br/> 8 district court found that the 40 mg per milliliter<br/> 9 of Aflibercept claimed and all of the asserted<br/> 10 claims, had three critical and unexpected<br/> 11 properties, safety, efficacy, and durability.<br/> 12 And the court went on to explain how it<br/> 13 was that this 40 mg per milliliter concentration<br/> 14 was surprisingly comparable with respect to safety<br/> 15 and efficacy compared to the closest prior art,<br/> 16 with [inaudible] gentic, Lucentis -- sorry could<br/> 17 draw reference and also had durability to be do,<br/> 18 dose half as frequency.<br/> 19 As, as Your Honors can imagine, getting an<br/> 20 injection into the eyeball is not a pleasant<br/> 21 experience for patients, and so this was a<br/> 22 revolutionary advance that this report found to<br/> 23 have to dose patients only half as often.<br/> 24 So, that finding as well I think supports<br/> 25 the district court's finding of criticality because</p> | <p style="text-align: right;">44</p> <p>1 treatment that was disclosed [inaudible]?<br/> 2 MR. TRASK: The preamble was never a basis<br/> 3 to distinguish the prior art.<br/> 4 JUDGE 2: I saw the district court in part<br/> 5 relied on that, and then I saw that the record does<br/> 6 not.<br/> 7 MR. TRASK: I don't -- I don't think<br/> 8 that's right. I mean, it -- it's only try that's --<br/> 9 JUDGE 2: When you say that's not right,<br/> 10 which part is not right?<br/> 11 MR. TRASK: Oh, yes. I don't view the -- I<br/> 12 don't read the district court's decision as relying<br/> 13 upon the -- the preambles.<br/> 14 JUDGE 2: Okay. I just got those words<br/> 15 from his opinion then [inaudible].<br/> 16 JUDGE 1: Can I ask you one other --<br/> 17 MR. TRASK: Okay. I don't -- I'm not sure,<br/> 18 Your Honor, which passage [inaudible] that you're<br/> 19 referring to, but -- but there was no dispute by<br/> 20 the parties that there was no efficacy limitation<br/> 21 built into the suitable for intravitreal term.<br/> 22 It was never a term that -- that either<br/> 23 party had proposed to construe. And so, there's<br/> 24 un rebutted testimony by Dr. Trout that what that<br/> 25 limitation means is contains components that can be</p>                                                                |

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| <p>45</p> <p>1 used intravitreally and nothing more.</p> <p>2 JUDGE 2: What about 98 percent? Are do I</p> <p>3 -- how are we supposed to think about that? The</p> <p>4 other side you heard say essentially the 98 percent</p> <p>5 would be there in Dix but you use the 40 mg per</p> <p>6 milliliter because all the examples that other</p> <p>7 concentration levels got [inaudible] 98 percent.</p> <p>8 And I don't know, 98 percent is what the FDA want</p> <p>9 so 98 percent is really n- -- not very meaningful</p> <p>10 here.</p> <p>11 MR. TRASK: So t- -- two responses to</p> <p>12 that, Your Honor. One is, I think you put your</p> <p>13 finger on it when -- when you asked my friend on</p> <p>14 the other side about the testimony that best</p> <p>15 supported the notion that there would be 98 percent</p> <p>16 and 40 [inaudible] from the Dix reference. And you</p> <p>17 pointed out that the most the expert said is it</p> <p>18 would be most likely. That's in A10526.</p> <p>19 JUDGE 2: That is your expert, right?</p> <p>20 MR. TRASK: That's our expert, correct. He</p> <p>21 acknowledged that it would be --</p> <p>22 JUDGE 2: Their expert offered no -- no</p> <p>23 testimony on that fact. And then what it seems to</p> <p>24 be on appeal is that they're arguing almost kind of</p> <p>25 an inherency type -- type analysis, but certainly,</p> | <p>47</p> <p>1 said that 98 percent native confirmation was "not</p> <p>2 an obligate requirement" for -- for [inaudible].</p> <p>3 JUDGE 2: What volume are you in?</p> <p>4 MR. TRASK: This is, sorry, A10102, which</p> <p>5 is long and [inaudible].</p> <p>6 JUDGE 2: We've been talking about Dix</p> <p>7 102, just curious. Dix 103 -- your reliance on</p> <p>8 103C1, it couldn't be conclusive yet, right, if we</p> <p>9 were to conclude that there was a problem with</p> <p>10 criticality because the district court never made</p> <p>11 an assessment on whether 865 is entitled to an</p> <p>12 earlier provision application final [inaudible].</p> <p>13 MR. TRASK: So --</p> <p>14 JUDGE 2: Is that right?</p> <p>15 MR. TRASK: -- so I think part of the</p> <p>16 reason that -- that Dix was not a -- a focus of</p> <p>17 Mylan's --</p> <p>18 JUDGE 2: I -- I am just trying to get to</p> <p>19 the bottom of something.</p> <p>20 MR. TRASK: Yeah.</p> <p>21 JUDGE 2: I just need to know for</p> <p>22 housekeeping.</p> <p>23 MR. TRASK: Sure. So -- so our -- our view</p> <p>24 is that Dix is not a proper reference under 103 by</p> <p>25 virtue of the fact.</p>                                                               |
| <p>46</p> <p>1 that was not a theory that was from below and</p> <p>2 there's no evidence to support that necessarily</p> <p>3 there would have been 98 percent negative</p> <p>4 confirmation in -- in one of the Dix formulations.</p> <p>5 JUDGE 2: Frankly, what impressed me was</p> <p>6 how often Raveno and Trout agreed with each other,</p> <p>7 which his usual [inaudible].</p> <p>8 MR. TRASK: It -- it is refreshing</p> <p>9 perhaps. I -- I agree with you, Your Honor. The --</p> <p>10 the other point I want to make in response to Judge</p> <p>11 Chen's question --</p> <p>12 JUDGE 2: You know some lawyers have,</p> <p>13 like, 40 disagreements.</p> <p>14 MR. TRASK: Well, I -- I -- I can't help</p> <p>15 that. There were a lot of issues raised in the</p> <p>16 opening brief. On the point about 98 percent being</p> <p>17 a known FDA requirement I think is an -- it is an</p> <p>18 important point to -- to flag.</p> <p>19 Mylan made this argument at -- at Page 24</p> <p>20 of their reply brief, they said, "98 percent native</p> <p>21 confirmation was known FDA stability requirement."</p> <p>22 In support of statement, they cite Dr. Graham. And</p> <p>23 I encourage Your Honors to look at that testimony.</p> <p>24 This is at A10102303. Dr. Graham said precisely the</p> <p>25 opposite of Mylan represented there. Dr. Graham</p>             | <p>48</p> <p>1 JUDGE 2: Right, but this report did not</p> <p>2 [inaudible] assessment on --</p> <p>3 MR. TRASK: The district court did not --</p> <p>4 JUDGE 2: -- whether the patent is</p> <p>5 entitled to provisional priority [inaudible].</p> <p>6 MR. TRASK: -- the district court did not</p> <p>7 make that finding. That's right, Your Honor.</p> <p>8 JUDGE 2: [Inaudible].</p> <p>9 MR. TRASK: Yeah. And so, if -- if the</p> <p>10 court decides that it can't reach that question as</p> <p>11 a result then -- then it wouldn't -- wouldn't reach</p> <p>12 the 103C question but our -- our view is that Dix -</p> <p>13 - there's --</p> <p>14 JUDGE 2: I mean, I -- I could just keep</p> <p>15 asking questions. I don't know.</p> <p>16 JUDGE 1: Well, do I get to teaching away</p> <p>17 because I'm sorry, I'm thinking about too many</p> <p>18 things at one point, so maybe this is redundant --</p> <p>19 JUDGE 2: Yeah, okay.</p> <p>20 JUDGE 1: -- but I want to get to the</p> <p>21 teaching away argument.</p> <p>22 MR. TRASK: Yes, Your Honor.</p> <p>23 JUDGE 1: And it seems to me the district</p> <p>24 court relied heavily on Dr. Trout's analysis of the</p> <p>25 Scudro [ph] reference. But I don't see anywhere in</p> |

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| <p style="text-align: right;">49</p> <p>1 the record where he explains what a reference about</p> <p>2 [inaudible] --</p> <p>3 MR. TRASK: Yeah.</p> <p>4 JUDGE 1: -- formulation is indicative of</p> <p>5 how the A formulation will be paid. And I only see</p> <p>6 discussions about A is more potent than R. But did</p> <p>7 your expert provide anything additional as to why R</p> <p>8 and A would behave similarly. I mean, this is just</p> <p>9 an odd kind of teaching away when you're not direct</p> <p>10 -- directing me to what -- what we're talking</p> <p>11 about. Right?</p> <p>12 MR. TRASK: Sure. Well, I -- I -- I -- I -</p> <p>13 -</p> <p>14 JUDGE 1: So how do you get there?</p> <p>15 MR. TRASK: Sure. So it was undisputed at</p> <p>16 the trial that this reference is the subject of</p> <p>17 teach away, the Godrell reference was the closest</p> <p>18 prior art. The district court found that at A197.</p> <p>19 And the only thing that Mylan cites to support --</p> <p>20 they -- they -- they claimed unappeal on Page 36 of</p> <p>21 their reply brief but they disputed that</p> <p>22 contention.</p> <p>23 The only thing they cite is their proposed</p> <p>24 order -- proposed trial order to the district</p> <p>25 court, which of course, is not evidence at A1 1698.</p>                                                                                                                                                    | <p style="text-align: right;">51</p> <p>1 talking and that's helpful but --</p> <p>2 MR. TRASK: Sure.</p> <p>3 JUDGE 2: -- I -- I need something in the</p> <p>4 district court's findings and rationale analysis</p> <p>5 that I can focus on and -- and see okay, oh,</p> <p>6 they're -- no, that's a fair fact finding that I</p> <p>7 can get behind versus, oh, there's a hole in the</p> <p>8 analysis that leaves me wanting and I can't just</p> <p>9 rely on an attorney argument today trying to talk</p> <p>10 it away.</p> <p>11 MR. TRASK: Sure. I mean -- so I think --</p> <p>12 focusing on the -- the -- the pages that I just</p> <p>13 referenced, the A174 to 177, it was -- it seemed to</p> <p>14 be understood through the eyes of the poser that</p> <p>15 these two molecules had simil- -- had the same</p> <p>16 mechanis- -- mechanism of action and the</p> <p>17 performance of one would be indicative of the</p> <p>18 performance of the other.</p> <p>19 So for example, a A175, the district court</p> <p>20 found that because of Aflibercept was much more --</p> <p>21 JUDGE 1: Where are you on the page?</p> <p>22 MR. TRASK: Sure. This is A175.</p> <p>23 JUDGE 1: Yeah. I'm there but --</p> <p>24 MR. TRASK: And on the -- it's the second</p> <p>25 beginning of the paragraph there. It says,</p>                                                                                                   |
| <p style="text-align: right;">50</p> <p>1 And so, there is no evidence of record that could</p> <p>2 draw as not closest prior art and it was not a</p> <p>3 position that Mylan ever advanced below. So -- so</p> <p>4 there's --</p> <p>5 JUDGE 2: I guess the -- to put a final</p> <p>6 point on it, the -- the -- your theory of teaching</p> <p>7 away, the district court's theory of teaching away</p> <p>8 is that Aflibercept and the R drug are essentially</p> <p>9 interchanged role and the R drug stands as a proxy</p> <p>10 for what [inaudible] would think about Aflibercept.</p> <p>11 And yet, I don't see the basis for that</p> <p>12 premise that these two things are interchanged or -</p> <p>13 - or one is this affair substitute for the other.</p> <p>14 Where is the bridge for that kind of thinking that</p> <p>15 allows to do -- assume that whatever that might be</p> <p>16 bad about the R drug necessarily is also going to</p> <p>17 be equally bad if not worse for Aflibercept.</p> <p>18 MR. TRASK: Sure. So the district court's</p> <p>19 teach away findings are at A174 to 77, and there</p> <p>20 were a number of findings there of relevance. But</p> <p>21 to your -- to Your Honor's point, both of these</p> <p>22 drugs, the R drug and Aflibercept, FDA drug, has</p> <p>23 the [inaudible] mechanism of action where they bind</p> <p>24 the [inaudible] in the retina to --</p> <p>25 JUDGE 2: Okay. This -- this is you</p> | <p style="text-align: right;">52</p> <p>1 "Moreover, it was undisputed that Aflibercept --</p> <p>2 JUDGE 1: Yeah.</p> <p>3 MR. TRASK: -- was much more potent than</p> <p>4 Ranibizumad. Because of its higher potency, less</p> <p>5 Aflibercept is needed to inhibit the same amount of</p> <p>6 VEGF as compared to Ranibizumad."</p> <p>7 And then a little further down it says,</p> <p>8 "Doctor tried to explain that the poser would have</p> <p>9 been motivated to use the concentration of</p> <p>10 Aflibercept lower than the 10 milligrams of</p> <p>11 milliliter of Ranibizumad in view of Aflibercept's</p> <p>12 higher potency." And so, Dr. --</p> <p>13 JUDGE 2: That's not quite teaching away.</p> <p>14 That is more like about how perhaps [inaudible]</p> <p>15 just to be motivated to crank up the concentration</p> <p>16 up to 40 milligrams for -- that -- that's -- that -</p> <p>17 - that's not saying it's a really bad idea to use</p> <p>18 Aflibercept of 40 milligrams per milliliter.</p> <p>19 JUDGE 1: And just to tag onto that, I --</p> <p>20 I -- I can't recall any other cases on teaching</p> <p>21 away where one as relying on something different</p> <p>22 because maybe there's some similarity to them say</p> <p>23 this teaches away even though it's different for</p> <p>24 this. Do you know of any cases that have done that?</p> <p>25 MR. TRASK: Well, I -- I don't -- I'm not</p> |

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| <p style="text-align: right;">53</p> <p>1 sure I know exactly this particular scenario but --</p> <p>2 but this is not a different -- these are not two</p> <p>3 different disclosures in the sense that they're</p> <p>4 both was -- these are the two leading VEGF</p> <p>5 antagonist at the time.</p> <p>6 They were both in development at the time,</p> <p>7 and the evidence is that the poser was looking at</p> <p>8 the development of Ranibizumad, the R drug, in</p> <p>9 order to inform how to go about developing</p> <p>10 Aflibercept, the -- the A drug.</p> <p>11 And so, these are drugs that had the same</p> <p>12 mechanism action, and the undisputed testimony at</p> <p>13 trial through Dr. Trout over pages of the district</p> <p>14 court's findings is that the performance of</p> <p>15 Ranibizumad informed in poser how one would expect</p> <p>16 Aflibercept to perform because they had the</p> <p>17 identical mechanism of action, and so there was a</p> <p>18 finding that this --</p> <p>19 JUDGE 2: And where is that finding? Same</p> <p>20 mechanism of action and then next [inaudible]</p> <p>21 because they have the same mechanism of action we</p> <p>22 would certainly think of Aflibercept in the same</p> <p>23 way that we would think of the R drug.</p> <p>24 MR. TRASK: I might need a moment to run -</p> <p>25 -</p> | <p style="text-align: right;">55</p> <p>1 [inaudible].</p> <p>2 JUDGE 1: Okay.</p> <p>3 MR. TRASK: And the discussion here on</p> <p>4 A187 talks about the poser wouldn't expect that a</p> <p>5 different protein with have the same native</p> <p>6 confirmation. The higher re- -- required</p> <p>7 concentration of Aflibercept compared to</p> <p>8 Ranibizumad undermine any reasonable expectation of</p> <p>9 success.</p> <p>10 So again, comparing these two drugs of the</p> <p>11 same mechanism of actions, both VEGF antagonist and</p> <p>12 comparing their -- and -- and contrasting the</p> <p>13 expectation of that.</p> <p>14 JUDGE 2: This -- this -- this -- this</p> <p>15 seems to -- if I'm not, if I'm not mistaken, kind</p> <p>16 of work against what your position is.</p> <p>17 Your -- your position for purposes of</p> <p>18 teaching away is to tell us that these two drugs</p> <p>19 area very, very, very close cousins. This passage</p> <p>20 seem to say just because you would get some line of</p> <p>21 stability in one doesn't necessarily mean you'll</p> <p>22 get that same stability in the other.</p> <p>23 MR. TRASK: So there -- there's no --</p> <p>24 there was no contrary testimony on -- on this point</p> <p>25 that the two drugs have the same mechanism for</p> |
| <p style="text-align: right;">54</p> <p>1 JUDGE 2: Okay.</p> <p>2 MR. TRASK: -- locate that. But I would</p> <p>3 say that the -- the -- all of the testimony that I</p> <p>4 can affirm to is -- is based upon the</p> <p>5 understanding, which is undisputed that the</p> <p>6 performance of the R drug in- -- inform the -- the</p> <p>7 poser's expectations regarding Aflibercept. Right?</p> <p>8 That -- that was the -- the understanding</p> <p>9 that -- on which Dr. Trout was -- was testifying is</p> <p>10 that --</p> <p>11 JUDGE 1: Did -- did the dis- -- I'm</p> <p>12 looking at that page with the district court, I'm</p> <p>13 not -- is there anything the district court -- did</p> <p>14 the district court make a finding like that? I</p> <p>15 mean, she says the comparison she has that you</p> <p>16 called out, which is that Aflibercept is more</p> <p>17 potent than the R drug but the -- you know -- okay</p> <p>18 --</p> <p>19 MR. TRASK: Phoning a friend here. It's --</p> <p>20 so the -- another -- another finding here is at</p> <p>21 A187, which compares Ranibizumad and fusion</p> <p>22 proteins like Aflibercept.</p> <p>23 JUDGE 1: What heading is this under?</p> <p>24 MR. TRASK: This is in the, in the context</p> <p>25 of -- this is the invalidity analysis for</p>                                                  | <p style="text-align: right;">56</p> <p>1 action and would have performed similarly but the -</p> <p>2 - the poser would have understood that the cause of</p> <p>3 the severe inflammation exhibited by Lucentis at 40</p> <p>4 mg per milliliter you would expect that Aflibercept</p> <p>5 with need a far lower concentration in order to</p> <p>6 achieve the max -- in order to achieve a beneficial</p> <p>7 therapeutic effect with a -- with a lower amount of</p> <p>8 --</p> <p>9 JUDGE 2: So what are your backup</p> <p>10 arguments on this, right, like, --</p> <p>11 MR. TRASK: We do. We do, Your Honor.</p> <p>12 JUDGE 2: -- is there some problem with</p> <p>13 the teaching away analysis yet there's, I don't</p> <p>14 know, half a dozen [inaudible] that have been</p> <p>15 identified.</p> <p>16 MR. TRASK: That's exactly right. There's</p> <p>17 -- the Aflibercept sequence is not disclosed in the</p> <p>18 Fraser and Lucentis combination. The -- like</p> <p>19 [inaudible] Aflibercept is not disclosed in that</p> <p>20 combination.</p> <p>21 JUDGE 2: Neither reference has</p> <p>22 Aflibercept?</p> <p>23 MR. TRASK: No, I'm talking about the</p> <p>24 Fraser and Lucentis combination. So --</p> <p>25 JUDGE 2: Right.</p>                                                        |

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| <p>57</p> <p>1 MR. TRASK: Yeah.</p> <p>2 JUDGE 2: Neither reference has</p> <p>3 Aflibercept?</p> <p>4 MR. TRASK: In -- in Fraser and Lucentis -</p> <p>5 - I'm sorry the -- the Fraser dis- -- discloses</p> <p>6 what's called the VGEF Trap R102, it does not</p> <p>7 disclose Aflibercept, it does not disclose the</p> <p>8 amino acid sequence of Aflibercept. That's right.</p> <p>9 And Lucentis, of course, was about their</p> <p>10 Ranibizumad drug. There's no disclosure of, like,</p> <p>11 conciliated Aflibercept, there's no motivation to</p> <p>12 conciliate Aflibercept. This court found last week</p> <p>13 in a related appeal involving Samsung the --</p> <p>14 JUDGE 2: How come we didn't get a 28 J</p> <p>15 [inaudible]?</p> <p>16 JUDGE 1: Oh, yes, that's -- well, that's</p> <p>17 goes to the next case though because we --</p> <p>18 JUDGE 2: No, it counts here too.</p> <p>19 MR. TRASK: Sure.</p> <p>20 JUDGE 1: No, but it counts more on the</p> <p>21 last case.</p> <p>22 MR. TRASK: Yeah, I -- I will -- I will</p> <p>23 take responsibility for that. I -- we -- we weren't</p> <p>24 sure if the --</p> <p>25 JUDGE 1: Well, the other side as well, we</p>                                                                                                                                                                                          | <p>59</p> <p>1 references.</p> <p>2 In their briefing they combined those --</p> <p>3 those teachings. This is -- this is at A6 -- I</p> <p>4 believe it's at Page 69 of their briefing.</p> <p>5 JUDGE 2: Did you say in your rhetoric</p> <p>6 that they didn't raise that to the trial judge?</p> <p>7 MR. TRASK: They -- no, they -- that's not</p> <p>8 right, Judge Wallach. They -- we objected to the</p> <p>9 trial judge -- in front of the trial judge to the</p> <p>10 combination because it wasn't disclosed. The</p> <p>11 district -- district court precluded Mylan from the</p> <p>12 lying on that combination. This is a A167 to 168.</p> <p>13 And yet, their opening brief argues these</p> <p>14 references together as if it's a proper</p> <p>15 combination. And so, I just wanted to make sure the</p> <p>16 court was aware of that point.</p> <p>17 JUDGE 1: Objection -- mm-hmm. Thank you.</p> <p>18 MR. TRASK: Thank you very much, Your</p> <p>19 Honors.</p> <p>20 JUDGE 1: Okay. Trying to keep things even</p> <p>21 if necessary on my calculations, which may be</p> <p>22 wrong, but I think you went eight over and he went</p> <p>23 18 over, so that gives you plus 10 but we hope you</p> <p>24 don't need it.</p> <p>25 FEMALE 2: I will try not to use it all if</p>                                                               |
| <p>58</p> <p>1 shouldn't have gotten something --</p> <p>2 MR. TRASK: -- we -- we weren't sure if</p> <p>3 the -- we should presume that the court was aware</p> <p>4 of the decision in -- in the same consolidated</p> <p>5 appeal. Perhaps we should have just submitted the</p> <p>6 28 J letter [inaudible].</p> <p>7 JUDGE 1: Well, that's a fair assumption</p> <p>8 but that doesn't answer the next question of the</p> <p>9 reason we have 28 J letters was to explain the</p> <p>10 relevance of that opinion to what the case is, the</p> <p>11 case we haven't gone to yet. And we're talk more</p> <p>12 about that in the [inaudible].</p> <p>13 MR. TRASK: Okay. Yeah, yeah. But -- but</p> <p>14 there -- to -- to your -- to Your Honors point,</p> <p>15 there are a number of differences with respect to</p> <p>16 the reasonable expectation of success, the</p> <p>17 motivation, as well as the Aflibercept sequence</p> <p>18 that differentiate the prior art from the -- from</p> <p>19 the claim they mentioned here.</p> <p>20 The -- the last point I'll raise is that</p> <p>21 the -- you -- you started, Judge Krause [ph], by</p> <p>22 asking my friend on the other side what obvious</p> <p>23 discombinations they're running here, and I heard</p> <p>24 that they're run- -- that they're ru- --</p> <p>25 maintaining the Fraser and Lucentis and the Dix</p> | <p>60</p> <p>1 I don't have to, Your Honor. Couple things I'd like</p> <p>2 to point out.</p> <p>3 First, if the tenth -- if the tenths and</p> <p>4 hundredths apply from the perspective of a person</p> <p>5 of ordinary skill in the art to 10 to 50, then it</p> <p>6 also applies to 40. So then you've got a range</p> <p>7 versus a range as opposed to a point within a</p> <p>8 range. In addition, I do want to point out that my</p> <p>9 co- --</p> <p>10 JUDGE 1: Did -- but you -- you agreed</p> <p>11 with your friend that your -- your -- your expert</p> <p>12 conceded that?</p> <p>13 FEMALE 2: Well, what he said is</p> <p>14 numerically, 10 to 50, well, can include tenths and</p> <p>15 hundredths. That's not necessarily the same thing.</p> <p>16 I don't think is a person of ordinary</p> <p>17 skill in the art would concede all of those to be</p> <p>18 the same, but nonetheless, if a person of ordinary</p> <p>19 skill in the art is going to see a number 10 to 50</p> <p>20 and see tenths and hundredths and then they're</p> <p>21 going to see a number 40, then that also means you</p> <p>22 see tenths and hundredths, and that's a range.</p> <p>23 When it comes to the -- you know, what Dix</p> <p>24 says about this class of VEGF antagonist, and that</p> <p>25 I think is actually where the Samsung decision that</p> |

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| <p style="text-align: right;">61</p> <p>1 this court recently issued, would in fact be<br/>2 relevant here.</p> <p>3 So one of the things that my colleague<br/>4 argued is that well, Dix doesn't actually tell you<br/>5 about the full sequence that we've got claimed in<br/>6 Claim 1.</p> <p>7 Well, here is what Dix does do, Dix in its<br/>8 examples, always uses sequence I.D. Number 4. Dix<br/>9 in the specification, has a clear preference for<br/>10 Sequence I.D. Number 4. And if we go to Dix, this<br/>11 is in A12595, under the heading, VEGF antagonist,<br/>12 so he's talking about the fusion proteins. Column 5<br/>13 Lines 30 to 42, he specifically says, "Here's what<br/>14 the VEGF antagonists are, it includes fusion<br/>15 proteins in a preferred embodiment. The VEGF<br/>16 antagonist is the fusion protein of two of four<br/>17 more preferably Sequence I.D. Number 4."</p> <p>18 And then further on then -- then the next<br/>19 couple lines, this is the same thing that the<br/>20 Samsung decision decided was going to be written<br/>21 description support for Regeneron for its claims in<br/>22 the 865 patent relating to the sequence in like<br/>23 consolation patterns.</p> <p>24 Dix has these same identical language<br/>25 under the same heading because Dix and the 865</p>                                                                                                   | <p style="text-align: right;">63</p> <p>1 now let's go to the 865 patent Example 1. What are<br/>2 the ingredients?</p> <p>3 They -- they're titled the same, stability<br/>4 of a 15 mg per ML. Now, the 865 patent says it's<br/>5 VEGF trap with -- with formulation. Dix just says<br/>6 liquid formulation of VEGF trap. What's contained<br/>7 in it? 10 millimoles -- 10 millimoles of phosphate<br/>8 and Dix's, 10 millimoles of phosphate and the 865<br/>9 patent.</p> <p>10 15 milli- -- millimoles of NaCl, also 15<br/>11 millimoles of NaCl in the 865 patent. Then we've<br/>12 got .1 percent polysorbate 20.</p> <p>13 JUDGE 2: Just so I can clarify, which<br/>14 specific issue is what you're talking about driving<br/>15 at?</p> <p>16 FEMALE 2: Right. This gets to the idea of<br/>17 -- my colleague from Regeneron was saying that<br/>18 somehow there's other elements that were missing<br/>19 from the Dix formulations that didn't get you to<br/>20 the complete claim, and particularly the stability<br/>21 on it.</p> <p>22 Well, as you go down -- as you march<br/>23 through these -- you then get to Table 1 in Dix,<br/>24 Table 1 in the 865 patent. You've got the same<br/>25 visual appearance turbidity PH and stability data,</p>            |
| <p style="text-align: right;">62</p> <p>1 patent -- I'm reading almost verbatim on this -- it<br/>2 then says, "In a specifically embodiment, fusion<br/>3 protein comprises amino acids 257 to 457 of<br/>4 Sequence I.D. Number 4 and is [inaudible] a at ASN<br/>5 residues 62, 94, 149, and 122 and [inaudible]. That<br/>6 is the single sequence that is claimed in Claim 1<br/>7 of the 865 patent here.</p> <p>8 So Dix if -- this is where the district<br/>9 court went wrong, because the district court only<br/>10 focused on just that one description of Column 2<br/>11 that say, here is what the embodiment is for 10 to<br/>12 50 milligrams, but then he ignored where the<br/>13 specification then expands on what it means to be a<br/>14 VEGF fusion protein of the invention.</p> <p>15 So I think in this court's claims what<br/>16 we're talking about is something arranged as in the<br/>17 claim when we -- we clearly have an interrelated<br/>18 teaching, here's the fusion proteins, here's the<br/>19 ones that I prefer, here is what I most prefer. So<br/>20 the district court was -- went wrong by not looking<br/>21 at that particular thing go say, oh, Afibercept is<br/>22 something that Dix is specifically contemplating.</p> <p>23 Similarly, if we then go to Dix's<br/>24 examples, the 226 patent, Example 1 -- so Dix, this<br/>25 is A12596, Example 1, what does Dix have there? And</p> | <p style="text-align: right;">64</p> <p>1 all above 98 percent.</p> <p>2 So you've got the i- -- the near identical<br/>3 ingredients, and both Dix's 15 mg Example 1, that<br/>4 meets each and every element of Claim 1 or Claim 4<br/>5 and all the other asserted claims here. It just<br/>6 doesn't have the number 40 in it.</p> <p>7 You go to the 865 patent, yes, they've got<br/>8 a 15 mg example, same stability numbers as in Dix.<br/>9 They got a 40 mg number, same stability results in<br/>10 Dix, then you look at the Dix 25 mg per ML, so he<br/>11 dropped the concentration. And that's in Column 12.<br/>12 And guess what, he uses those same formulation<br/>13 ingredients, gets the same stability outcome. So --</p> <p>14 JUDGE 1: Do you have expert testimony on<br/>15 this?</p> <p>16 FEMALE 2: Yes.</p> <p>17 JUDGE 1: And where is that?</p> <p>18 FEMALE 2: That -- it -- it is -- it is<br/>19 [inaudible]. Let me pull out some of those. I<br/>20 apologize, Your Honor. I -- I will get you those. I<br/>21 know -- I know we had the -- the citations in there<br/>22 where they basic -- where we basically did go back<br/>23 and forth between matching each of these up. So --</p> <p>24 JUDGE 1: Okay. Can I -- you have<br/>25 anything?</p> |

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| <p>65</p> <p>1 FEMALE 2: Yeah. Couple other points, Your<br/>2 Honor, that I did want to make.</p> <p>3 JUDGE 1: They -- one -- just one quick<br/>4 point as I -- I -- it was so long ago that I don't<br/>5 remember but I know your friend said something<br/>6 about [inaudible] brief and a citation to one of<br/>7 the experts and that your description of what he<br/>8 said was the ex- -- exact opposite I think your<br/>9 friend said of what he actually said. Do you have a<br/>10 response to that/</p> <p>11 FEMALE 2: Right. I -- I -- I -- I did not<br/>12 get a chance to check it.</p> <p>13 JUDGE 1: Okay.</p> <p>14 FEMALE 2: If we did then, you know,<br/>15 obviously, we would --</p> <p>16 JUDGE 1: Okay.</p> <p>17 FEMALE 2: -- we would withdraw that or<br/>18 see if there -- there was an error in sight and<br/>19 there's a additional citation that needs to be<br/>20 made. But on a certain level, I don't think it's<br/>21 actually relevant because Dix already achieved 98<br/>22 percent stability.</p> <p>23 He teaches it, he talks about it, he<br/>24 specifically teaches one of ordinary skill in the<br/>25 art how to get there. So you don't even need to</p>                    | <p>67</p> <p>1 supposed to be looking at what's happening with<br/>2 another drug to say, is -- is this, you know -- to<br/>3 say this is how it's going to behave for hours.</p> <p>4 And then, additionally, I also wanted to<br/>5 point out that when it comes to this issue of<br/>6 criticality, we do know from Dix that the desirable<br/>7 benefit of stability was actually achieved, not<br/>8 only for the lower concentration but for even high<br/>9 concentrations, 50 mg, 75, 100 mg ML.</p> <p>10 So under Amed v. Baxter 471 at 3rd &amp; 1368.<br/>11 The fact that they may have found even if we<br/>12 assumed from the district court's findings, we may<br/>13 have found some additional property that we think<br/>14 is beneficial, that doesn't change the fact.</p> <p>15 Even -- and I think Amed even said even if<br/>16 you put it in your claims, that still doesn't<br/>17 change the fact that when these are composition<br/>18 claims and the compositions are achieving the same<br/>19 outcomes, the same utilities, they're -- there are<br/>20 just isn't any difference there, and there isn't --<br/>21 there is no anticipation.</p> <p>22 And I think that INEOS likewise rejected<br/>23 the idea that you can start having these little<br/>24 change of inferences to also get to criticality to<br/>25 somehow support the claim. All right. Thank you</p> |
| <p>66</p> <p>1 look at FDA's motivations to get you there. He<br/>2 already got you there.</p> <p>3 So once -- so there again, that's where I<br/>4 get to -- the ena- -- what is the enabling<br/>5 disclosure? In addition, Your Honor, I did want to<br/>6 point out, we did dispute below that this<br/>7 Ranibizumad med drug was in fact the closest prior<br/>8 art.</p> <p>9 Now, I know my colleagues from Regeneron<br/>10 said, well, you just talked about that in your<br/>11 briefing. That's because our whole point was, it's<br/>12 not legally relevant. The -- the --</p> <p>13 JUDGE 1: Well, did you ever say it's not<br/>14 legally relevant?</p> <p>15 FEMALE 2: Yes.</p> <p>16 JUDGE 1: Did you tell that to the<br/>17 district court? Was that in our report?</p> <p>18 FEMALE 2: Yes, that was in our proposed<br/>19 findings of fact conclusions and law that the court<br/>20 had submitted that -- that -- that the closest<br/>21 prior art was going to be the Dix formulation.</p> <p>22 And -- and it was not going to be<br/>23 Ranibizumad. And I think the Jensen Betova [ph]<br/>24 case that was -- I decided that we cited in our<br/>25 brief, also bears this out, is that you're not</p> | <p>68</p> <p>1 very much, Your Honor.</p> <p>2 JUDGE 1: We thank you [inaudible]. We<br/>3 thank both sides. The case is submitted.</p> <p>4<br/>5<br/>6<br/>7<br/>8<br/>9<br/>10<br/>11<br/>12<br/>13<br/>14<br/>15<br/>16<br/>17<br/>18<br/>19<br/>20<br/>21<br/>22<br/>23<br/>24<br/>25</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

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## 1 CERTIFICATE OF TRANSCRIBER

2 I, Chris Naaden, a transcriber, hereby declare  
3 under penalty of perjury that to the best of my  
4 ability from the audio recordings and supporting  
5 information; and that I am neither counsel for,  
6 related to, nor employed by any of the parties to  
7 this case and have no interest, financial or  
8 otherwise, in its outcome, the above 68 pages  
9 contain a full, true and correct transcription of  
10 the tape-recording that I received regarding the  
11 event listed on the caption on page 1.

12  
13 I further declare that I have no interest  
14 in the event of the action.

15 

16  
17 May 20, 2025

18 Chris Naaden  
19

20 (585226, Oral Testimony in re: Regeneron  
21 Pharmaceuticals v. Mylan, 2-7-25)

| A                  |                     |                       |                    |
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| 30:23              | <b>acids</b>        | 22:13, 43:25          | <b>aggregation</b> |
| <b>a6</b>          | 62:3                | <b>admits</b>         | 40:11, 40:13,      |
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| <b>able</b>        | 40:15, 45:21        | <b>advanced</b>       | <b>agree</b>       |
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