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1 AUDIO RECORDING 2 FILE TITLE: 24-2002_02072025 3 AUDIO RUN TIME: 1:09:22 4 5 (Whereupon, the video recording started at 6 timestamp 0:00:00.) 7 JUDGE SHARON PROST: The next case for argument 8 is 24-2002, Regeneron Pharmaceuticals versus Mylan. 9 MS. MAZZOCHI: Good morning, Your Honor. 10 May it please the Court. 11 Deanne Mazzochi for Biocon and Mylan 12 Defendants-Appellants. 13 May I proceed? 14 JUDGE SHARON PROST: Yes, please. 15 MS. MAZZOCHI: Thank you. 16 JUDGE SHARON PROST: Good morning. 17 MS. MAZZOCHI: Thank you. 18 The District Court's infringement validity and a 19 remedy judgments for -- 20 JUDGE EVAN WALLACH: Counsel, let me ask you a 21 housekeeping question. 22 MS. MAZZOCHI: Sure. 23 JUDGE EVAN WALLACH: Page 7 of your blue brief. 24 MS. MAZZOCHI: Yes. 25 JUDGE EVAN WALLACH: There's a chart. I'd like Page 2	1 Polysorbate is the same for Lucentis and ours; 2 And then water. 3 So all -- so those fiv- -- those ingredients, 4 they're under anti-VEGF, those are the formulation 5 ingredients. So the drug is the anti-VEGF compound. 6 So Lucentis has the anti-VEGF drug compound 7 ranibizumab, and Yesafili and Eylea have the 8 anti-drug -- the anti-VEGF drug called aflibercept. 9 However, if you look at the formulation 10 ingredients -- and that's what the '865 patent is about. 11 It's directed to pharmaceutical formulations. 12 Our pharmaceutical formulation is actually 13 different from the commercially marketed product. We 14 use a histidine buffer; they use sodium phosphate 15 buffer. 16 We use trehalose as a sugar stabilizer; they use 17 sucrose. 18 Polysorbate, yes, in water, obviously, those are 19 all the same. 20 But Regeneron also adds on a salt that's called 21 sodium chloride. 22 So they're not identical formulations. 23 JUDGE SHARON PROST: Okay. There are a lot of 24 issues in this case -- 25 MS. MAZZOCHI: Correct. Page 4
1 you to turn to it. 2 MS. MAZZOCHI: Yes. 3 JUDGE EVAN WALLACH: That chart shows that 4 Lucentis says "Anti-VEGF ranibizumab." 5 Am I right? 6 MS. MAZZOCHI: Yes, that is correct. 7 JUDGE EVAN WALLACH: I -- it then shows that 8 both Yesap- -- Yesafili and Eylea have anti-VEGF 9 aflibercept; right? 10 MS. MAZZOCHI: Correct. 11 JUDGE EVAN WALLACH: On the same page, you say 12 "Yesafili adopts Genentech's prior art Anti-VEGF 13 intravitreal ranibizumab form- -- formulation Lucentis, 14 not Regeneron's." 15 MS. MAZZOCHI: Correct. 16 JUDGE EVAN WALLACH: Is that correct? 17 MS. MAZZOCHI: Yes. So the -- we -- we're 18 differentiating between the active ingredient, which is 19 the anti-VEGF compound, and the formulation that you 20 actually carry the drug in, which is the formulation. 21 So all of the formulation ingredients are -- all 22 of the ones that are under the anti-VEGF drug 23 descriptor. 24 So histidine is the same for Lucentis and ours; 25 Trehalose is the same for Lucentis and ours; Page 3	1 JUDGE SHARON PROST: -- and you've got a 2 300-page District Court opinion -- 3 MS. MAZZOCHI: We do. 4 JUDGE SHARON PROST: -- so it's kind of hard to 5 tackle, and -- but -- so let me just ask you some 6 scattered questions -- 7 MS. MAZZOCHI: Sure. 8 JUDGE SHARON PROST: -- and the right questions 9 about obviousness and then about anticipation. 10 MS. MAZZOCHI: Okay. 11 JUDGE SHARON PROST: But what obviousness 12 combination are you appealing? 13 Is it Dix alone? Or is it Fraser and Guader- -- 14 whatever the other one is? 15 MS. MAZZOCHI: Yeah. Both. 16 So there were -- there were two issues. 17 So, first, we said that that the -- the claims 18 were obvious in view of Dix alone because Dix is the one 19 that basically does have the Eylea formulation, and 20 really the only difference is the dose amount in terms 21 of a range or where Regeneron calls its species. 22 Then we also had what we are referring to as the 23 descriptions of aflibercept that were in the prior art, 24 which was the Fraser reference, in combination with what 25 we're calling the "Lucentis prior art." And that's Page 5

1 comprised of two main references, one of which is the 2 Gaudreault reference, the other of which is called the 3 Shams reference. 4 But both of those references were, essentially, 5 discussing this -- this type of Lucentis formulation 6 here, where it's an intravitreal formulation; It was 7 actually used in the eye; and, you know, it had the -- 8 the anti-VEGF drug in it. 9 So one of the -- 10 JUDGE RAYMOND CHEN: How do you pronounce that 11 anti-VEGF drug? 12 MS. MAZZOCHI: So ranibizumab is -- 13 JUDGE RAYMOND CHEN: Oh. Can we just call it 14 the "R drug"? 15 MS. MAZZOCHI: We can absolutely call it the 16 "R drug." 17 JUDGE RAYMOND CHEN: Okay. 18 MS. MAZZOCHI: And then the other one, the "A 19 drug," is aflibercept. 20 JUDGE RAYMOND CHEN: Aflibercept. That's 21 important one. We should say "aflibercept." 22 MS. MAZZOCHI: Yeah. 23 JUDGE RAYMOND CHEN: Okay. 24 JUDGE SHARON PROST: Well, let me take you back 25 to the list, on to the anticipation. Page 6	1 Epic. 2 In that instance, you had a situation where -- 3 it's similar to what Regeneron is arguing here, in the 4 sense that you had a broad description for the drug 5 compound to be -- that was in the prior art, that was 6 for analgesics treating pain. 7 And then this Court said it was anticipatory to 8 have a formulation that was directed to opioids and 9 opioids in analgesics. And the reason why is because 10 opioids were obviously -- were -- were known and 11 established to those of ordinary skill in the art in -- 12 in the background knowledge as drugs that were used as 13 analgesics to treat pain. 14 And in that instance, you didn't even have the 15 prior reference mentioning opioids specifically. But, 16 again, it was understood in the sense of what does a 17 person of ordinary skill in the art, when they see the 18 reference, actually understand it to be, not just 19 teaching in terms of specific examples, but also what is 20 is the nature of the enabling disclosure? 21 And I think that's fundamentally where the 22 District Court fell down here because the District Court 23 was very much focused on, "Well, you don't have an 24 example that was actually put to intravitreal use in 25 Dix." Page 8
1 MS. MAZZOCHI: Sure. Sure. 2 JUDGE SHARON PROST: I mean, the two issues that 3 are not disturbing to me but that raise some questions 4 are this criticality and the anticipation of 40 versus 5 10 to 50. 6 MS. MAZZOCHI: Correct. 7 JUDGE SHARON PROST: And then the teaching away 8 that the District Court found. 9 So what is your view of our case law and what it 10 compels with respect to that? 11 MS. MAZZOCHI: Sure. 12 And I think you see that in cases such as 13 peer-view -- 14 JUDGE SHARON PROST: Yeah, it's hard, though, 15 because I don't think we've found a case. You've got 16 cases with one range and the other prior art -- 17 MS. MAZZOCHI: Right. 18 JUDGE SHARON PROST: -- has one range, and the 19 PAM [phonetic] has another. You've got some where the 20 prior art has one and the other -- but I haven't found a 21 case, which is our case, which is the prior art has the 22 range, and the patent has just one. 23 MS. MAZZOCHI: Right. 24 Well, I -- I think that one of the close ones 25 that would come up would be the Purdue Pharma versus Page 7	1 The problem with that, though, is that if -- 2 and -- and, Your Honor, to get to your point in terms of 3 the chart on Page 7, if we were to look at the Eylea 4 formulation and we look at the formulations that are in 5 the examples in Dix, you have those identical 6 ingredients there, and, in instances, in the same 7 amounts. 8 And so the only distinction in terms of what was 9 there was a drug amount 10 to 50 versus they had limited 10 their claims here to 40. 11 And when you have an enabling disclosure -- and, 12 in fact, when the '865 patent itself says that not only 13 that particular drug range in Dix but an even broader 14 range from 1 to a 100 is also going to work to give you 15 the stable -- 16 JUDGE RAYMOND CHEN: I'm sorry to interrupt. 17 I'm a little confused. I would have expected you to 18 have said the word "criticality" by now. 19 MS. MAZZOCHI: Sure. 20 JUDGE RAYMOND CHEN: And you didn't say it. So 21 I'm now -- 22 MS. MAZZOCHI: Well, and that's why -- 23 JUDGE RAYMOND CHEN: You went off on Purdue 24 Pharma and then went to some other territory. And my 25 understanding was the focus of your briefing was it was Page 9

1 the patent owner's burden to show that the 40 milligram 2 per milliliter formulation was critical. 3 MS. MAZZOCHI: Right. Because that gets to the 4 genus-species issue. 5 JUDGE RAYMOND CHEN: And then, obviously, the 6 District Court found otherwise. And now we have to sort 7 out what does our range case law really say -- 8 MS. MAZZOCHI: Right. 9 JUDGE RAYMOND CHEN: -- and -- and demand of -- 10 in terms of making an anticipation case. 11 MS. MAZZOCHI: Right. 12 And -- and you're exactly right, Judge Chen. 13 And I think the District -- this is where -- 14 this is where -- one of the reasons why the District 15 Court went astray as well. 16 To me, when you're looking at criticality 17 issues, you're looking at what is claim as compared 18 to -- 19 JUDGE RAYMOND CHEN: Well, the first question 20 is -- 21 (Simultaneously speaking.) 22 MS. MAZZOCHI: -- what is in the prior art 23 range. 24 JUDGE RAYMOND CHEN: First question is -- before 25 we try to assess what does criticality mean is do we Page 10	1 be a claimed range inside of a broader prior art range; 2 right? 3 MS. MAZZOCHI: Sure. 4 JUDGE RAYMOND CHEN: And here we have not a 5 claimed range but a claimed point. 6 And then the question is, Well, when we look at 7 any Ineos or Clearvalue or anything else I can get my 8 hands on, I don't see that specific fact pattern, a 9 prior art range and then a claimed point inside of that 10 range. 11 Do we think about that fact pattern the same or 12 differently from the claimed range inside of a prior art 13 range? 14 MS. MAZZOCHI: Right. 15 And that's why we went back to some of the -- 16 the early -- you know, the earlier classic cases, such 17 as Petering and Rosig. 18 And I think, there again, when you look at what 19 those claims are talking about, when they're saying -- 20 you know, it -- it really gets back to -- I think the 21 phrase used was, was it really described for purposes of 22 Section 102 (b). 23 So I think here, when you have a situation where 24 we have -- with Dix and with the formulations here, 25 You have the same ingredients, the same drug involved, Page 12
1 even look to criticality in the first place. 2 MS. MAZZOCHI: Right. 3 JUDGE RAYMOND CHEN: And so the District Court 4 said no. In this context, we don't because there's a 5 case called Atofina that says you just look at size of 6 the genus. And then if I conclude that the genus was 7 too big, then I don't have to go any further. There's 8 no anticipation. 9 MS. MAZZOCHI: Right. 10 But I think that if you look at subsequent 11 cases, though, that have interpreted and applied 12 Atofina, such as the Clearvalue Polymer's case, the 13 critical issue that -- in terms of why were we concerned 14 that that genus in Atofina was so big is because it was 15 not actually describing and enabling what came later in 16 the claimed species, so much so that it actually did 17 operate in a different way. 18 And I think that in the Clearvalue case they 19 make that clear that when they are discussing Atofina, 20 they said, "Yeah, but in Atofina, that species that was 21 selected fundamentally worked in a different way." 22 So that, to me, is -- 23 JUDGE RAYMOND CHEN: And just getting to the 24 Judge Prost's initial question. Cases like -- I don't 25 know -- Ineos and Clearvalue, et cetera, those seem to Page 11	1 and you've got a range of 10 to 50 -- 2 JUDGE RAYMOND CHEN: You're -- you're -- 3 MS. MAZZOCHI: -- to select the 4 same genus species. 5 (Simultaneously speaking.) 6 JUDGE RAYMOND CHEN: -- getting back to the 7 facts, and I'm -- I'm thinking about the law. 8 MS. MAZZOCHI: Well, then -- right. 9 But I think -- from the legal perspective, I 10 think you make the -- you just get back to what was 11 described and enabled. 12 So, for example, you know, do we have any blaze 13 marks that sufficiently direct a person of ordinary 14 skill in the art towards a particular issue. 15 That -- you know, maybe if you've got a genus 16 that's got, you know, 10 billion compound possibilities 17 in it and now I'm going to select a single compound 18 species, maybe that's not going to be good enough. 19 However, if you have a situation where you've 20 already got an existing range, and the District Court 21 here actually made findings that, you know, who -- 22 that -- that a person of ordinary skill in the art would 23 certainly be able to make the full scope of what's 24 within this range, and it's the composition, and you 25 haven't articulated any new use or any particular way in Page 13

1 which this composition behaves differently -- 2 JUDGE EVAN WALLACH: But if it's not that 3 specific number, the patient -- it -- has a possibility 4 of blindness. 5 MS. MAZZOCHI: No. See, that -- that's one of 6 the issues with the District Court where I think the 7 District Court actually got the test wrong. 8 Because when you're going to talk about 9 criticality, it has to be criticality against what that 10 prior art range was. So show me that 40, the species, 11 somehow performs differently than 10 to 50. And he 12 didn't make that finding. He said, "Oh, well, let me 13 look at how it's going -- how I think it might compare 14 based on how ranibizumab drug compared, and how 15 ranibizumab drug performed on the" [inaudible] -- 16 (Simultaneously speaking.) 17 JUDGE SHARON PROST: But is it also your view 18 that the burden was placed on the wrong side in terms of 19 establishing criticality? 20 MS. MAZZOCHI: Yeah. I think Regeneron had to 21 first come forward with some type of demonstration that 22 there was criticality. 23 And, moreover, to get to your point, tie it to 24 some teaching in their specification that -- so that the 25 public is actually getting the benefit of a quid pro Page 14	1 And that's where I think we get to the 2 fundamental problem here. Is that, particularly, once 3 the District Court said that these claims -- that -- 4 (Simultaneously speaking.) 5 JUDGE RAYMOND CHEN: Getting to some of the 6 other issues on 102 -- 7 MS. MAZZOCHI: Sure. 8 JUDGE RAYMOND CHEN: -- It seems like the 9 District Court identified other reasons for why there's 10 a lack of anticipation with the Dix reference aside from 11 this 40, 10 to 50 business. 12 MS. MAZZOCHI: Sure. 13 Well, the only other one that he really focused 14 on is he said, "Well, I don't see that you have an 15 actual example of 40 milligrams per mL being put to 16 intravitreal use in Dix." 17 However -- and -- and he said that -- that when 18 Dix was talking about use of VEGF fusion protein that 19 that wasn't specific enough to get you to SEQ ID NO:4 20 that's glycosylated as in the claims. 21 The problem, however, is that when -- is that 22 when you -- is that is a very myopic view. It's not 23 actually looking at the specification as a whole. 24 Because in the specification as a whole, number one, all 25 of Dix's examples use SEQ ID NO:4. In the preferences Page 16
1 quo. 2 JUDGE RAYMOND CHEN: Well, let's assume for the 3 moment that we don't have to worry about expressed 4 disclosure in specification. 5 MS. MAZZOCHI: Okay. 6 JUDGE RAYMOND CHEN: But I am trying to 7 understand what, in your view, should Regeneron have 8 done to establish criticality? 9 MS. MAZZOCHI: I think Regeneron should have 10 shown that there was something unique and special about 11 40 that worked better or differently as compared to -- 12 JUDGE RAYMOND CHEN: Can you give me an example? 13 I mean -- 14 MS. MAZZOCHI: Everything else in the range of 15 10 to 50. 16 So -- and I -- I think -- 17 JUDGE RAYMOND CHEN: When you say "better," I'm 18 just trying to get a -- an understanding what you think. 19 MS. MAZZOCHI: Sure. 20 One -- one that meets this Court's standards, 21 for example, of a difference of degree and not in kind, 22 or a new established utility, or something that actually 23 a person of ordinary skill in the art wouldn't have been 24 enabled to do with this composition that they already 25 had in Dix. Page 15	1 that Dix expressed for his preferences for the VEGF 2 antagonist, he says, "I prefer, you know, more -- 3 preferably SEQ ID NOS: 2 and 4, more preferably SEQ ID 4 NO:4." 5 Well, that's a blaze mark to that. So -- 6 (Background noise disturbance.) 7 JUDGE SHARON PROST: It might have checked if 8 that was a test or anything. 9 Do you know what it was? 10 UNIDENTIFIED MALE SPEAKER: I don't, Your Honor. 11 JUDGE SHARON PROST: Okay. Why don't you just 12 go ask the CFO. 13 JUDGE RAYMOND CHEN: Let's pretend that's a 14 false alarm. 15 What about -- 16 JUDGE SHARON PROST: Did he say it was okay? 17 UNIDENTIFIED MALE SPEAKER: She's -- she's 18 checking. 19 JUDGE SHARON PROST: Okay. Thank you. 20 Go ahead. 21 JUDGE RAYMOND CHEN: What about the 98 percent 22 stability limitation? 23 I think there was a finding that, "All right, 24 Even if Dix discloses the 40 milligrams per milliliter 25 [inaudible], there's -- there's nothing in Dix that Page 17

1 necessarily leads to that particular formulation that 2 would get you this particular -- particularized 3 stability limitation in the claim." 4 MS. MAZZOCHI: Sure. 5 And I think there, again, the District Court was 6 not focused on does Dix have an enabling disclosure? 7 And here, again, that's where I think the 8 Clearvalue Polymers case, you know, is quite relevant 9 because in Clear- -- in that case, they had the 150 or 10 less, they only had an example at 60 to 70, but, 11 nevertheless, 50 was sufficiently enabled. 12 Here, Dix had a 25 milligrams -- 13 JUDGE SHARON PROST: Sorry. 14 We good? 15 UNIDENTIFIED MALE SPEAKER: Yes. 16 JUDGE SHARON PROST: Thank you. 17 MS. MAZZOCHI: Dix had a specific example with 18 aflibercept, all the same ingredients as Eylea, that was 19 98 percent stable or more at 25 milligrams per mL. 20 He had another one at 50 milligrams per mL. 21 Also more than 98 percent stable. 22 So there, again, is where I get into -- so 23 okay -- 24 JUDGE RAYMOND CHEN: So did you have -- I don't 25 know -- expert testimony or somebody saying "Yes, Page 18	1 issue is, Your Honor, again, these are formulation 2 claims, and Regeneron, to justify enablement, they -- 3 and the District Court made findings. I'll have to find 4 the specific page where he said, "Well, you know, once 5 you have a stable example to follow, and you have an 6 ingredient list, then, of course you can make all of 7 these other formulations stable because that's just 8 routine experimentation." 9 And, furthermore, even in the '865 patent 10 itself, it concedes that -- and this is at Column 2 11 Lines 53 to 57. They say that an even broader set of 12 stable liquid formulations are going to have 40 to 50, 13 which includes Dix's number, and are going to be able to 14 be these stable liquid formulations of the invention. 15 It actually does happen. 16 And McLan, these prior art references are also 17 under this Court's case law presumed enabling for the 18 full scope of what they disclose. 19 Regeneron is the one -- is the party that should 20 have had the burden to come forward to say, "Well, if 21 somehow there's a way in which you practice this, that 22 does not actually lead to stability," but they couldn't 23 do that here because the very argument that they made to 24 justify enablement is that once "you've got an example 25 to follow," and they used 40 and 50 milligram examples, Page 20
1 definitely. You can take it to the bank. If you did a 2 40 milligram version of Dix, you would get the 3 98 percent stability"? 4 MS. MAZZOCHI: Yes. 5 And, in fact, how do we know that you actually 6 do get 98 percent stability? Because that's what the 7 Eylea formulation is. It's got all of those -- 8 (Simultaneously speaking.) 9 JUDGE RAYMOND CHEN: I understand that -- 10 MS. MAZZOCHI: -- ingredients. 11 (Simultaneously speaking.) 12 JUDGE RAYMOND CHEN: -- but we're working 13 backwards with a -- 14 MS. MAZZOCHI: Right. 15 JUDGE RAYMOND CHEN: -- Dix formulation, a Dix 16 disclosure, and then trying to figure out whether Dix 17 discloses this claimed embodiment. 18 And at least on this 98 percent number, if 19 there's something you can show me in the record where 20 there's testimony, evidence, something -- I mean, I -- I 21 thought I saw something where an expert said, "Maybe 22 most likely you would get 98 percent," but then, to me, 23 that doesn't quite tie things off for a true 24 anticipation. 25 MS. MAZZOCHI: Right. Well -- but, I guess, the Page 19	1 here Dix has 25 and 50 milligram examples, "then you are 2 sure you have enough to get your stable formulation." 3 So if it's -- 4 JUDGE RAYMOND CHEN: I just -- I just want to 5 make it clear right now I'm not worried about 6 112 considerations or anything like that. 7 MS. MAZZOCHI: Okay. 8 JUDGE RAYMOND CHEN: I'm only concerned about 9 little ol' 102, and whether this one reference has 10 everything that's in the claim. And that's all I need 11 to know. 12 Why should I feel comfortable in flipping the 13 District Court for making an unreasonable finding that 14 Dix does not disclose the 98 percent limitation, even if 15 it discloses the 40 milligram per milliliter limitation. 16 MS. MAZZOCHI: Right. 17 Because Dix actually made the 50 milligram 18 formulation 98 percent stable. He made a less 19 concentrated version 98 percent stable. 20 And this Court has never held that you have to 21 have an actual practiced example in the specification in 22 order to anticipate. 23 You need the enabling disclosure. That's the 24 critical issue. And Dix gave the person of ordinary 25 skill in the art the enabling disclosure for 40. Page 21

1 And if I may, I would -- if I can talk -- I 2 don't know if you need me to -- 3 JUDGE SHARON PROST: Well, I want -- I want to 4 take you back to criticality. 5 MS. MAZZOCHI: Sure. 6 JUDGE SHARON PROST: Do you have something else 7 on this -- 8 MS. MAZZOCHI: No. No. Go ahead. 9 JUDGE SHARON PROST: I had -- I just -- just 10 have one question -- 11 (Simultaneously speaking.) 12 MS. MAZZOCHI: I -- I just know my time -- my 13 time, Your Honor. 14 JUDGE SHARON PROST: I tell you -- no, I know. 15 No, we'll restore your -- 16 JUDGE RAYMOND CHEN: We're going to be here a 17 while. 18 MS. MAZZOCHI: Okay. 19 JUDGE SHARON PROST: Did -- back to criticality. 20 MS. MAZZOCHI: Right. 21 JUDGE SHARON PROST: I mean, I think -- and I'll 22 discuss with your friend why I think the District 23 Court's findings may have put the burden -- wrong burden 24 and asked the wrong question, but did Regeneron put up 25 any evidence to show criticality? Page 22	1 JUDGE EVAN WALLACH: At 8159, the District Court 2 makes a finding that this 40 mg per mL limitation put 3 some kind of sweet spot maximizing half-life of 4 aflibercept well -- in the eyeball while at the same 5 time minimizing toxicity and stability concerns. 6 MS. MAZZOCHI: Right? And -- 7 JUDGE EVAN WALLACH: So the question, in my 8 mind, is, is that enough to show this is something -- 9 this establishes that this particular value, 40, is 10 critical to the operability of this drug product. 11 MS. MAZZOCHI: Right. It's not, Your Honor. 12 Because, first, if you actually go look at the citations 13 that the District Court offered, the cited, those 14 citations don't actually say that. 15 Second, because Regeneron here is trying to say 16 there's something special about 40, well, you're going 17 to get those same results if you're at 41. You're going 18 to get those same results if you're at 39. 19 JUDGE EVAN WALLACH: How do we know that? 20 MS. MAZZOCHI: We know -- well, we know that 21 because there is -- there is -- 22 JUDGE EVAN WALLACH: What is the testimony to 23 that effect? 24 MS. MAZZOCHI: Well, because the testimony -- 25 JUDGE EVAN WALLACH: This is Dr. Trout now. Page 24
1 MS. MAZZOCHI: Within the range of what was 2 already disclosed by Dix, no. All of the criticality 3 evidence -- and this is reflected in the District 4 Court's findings -- was focused on, "Well, here's how 5 aflibercept performs relative to ranibizumab because of 6 this inflammation risk." 7 And because of that, that, to me, is exactly the 8 problem here. Is that these are composition claims. 9 The District Court construed the claims that's suitable 10 for intravitreal administration. It only meant you need 11 to have, Judge Wallach, the -- the list of ingredients 12 on Claim 7 that had previously been used in intravitreal 13 formulations or in another example. We have that in 14 Dix. 15 So if -- if we look at this Court's cases, 16 usually when you're assessing criticality, it's is 17 this -- are we seeing some unusual property as compared 18 to the genus. 19 And that's what we don't have here. We don't 20 have any evidence showing that 40 milligram per mL, 21 within the scope of the '865 claims, is always going to 22 outperform the Dix formulations -- 23 JUDGE EVAN WALLACH: And 8- -- 24 MS. MAZZOCHI: -- and they're not going to get 25 there. Page 23	1 MS. MAZZOCHI: Sure. 2 The testimony here is that -- I mean, all -- all 3 that he say -- all the District Court is saying is they 4 chose the 40 milimam- -- milligram concentration to 5 minimize -- to maximize the half-life of aflibercept in 6 the eye. Well, aflibercept, that's the molecule. 7 And then that was already known in the prior 8 art, that half-life had already been established. 9 That's in the Holash publication. 10 So that it -- the more potent- -- the higher 11 potency of the aflibercept and its expected longer 12 half-life in the eye that was already background 13 knowledge to one of ordinary skill in the art. 14 So when it comes to then minimizing toxicity and 15 stability concerns, this is where I get to -- to, Judge 16 Prost, to your point, is that Regeneron never came 17 forward to say there's anything different. 18 They don't say it in their own specification 19 there's anything different about 40. 20 The test -- I can certainly get you the 21 testimony where the named inventors and Dr. Trout all 22 agreed that in the spec- -- that in the '865 patent 23 specification, they say nothing about these -- this -- 24 these formulations are going to have a better half-life 25 if there's some kind of superior technology or outcome Page 25

1 that's going to result from this, as against the broader 2 range that was, you know, originally disclosed and 3 claimed, and in the specification itself, that it admits 4 is going to be a stable intravitreal formulation 5 suitable for injection. 6 And, furthermore, none of those particular 7 elements actually made their way into the claims. So if 8 we're going to look at the scope of what has actually 9 been claimed here, these particular efficacy elements 10 are not there. 11 And Regeneron, in their briefing, ada- -- it was 12 quite adamant that these claims should not be construed 13 as requiring anyone or any composition to meet any 14 efficacy standards. 15 So I think if we were to go back to this Court's 16 recent decision in Janssen v. Teva, which we cited in 17 our brief, 97 F.4th -- I'm not sure what the pincite 18 is -- you know, this Court was very clear that when it 19 comes to doing these types of comparative analyses, if 20 it involves an element that's not actually in the 21 claims, you should be very concerned -- you shouldn't be 22 considering that as somehow establishing unexpected 23 results or anything along those lines. 24 JUDGE SHARON PROST: Okay. We will restore some 25 rebuttal time. I have to hear from the other side. Page 26	1 if I'm wrong. District Court said you don't need to 2 show criticality because of the size relying on Atofina. 3 So let me, first, ask you about the size. 4 Two different -- even if we read Atofina, is -- 5 is -- our Court has not subsequently read it but, in any 6 event, the size is different and it's much larger in 7 Atofina than it is here. So I don't know how slam 8 dunks, full stop the size there takes the size here. 9 The other question I had about size, so you can 10 respond together, is that your expert talked about, 11 "Yeah, there are a million things in this because we're 12 down to the tenths and the hundredths," but there was 13 no -- nothing I could find in the record, so you can 14 show me where that's the way -- those are the kinds of 15 calculations that they use with respect to these drugs. 16 I mean, it seems to me, as in Atofina, we had 17 degrees of a 100, 200 integers, and not, you know, 18 expanding the scope into the hundredths or even the 19 thousandths, then you can have millions no matter what 20 the scope. 21 So if you could respond to that first step 22 before we get to criticality. 23 MR. TRASK: Yes, Your Honor. I'm happy to. 24 So on the size of the genus here, there's two 25 important considerations. Page 28
1 Must -- 2 MS. MAZZOCHI: Your Honor, I did want to 3 emphasize as well, if I could -- I don't know about the 4 non-infringement issues. 5 JUDGE SHARON PROST: No, we're not going to. We 6 don't have time. 7 MS. MAZZOCHI: Okay. 8 JUDGE SHARON PROST: We have the briefs for 9 that. 10 MS. MAZZOCHI: Okay. Okay. 11 JUDGE SHARON PROST: No. We've done that. 12 MS. MAZZOCHI: That's fine. 13 Thank you, Your Honor. 14 MR. TRASK: Good morning. 15 May it please the Court. 16 Andrew Trask for Regeneron. 17 My friend on the other side focused her remarks 18 on 102 and -- and briefly on 103. So I'll do the same 19 unless the Court has other questions. 20 JUDGE SHARON PROST: Can we start on 102. 21 MR. TRASK: Yes. 22 JUDGE SHARON PROST: And can we start on 23 criticality. 24 MR. TRASK: Yes. 25 JUDGE SHARON PROST: You -- I think -- tell me Page 27	1 One is that there was testimony from both sides' 2 experts that this was not a small range. So we have -- 3 JUDGE SHARON PROST: Well, not a small -- where 4 does that get us: "Not a small range"? 5 MR. TRASK: Right. 6 So that -- part of -- part of the analysis here 7 is -- as the OSRAM case explained, the perspective of 8 the person of ordinary skill in the art and how they 9 would view the size of the range is an important 10 consideration in these overlapping ranges cases. And so 11 that's where that testimony goes is to that factor under 12 the OSRAM case of this Court. 13 Both sides' experts acknowledge this was a large 14 range. 15 Dr. Rabinow, Mylan's expert, pointed out that it 16 encompassed digits to the tenths and hundredths place, 17 which the District Court found, That that encompassed 18 hundreds or potentially thousands of discrete values 19 of -- 20 JUDGE RAYMOND CHEN: So both experts agreed to 21 that? That you look at the range, you don't just look 22 at whole numbers, but you go all the way down to the 23 tenths or even the hundredths? 24 MR. TRASK: Dr. Rabinow, Mylan's expert, 25 testified on cross-examination that that range Page 29

1 encompassed not just whole values, but also digits to 2 the tenths and the hundredths place. 3 This is at -- the District Court acknowledges -- 4 made its finding at A157. 5 Dr. Rabinow's testimony was at A9496 through 6 -99, on that precise point, Your Honor. 7 And then Dr. Trout, Regeneron's expert, also 8 testified expressly that this was not a small range in 9 the eyes of the POSA. That's at A10448. 10 So -- so that goes to the size of the range. 11 But there's an even more fundamental issue here that 12 distinguishes this case from some of the other 13 overlapping ranges -- cases of -- of this court. 14 So in the -- in the Atofina case, the Clearvalue 15 case, the OSRAM case, and others, the difference between 16 the prior art and the claimed invention was the identity 17 of the range. Right. 18 There was -- in -- in Atofina, it was a range of 19 degrees Celsius disclosed, and a range of degrees 20 Celsius claimed. 21 Clearvalue is the PPM range disclosed, the PPM 22 range claimed, and so on. 23 Here, there's a different scenario. 24 There's agreement by the experts that the range 25 in the prior art of 10 to 50 milligrams per milliliter Page 30	1 they say it was four fusion proteins? 14? 400? 4,000? 2 MR. TRASK: That -- the upper bound on the 3 number of fusion proteins encompassed by this class was 4 not the subject of precise testimony. 5 But the testimony was clear, and it was agreed 6 by both sides, and the District Court found -- 7 JUDGE SHARON PROST: Can you -- 8 MR. TRASK: -- at A157 -- 9 JUDGE SHARON PROST: -157? 10 MR. TRASK: Yeah. 11 That -- that the 10 to 50 range in the prior art 12 was not linked to aflibercept -- aflibercept 13 specifically. 14 And because of that, what we have here is a 15 genus on top of a genus. So we have a genus of fusion 16 proteins and a genus of concentrations of fusion 17 proteins. And so this is unlike -- 18 JUDGE RAYMOND CHEN: But the -- I'm just 19 confused. Because the Dix reference only calls out 20 to species; right? 21 MR. TRASK: The -- the disclosure -- the Dix 22 reference -- apologies. 23 The passage of the Dix reference that we're 24 referring to here is at Column 2, Lines 21 to 23, and 25 this disclosure of the 10 to 50 range refers to this Page 32
1 was not specific to the claimed protein. It was not as 2 close as a range of 10 to 50 milligrams per milliliter 3 of aflibercept. It was disclosed as a range of a genus 4 of fusion proteins. 5 And it has -- 6 JUDGE RAYMOND CHEN: And genus of what? Two? 7 MR. TRASK: No, more than two, Your Honor. 8 So Mylan's own expert agreed with this point. 9 He testified it was a class of proteins. That's at 10 A9497. 11 And what the Dix reference says, expressly, at a 12 A12593, is that it is a -- this 10 to 50 range 13 corresponds to a genus of, quote, "VEGF specific fusion 14 proteins." 15 And there were two proteins called out 16 specifically by their amino acid sequence -- sequences 17 in the Dix specification, but there are other proteins 18 within this class of fusion proteins that apply to this 19 range. 20 JUDGE RAYMOND CHEN: How do we know that? 21 MR. TRASK: Dr. Rabinow testified to it at A9496 22 through 99. 23 And Dr. Trout testified to the same at 10 -- 24 it's -- sorry -- A10. 25 JUDGE RAYMOND CHEN: So what did they say? Did Page 31	1 genus of fusion proteins, and it describes how they're 2 made up. They have receptor regions. They have a 3 constant region. So it's describing this genus as more 4 than just the two discrete, disclosed amino acid 5 sequences, but, rather, this genus of -- of proteins 6 that contain these different structural features. 7 So that's clear from the Dix reference. 8 It's -- it was agreed upon by the -- by the -- 9 both experts from both sides. 10 And it was found by the District Court without, 11 we would submit, clear error. 12 So this is -- this is a different scenario from 13 the other overlapping range cases where you have the 14 same parameter in the prior art and in the claimed 15 range. 16 JUDGE RAYMOND CHEN: But if we were to just put 17 that to the side for a moment then if we were to read 18 Ineos and Clearvalue, especially with the way they 19 explain the meaning of Atofina, then would you agree 20 that putting this one factor to the side, that -- when 21 we have something like this, 40 milligrams per 22 milliliter inside the range from the prior art of 10 to 23 50, then it's incumbent upon the patent owner to show 24 and demonstrate some kind of criticality? 25 MR. TRASK: So I acknowledge that those cases Page 33

1 involve criticality in the context of overlapping 2 ranges, of course. 3 Criticality was not required here, as the 4 District Court correctly found, for several reasons. 5 One, there were other -- 6 JUDGE RAYMOND CHEN: I -- 7 MR. TRASK: Yes. 8 JUDGE RAYMOND CHEN: I'm just trying to 9 understand our case law. 10 MR. TRASK: Yes. 11 JUDGE RAYMOND CHEN: That's -- that's what our 12 case law calls for -- 13 (Simultaneously speaking.) 14 MR. TRASK: So what -- 15 JUDGE RAYMOND CHEN: -- right? 16 MR. TRASK: -- the case law calls for, and I 17 think what you're referring to, Judge Chen, is that upon 18 a showing of prima fascia anticipation, the burden 19 shifts to the patent team to show criticality. 20 So the threshold question is, did -- 21 JUDGE RAYMOND CHEN: If the range overlaps with 22 the prior art language, then it's incumbent upon the 23 patent owner to show criticality for its claimed range. 24 MR. TRASK: Well -- 25 JUDGE RAYMOND CHEN: Is that a correct Page 34	1 certainly discusses that as a factor in -- in deciding 2 whether the burden shifts to the -- to the patentee. 3 And all of -- you know, as I think Your Honor 4 pointed out earlier -- 5 JUDGE RAYMOND CHEN: Okay. So as I understand 6 your argument, you've got road blocks you're putting up 7 before we have to worry about criticality. 8 One is we're dealing with, as you would call it, 9 a class of VEGF antagonists; 10 And, two, the size of the prior art range is 11 just too big. 12 MR. TRASK: That's -- that's right. 13 There's also -- there's no -- well, I would say 14 those are the main -- those are the main considerations. 15 JUDGE SHARON PROST: Okay. But didn't the 16 District Court also say, "Even if there were criticality 17 and go ahead and analyze criticality"? 18 MR. TRASK: That's correct, Judge Prost. 19 And so -- 20 JUDGE SHARON PROST: Okay. 21 MR. TRASK: We stand by the District Court's 22 finding that there was no need to show criticality. 23 But even if there were a need to find 24 criticality, the District Court made ample findings on 25 the record here regarding criticality. And so -- Page 36
1 understanding of our case law? 2 MR. TRASK: That's not my reading of the case 3 law, precisely. I think it -- 4 JUDGE RAYMOND CHEN: Okay. Then what is it? 5 MR. TRASK: It's if there's a prima fascia case 6 of anticipation. It's not simply a question of whether 7 the ranges overlap. 8 But as OSRAM explained, for example, what is the 9 size of the genus in the eyes of the POSA? That's an -- 10 that's an important consideration this Court precedent 11 says. 12 And so the question of whether that threshold 13 has been crossed and whether a prima fascia anticipation 14 case has been made out needs to consider the size of the 15 range, that -- you know, whether there's an overlapping 16 genus, as we discussed a moment ago, all of those factor 17 into whether a prima fascia -- 18 JUDGE RAYMOND CHEN: Did Ineos or Clearvalue 19 talk about the size of the cataract [phonetic] range? 20 MR. TRASK: I don't -- Clearvalue talked about 21 the relative size of the prior art of genus -- I'm 22 sorry. The -- I think -- I don't know the answer to 23 that question off the top of my head, Your Honor. 24 JUDGE RAYMOND CHEN: Yeah. 25 MR. TRASK: But, I mean, the OSRAM case Page 35	1 JUDGE RAYMOND CHEN: Isn't it peculiar, though, 2 to try to do a comparison with the claimed embodiment 3 against this R drug, you know, for teaching away in 4 unexpected results? 5 Because, as I understood -- I mean, there's not 6 a lot of case law in criticality, but it seems like the 7 thrust of the thinking of -- for criticality is 8 comparing what you've claimed against other embodiments 9 that come within the prior art range. 10 MR. TRASK: So the District Court didn't 11 elapse -- 12 JUDGE RAYMOND CHEN: So that's the type of 13 apples-to-apples analysis you have to do and not an 14 apples-to-oranges analysis comparing your drug to some 15 other drug. 16 MR. TRASK: So there was no dispute here that 17 the Gaudreault reference, which is the one that 18 discloses the R drug, was the closest prior art here. 19 And so, in our view, it was appropriate for the 20 District Court to draw upon those comparisons, but there 21 were also comparisons that were specific to aflibercept. 22 So I would direct Your Honor's attention to the 23 Court's findings at A159. These are the findings of 24 criticality that I think, Judge Chen, you pointed to 25 earlier in the District Court's opinion. Page 37

1 JUDGE RAYMOND CHEN: I didn't really see a 2 comparison between "here's why 40," especially. 3 MR. TRASK: Right. 4 JUDGE RAYMOND CHEN: Because look what happens 5 when you do 45 or 35.. 6 (Simultaneously speaking.) 7 MR. TRASK: Right. Let me address that because 8 I do think that there's a direct linkage between the 9 claims of 40 milligrams per milliliter and the 10 criticality findings on Page A159. 11 And so the District Court on A159 cited several 12 witnesses' testimony. 13 JUDGE SHARON PROST: Well, first, she says [as 14 read]: 15 "No record evidence shows that these 16 desirable benefits of the claimed 17 invention would obtain at other 18 concentrations between 10 and 40." 19 Right? 20 That's what she says in the middle of 159. 21 MR. TRASK: That's correct, Your Honor. 22 JUDGE SHARON PROST: And, accordingly, even 23 anticipation law required a showing a criticality, 24 Undisputed evidence at trial demonstrates that the 25 authority concentration is critical to the benefits. Page 38	1 are -- is the testimony of two of the inventors of 2 '865 patent, Dr. Furfine and Dr. Graham. 3 And what that cited testimony says is -- first 4 of all, Dr. Furfine, this is at A9075, said that "If you 5 double the concentration of aflibercept, you get an 6 extra half-life." So the concentration of aflibercept 7 in the formulation is tied directly -- 8 JUDGE RAYMOND CHEN: Everybody knew that, 9 though; right? 10 MR. TRASK: That's not right. That -- the 11 District -- 12 JUDGE RAYMOND CHEN: That everybody knew that if 13 you increase the concentration, you're going to improve 14 the half-life. 15 MR. TRASK: That's -- that's not -- there's no 16 finding to that effect, Judge Chen. 17 And that assumes some kind of a constant -- 18 like, a linear increase in pharmacokinetics, of which 19 there was no -- no finding that that would have been the 20 case here. 21 This -- This was found by the District Court to 22 be a key insight of the inventors in developing this 23 formulation. 24 JUDGE RAYMOND CHEN: When say "key insight," 25 what is the key insight in particular? Not that you Page 40
1 Is that the right standard? 2 Firstly, I think she put the burden on -- Let me 3 just throw this up. 4 She put -- arguably, she put the burden on them, 5 not on you; is that right? 6 And the inquiry, doesn't seem to me, is whether 7 the 40 milligram concentration is desirable but whether 8 it's critical to the operability of the claimed 9 invention. In other words, the claimed invention is 10 critical only if it can be shown that the claimed 11 invention only works for 40 milligrams and not for 12 others. 13 So I don't understand how her analysis of the 14 evidence jives with what I understand to be the 15 criticality analysis. 16 MR. TRASK: Understood, Your Honor. Let me 17 explain that. 18 So on that same page -- and, in fact, the 19 sentence before the one that Your Honor just quoted, the 20 District Court Judge Kleeh found that the testimony at 21 trial "demonstrated that the inventor specifically chose 22 the 40 milligram per milliliter concentration to 23 maximize the half-life of the aflibercept in the eye 24 while minimizing toxicity and stability concerns." 25 And what the District Court is citing there Page 39	1 drive up concentration, you drive up half-life, but 2 there's a correlation. 3 MR. TRASK: The -- the finding was that the -- 4 the concentration is directly tied to the half-life, 5 such that, if you double the concentration, you get an 6 extra half-life, Coupled with the additional testimony 7 cited by Dr. Kleeh -- or, excuse me, cited by 8 Judge Kleeh, on that -- on that same page of Dr. Graham. 9 Dr. Graham testified that the propensity for 10 aggregation -- and sorry. This is at A10040. "That the 11 propensity for aggregation of aflibercept increases as 12 the square of the concentration. 13 And so aggregation as well, which was 14 acknowledged by experts at trial from both sides, was an 15 extremely concerning phenomenon for this drug, which is 16 injected into the eyeball. 17 And so what the inventors found was that the -- 18 the propensity for aggregation increased as the square 19 of the concentration, again, supporting Judge Kleeh's 20 finding that they minimized toxicity and stability 21 concerns by using this particular concentration. 22 And so -- 23 JUDGE RAYMOND CHEN: The question that still 24 remains is that the prior art range is 10 to 50, you've 25 claimed 40, and I -- and I don't see anything in the Page 41

1 record that indicates "Here's why 40 is something 2 different," and, therefore, critical to the operability 3 of our claim drug pro- -- product compared to other 4 things that are in that prior art range. 5 And I thought that that is the nature of the 6 criticality analysis. 7 I mean, can we agree on that, that we have to 8 look at the performance or the properties or the 9 operability of the claimed embodiment against other 10 things that are in the prior art range? 11 MR. TRASK: I think that's a fair 12 characterization of the criticality inquiry, that OSRAM, 13 for example, says -- asks whether the claim value is 14 central to the invention. I think the -- and -- and 15 whether the invention would operate differently at 16 various points within the range. So -- 17 JUDGE RAYMOND CHEN: Okay. So that, I think -- 18 that's what I'm wondering if whether there's a gap in 19 this record, or in this case, when it comes to the 20 analysis on criticality. 21 MR. TRASK: So I don't think there's a gap, Your 22 Honor, for -- for a couple of reasons. 23 One is the testimony concerning the precise 24 concentration selected by the inventors, as found by the 25 District Court, at A159, which balanced the -- the Page 42	1 closest prior art, which the parties agreed was the 2 Gaudreault reference, which -- which referenced the 3 R drug that Your Honor mentioned. 4 So the -- the other thing I point out is that 5 the -- the testimony from Dr. Furfine, one of the 6 inventors that connected the concentration, 40 milligram 7 per milliliter with the half-life of aflibercept was 8 un rebutted. The District Court found that at A200. 9 And there was no challenge by Mylan to that -- 10 to that finding at trial and certainly on appeal. 11 And so there's -- there's multiple ways in which 12 the District Court found criticality, the connection to 13 aflibercept itself through the testimony of Dr. Furfine 14 and Dr. Graham, as well as to the comparison to the 15 closest prior art in the Gaudreault case. 16 JUDGE RAYMOND CHEN: You're -- getting away from 17 the Dix's 102. You're not relying on the preamble -- 18 are you? -- of the -- for use in intravitreal 19 administration compared to the cancer treatment that was 20 disclosed in -- 21 MR. TRASK: The -- the preamble was never a 22 basis to distinguish the prior art. 23 JUDGE RAYMOND CHEN: Okay. I saw the District 24 Court, in part, relied on that, and then I saw that your 25 record does not. Page 44
1 half-life with concerns regarding safety and efficacy, 2 as well as the District Court's findings regarding 3 unexpected results. 4 And so these findings are at A198. 5 And the District Court found that the 6 40 milligrams per milliliter of aflibercept claimed in 7 all of the asserted claims had three critical and 8 unexpected properties: Safety, efficacy, and durability. 9 And the Court went on to explain how it was that 10 this 40 milligram per milliliter concentration was 11 surprisingly comparable with respect to safety and 12 efficacy compared to the closest prior art. 13 Parties agreed was the -- was the Genentech 14 Lucentis -- sorry, Gaudreault reference, and also had 15 durability to be dosed half as frequently. 16 As Your Honors can imagine, getting an injection 17 into the eyeball is not a pleasant experience for 18 patients. And so this was a revolutionary advance, the 19 District Court found, to have to dose patients only half 20 as often. 21 So that finding as well, I think, supports the 22 District Court's finding of criticality because it shows 23 that the 40 milligram per milliliter concentration 24 claimed in all of the asserted claims is critical to the 25 invention and distinguished the invention from the Page 43	1 MR. TRASK: I don't -- I don't think that's 2 right. I mean, it's certainly true. 3 JUDGE RAYMOND CHEN: When you say "that's not 4 right," which part's not right? 5 MR. TRASK: I'm sorry. Yes. I don't view 6 that -- I don't read the District Court's decision as 7 relying upon the -- 8 JUDGE RAYMOND CHEN: Okay. I'll just -- 9 MR. TRASK: -- preamble. 10 JUDGE RAYMOND CHEN: -- write those words from 11 his opinion then, right [inaudible] -- 12 (Simultaneously speaking.) 13 JUDGE SHARON PROST: Can I ask you one other -- 14 (Simultaneously speaking.) 15 MR. TRASK: Oh, Okay. I don't -- I'm not sure, 16 Your Honor, which passage was -- you're specifically 17 referring to -- 18 JUDGE RAYMOND CHEN: Okay. 19 MR. TRASK: -- but -- but there was no dispute 20 by the parties that there was no efficacy limitation 21 built into the "suitable for intravitreal 22 administration" term. It was never a term that -- that 23 either party had proposed to construe. 24 And so there's un rebutted testimony by Dr. Trout 25 that what that limitation means is -- contains Page 45

1 components that can be used intravitreally and nothing 2 more. 3 JUDGE RAYMOND CHEN: What about 98 percent? How 4 are -- how are we supposed to think about that? 5 The other side, you heard say, essentially, the 6 98 percent would be there in Dix if you use the 7 40 milligram per milliliter because all the examples at 8 other concentration levels got you to 98 percent and --I 9 don't know -- 98 percent of what the FDA wants. So 10 98 percent is really -- not really meaningful here. 11 MR. TRASK: So two responses to that, Your 12 Honor. 13 One is, I think you put your finger on it, when 14 you asked my friend on the other side about the 15 testimony that best supported the notion that there 16 would be 98 percent in 40 milligrams per mL from the Dix 17 reference, and if you pointed out that the most the 18 expert said is it would be most likely. 19 That's at A10526. 20 JUDGE RAYMOND CHEN: That was your expert; 21 right? 22 MR. TRASK: That's our expert, correct. 23 He acknowledged that -- 24 JUDGE RAYMOND CHEN: What did their experts say? 25 MR. TRASK: Their expert offered no testimony on Page 46	1 reply brief. They said, quote, "98 percent native 2 confirmation was a known FDA stability requirement," 3 unquote. 4 In support of that statement, they cite 5 Dr. Graham, and I encourage Your Honors to look at that 6 testimony. 7 This is at A10102 through 03. 8 Dr. Graham said precisely the opposite of what 9 Mylan represented there. 10 Dr. Graham said that 98 percent native 11 confirmation was, quote, "not an obligate requirement," 12 unquote, for -- for [inaudible] -- 13 (Simultaneously speaking.) 14 JUDGE EVAN WALLACH: What volume are you on? 15 MR. TRASK: -- product. 16 This is -- sorry -- A10102, which is Volume 2, I 17 believe. 18 JUDGE RAYMOND CHEN: We're -- we've been talking 19 about Dix 102. Just curious. Dix 103. You're reliance 20 on 103(c)(1), it couldn't be conclusive yet -- right? -- 21 if we were to conclude that there was a problem with 22 criticality because the District Court never made an 23 assessment on whether -- I think '865 is entitled to an 24 earlier provision application file in a day. 25 Is that right? Page 48
1 that fact. 2 And what it seems to me on appeal is that 3 they're arguing almost kind of an inherency type -- type 4 of analysis. But certainly that was not a theory that 5 was run below. And there's no evidence to support that 6 necessarily there would have been 98 percent native 7 confirmation in one -- in one of the Dix formulations. 8 JUDGE EVAN WALLACH: Frankly, what impressed me 9 was how often Rabinow and Trout agreed with each other, 10 which is unusual in [inaudible] -- 11 MR. TRASK: It is -- 12 JUDGE EVAN WALLACH: -- opinion. 13 MR. TRASK: It is refreshing, perhaps. I agree 14 with you, Your Honor. 15 The -- the other point I wanted to make in 16 response to Judge Chen's question -- 17 JUDGE RAYMOND CHEN: But the lawyers have, like, 18 40 disagreements. 19 (Laughter elicited.) 20 MR. TRASK: Well, I -- I can't help that. There 21 are a lot of issues raised in the opening brief. 22 On the point about 98 percent being a known FDA 23 requirement, I think is an important point to -- to 24 flag. 25 Mylan made this argument at Page 24 of their Page 47	1 MR. TRASK: So -- so I think part of the reason 2 that -- that Dix was not a focus of Mylan's -- 3 JUDGE RAYMOND CHEN: I'm just trying to get to 4 the bottom of something -- 5 MR. TRASK: Yes. 6 JUDGE RAYMOND CHEN: I just need to know for a 7 housekeeping. 8 MR. TRASK: Sure. 9 So -- so our view is that Dix is not a proper 10 reference under 103 -- 11 JUDGE RAYMOND CHEN: Right. 12 MR. TRASK: -- by virtually the fact -- 13 JUDGE RAYMOND CHEN: But the District Court did 14 not [inaudible] -- 15 (Simultaneously speaking.) 16 MR. TRASK: District Court did not -- 17 JUDGE RAYMOND CHEN: -- assessment on whether 18 the patents entitled to provisional priority 19 [inaudible] -- 20 (Simultaneously speaking.) 21 MR. TRASK: The District Court did not make that 22 finding. That's right, Your Honor. 23 JUDGE RAYMOND CHEN: Okay. 24 MR. TRASK: Yeah. 25 And so if -- if the Court decides that it can't Page 49

1 reach that question as a result, then -- then it 2 wouldn't -- wouldn't reach the 103(c) question. 3 But our argument is that Dix -- 4 JUDGE RAYMOND CHEN: I mean, I could just keep 5 asking questions. I don't know -- 6 JUDGE SHARON PROST: Well, can we get to 7 teaching away because -- I'm sorry. I'm thinking about 8 too many things at one point. So maybe this is 9 redundant. 10 JUDGE RAYMOND CHEN: Yep. Okay. 11 JUDGE SHARON PROST: But I want to get to the 12 teaching away argument. 13 MR. TRASK: Yes, Your Honor. 14 JUDGE SHARON PROST: And it seems to me that the 15 District Court relied heavily on Dr. Trout's analysis of 16 this Gaudreault reference, but I don't see anywhere in 17 the record where he explains what a reference about -- 18 we'll call it "R" -- right? -- 19 MR. TRASK: Yeah. 20 JUDGE SHARON PROST: -- formulation is 21 indicative of how the A formulation would behave. And I 22 only see discussions about how A is more potent than R. 23 But did your expert provide anything additional 24 as to why R and A would behave similarly? 25 I mean, this is just an odd kind of teaching Page 50	1 and, yet, I don't see the basis for that premise that 2 these two things are interchangeable, or one is a fair 3 substitute for the other. 4 Where is the bridge for that kind of thinking 5 that allows us to be -- assume that whatever that might 6 be bad about the R drug necessary is also going to be 7 equally bad, if not worse, for aflibercept study. 8 MR. TRASK: Sure. 9 So the District Court's teach-away findings were 10 A174 to -77. And there were a number of findings that 11 are relevant. 12 But to -- to Your Honor's point, both of these 13 drugs, the R drug, and the aflibercept, the A drug, had 14 the ideal mechanism of action. Right. They bind the 15 VEGF in the retina to -- 16 JUDGE RAYMOND CHEN: Okay. This is you talking, 17 and that's helpful -- 18 MR. TRASK: Sure. 19 JUDGE RAYMOND CHEN: -- but I -- I need 20 something in the District Court's findings and rationale 21 analysis that I can focus on and see, "Okay, oh, 22 they're -- you know, that's a fair fact-finding that I 23 can get behind" versus "Oh, there's a hole in the 24 analysis that leaves me wanting, and I can't just rely 25 on attorney argument today trying to talk it away." Page 52
1 away when you're not directing it to what -- what we're 2 talking about; right? 3 MR. TRASK: Sure. Well, so, I -- I -- 4 JUDGE SHARON PROST: So how do you get there? 5 MR. TRASK: Sure. 6 So it was undisputed at trial that this 7 reference, it's the subject of the teach-away, the 8 Gaudreault reference, was the closest prior art. 9 The District Court found that at A197. 10 And the only thing that Mylan cites to 11 support -- they -- they claim on appeal in -- on Page 36 12 of their reply brief that they disputed that contention. 13 The only thing they cite is their proposed 14 order, their proposed post-trial order to the District 15 Court, which is, of course, is not evidence at A11698. 16 And so there is no evidence of record. The 17 Gaudreault is not the closest prior art. And it was not 18 a position that Mylan ever advanced below. 19 So -- so -- 20 JUDGE RAYMOND CHEN: I guess, to put a finer 21 point on it, your theory of teaching away -- the 22 District Court's theory of teaching away is that 23 aflibercept and the R drug are essentially 24 interchangeable, and the R drug stands as a proxy for 25 what a skilled artisan would think about aflibercept, Page 51	1 MR. TRASK: Sure. 2 I mean, so, I think in -- focusing on the pages 3 that I just reference to A174 to 177, it was -- it 4 seemed to be understood through the eyes of the POSA 5 that these two molecules had the same mechanism of 6 action in the performance of one of -- would be 7 indicative of the performance of the other. 8 So, for example, at A175, the District Court 9 found that because of aflibercept was much more -- 10 JUDGE SHARON PROST: Where are you in the page? 11 MR. TRASK: Sure. 12 This is A175. 13 JUDGE SHARON PROST: Yeah, I'm there. But... 14 MR. TRASK: And I'm on the -- it's the second 15 beginning of the paragraph there, it says [as read]: 16 "Moreover, he was undisputed that. 17 aflibercept was much more potent 18 than ranibizumab. Because of its higher 19 potency less of aflibercept is needed to 20 inhibit the same amount of VEGF as 21 compared to ranibizumab." 22 And then a little further down, it says [as 23 read]: 24 "Dr. Trout explained that the POSA would 25 have been motivated to use a Page 53

1 concentration of aflibercept lower 2 than the 10 milligrams per milliliter 3 ranibizumab in view of the 4 aflibercept's higher potency." 5 And so Dr. -- 6 JUDGE RAYMOND CHEN: That's not quite teaching 7 away. That is more, like, about how, perhaps, a skilled 8 artisan just wouldn't be motivated to crank up the 9 concentration up to 40 milligrams for -- right? 10 That's -- that's not saying "that's a really bad 11 idea to use aflibercept for the milligram per 12 milliliter." 13 JUDGE SHARON PROST: If -- and just to tag on to 14 that, I -- I can't recall any other cases on teaching 15 away where one was relying on something different 16 because maybe there's some similarity to then say "this 17 teaches away, even though it's different, for this." 18 Do you know of any cases that have done that? 19 MR. TRASK: Well, I don't -- I'm not sure I know 20 exactly this particular scenario, but -- but it -- this 21 is not a different -- these are not two different 22 disclosures in the sense that they're both -- these are 23 the two leading VEGF antagonists at the time. They were 24 kind of both in development at the time. And the 25 evidence is that the POSA was looking at the development Page 54	1 JUDGE SHARON PROST: Did -- did -- I'm looking 2 at that page with the District Court. 3 I'm not see- -- is there anything that District 4 Court -- did the District Court make a finding like 5 that? 6 I mean, she says the comparison she has that you 7 called out, which is that aflibercept is more potent 8 than the R drop [verbatim], but that -- you know, okay. 9 MR. TRASK: Phoning a friend here. 10 It's about -- it -- so the -- another -- another 11 finding here is at A187, which compares ranibizumab and 12 fusion proteins like aflibercept. 13 JUDGE SHARON PROST: What heading is this under? 14 MR. TRASK: This is in the -- in the context 15 of -- this is the invalidity analysis for options 16 [phonetic]. 17 JUDGE SHARON PROST: Okay. 18 MR. TRASK: And the discussion here on A187 19 talks about the "POSA wouldn't expect that a different 20 protein would have the same native confirmation. The 21 higher required concentration of aflibercept compared to 22 ranibizumab undermine any reasonable expectation of 23 success." 24 So, again, comparing these two drugs, have the 25 same mechanism of action, both VEGF antagonists, and Page 56
1 of ranibizumab, the R drug, in order to inform how to go 2 about developing aflibercept, the -- the A drug. 3 And so these are drugs that had the same 4 mechanism of action. 5 And the undisputed testimony at trial through 6 Dr. Trout over pages of the District Court's findings is 7 that the performance of ranibizumab informed the POSA 8 how one would expect aflibercept to perform because they 9 had the identical mechanism of action. 10 And so there was a finding that -- 11 JUDGE RAYMOND CHEN: And where is that finding, 12 same mechanism of action and then the experts saying 13 "because they have the same mechanism of action, we 14 would certainly think of aflibercept in the same way 15 that we would think of the R drug"? 16 MR. TRASK: I might need a moment to -- 17 JUDGE RAYMOND CHEN: Okay. 18 MR. TRASK: -- locate that. 19 But I would say that the -- all of the testimony 20 that I've been referring to is -- is based upon the 21 understanding, which is undisputed, that the performance 22 of the R drug indicated -- informed the POSA's 23 expectations regarding aflibercept. Right. 24 That -- that was the understanding that -- on 25 which Dr. Trout was testifying, is that -- Page 55	1 comparing their -- and -- and contrasting the 2 expectation of success. 3 JUDGE RAYMOND CHEN: This seems to -- if I'm not 4 mistaken, kind of work against what your position is. 5 Your -- your position, for purposes of teaching 6 away, is to tell us that these two drugs are very, very, 7 very close cousins. 8 This passage seems to say "just because you 9 would get some amount of stability in one doesn't 10 necessarily mean you'll get that same stability in the 11 other." 12 MR. TRASK: So there's no -- there was no 13 contrary testimony on this point that the two drugs have 14 the same mechanism of action and would have performed 15 similarly, but the POSA would have understood that 16 because of the severe inflammation exhibited by Lucentis 17 at 40 milligrams per milliliter, you would expect that 18 aflibercept would -- you'd need a far lower 19 concentration in order to achieve the max- -- in order 20 to achieve a beneficial therapeutic effect with a -- 21 with a lower amount of -- 22 JUDGE RAYMOND CHEN: I suppose you have backup 23 arguments, though, on this; right? Like -- 24 MR. TRASK: We do, yes, Your Honor. Yes. 25 JUDGE RAYMOND CHEN: -- if there's some problem Page 57

1 with the teaching-away analysis, there's half a dozen 2 other reasons that have been identified. 3 MR. TRASK: That's exactly right. 4 There's -- the aflibercept sequence is not 5 disclosed in the Fraser and Lucentis combination. 6 The -- the glycosylated aflibercept is not 7 disclosed in that combination. 8 JUDGE RAYMOND CHEN: Neither reference has 9 aflibercept? 10 MR. TRASK: No, I'm talking about the Fraser and 11 Lucentis combination. 12 JUDGE RAYMOND CHEN: Right. 13 MR. TRASK: Yeah. 14 JUDGE RAYMOND CHEN: Neither reference has 15 aflibercept? 16 MR. TRASK: In Fraser and Lucentis -- I'm sorry, 17 the -- the Fraser discloses what's called a VEGF Trap 18 R1R2, which does not disclose aflibercept and does not 19 disclose the amino acid sequence of aflibercept. That's 20 right. 21 And Lucentis, of course, was about the 22 ranibizumab drug. 23 There's no disclosure of glycosylated 24 aflibercept. There's no motivation to glycosylate 25 aflibercept. Page 58	1 we haven't gone to yet. 2 And we'll talk more about that in the -- 3 (Simultaneously speaking.) 4 MR. TRASK: Okay. Yeah. 5 JUDGE SHARON PROST: -- other case. 6 MR. TRASK: Yeah. 7 But there -- to Your Honor's point, there are a 8 number of differences with respect to the reasonable 9 expectation of success, the motivation, as well as the 10 aflibercept sequence that differentiate the prior art 11 from the -- from the claimed invention here. 12 The last point I'll raise is that the -- you 13 started, Judge Prost, by asking my friend on the other 14 side what obvious miscombinations they're running here, 15 and I heard that they're maintaining the Fraser and 16 Lucentis and the Dix references. 17 In their briefing, they combined those -- those 18 two things. This is -- this is at A6- -- I believe it's 19 at Page 69 of their brief. 20 JUDGE EVAN WALLACH: Did you say in your 21 rhetoric that they didn't raise that to the trial judge? 22 MR. TRASK: No, that's not right, Judge Wallach. 23 They -- we objected to the trial judge -- in front of 24 the trial judge to the combination because it wasn't 25 disclosed. The District -- District Court precluded Page 60
1 As this Court found last week in the related 2 appeal involving Samsung -- 3 JUDGE RAYMOND CHEN: How come we didn't get a 4 28(j) letter? 5 JUDGE SHARON PROST: Oh, yes. That's -- 6 JUDGE RAYMOND CHEN: Yeah. 7 JUDGE SHARON PROST: Well, that goes to the next 8 case, though, because we -- 9 JUDGE RAYMOND CHEN: No, it counts here, too. 10 Sure. 11 JUDGE SHARON PROST: No, but it counts more on 12 the last case. 13 MR. TRASK: Yeah, I will -- I will take 14 responsibility for that. We -- we weren't sure -- 15 JUDGE SHARON PROST: Well, the other side as 16 well. We should have got something from someone. 17 MR. TRASK: We weren't sure if the -- we should 18 presume that the Court was aware of a decision in the 19 same consolidated appeal. 20 Perhaps we should have just submitted the 21 28(j) letter out of an abundance of caution. 22 JUDGE SHARON PROST: Well, that's a fair 23 assumption but that doesn't answer the next question of 24 the reason we have 28(j) letters is to explain the 25 relevance of that opinion to what the case is, the case Page 59	1 Mylan from relying on that combination. This is at A167 2 to -168. 3 And yet their opening brief argues these 4 references together as if it's a proper combination. 5 And so I just wanted to make sure the Court was 6 aware of that point. 7 JUDGE SHARON PROST: [Inaudible]. Thank you. 8 MR. TRASK: Thank you very much, Your Honors. 9 JUDGE SHARON PROST: Okay. Trying to keep 10 things even, if necessary, by my calculations, which may 11 be wrong, but I think you went eight over, and he went 12 18 over. So that gives you plus-ten. But we hope you 13 don't need it. 14 MS. MAZZOCHI: I will try not to use it all if I 15 don't have to, Your honor. 16 A couple of things I'd like to point out. 17 First, if the tenth -- if the tenths and 18 hundredths apply from the perspective of a person of 19 ordinary skill in the art to 10 to 50, then it also 20 applies to 40. So then you've got a range versus a 21 range, as opposed to a point within a range. 22 In addition, I do want to point out that my 23 co- -- 24 JUDGE SHARON PROST: Did -- but you'll agree 25 with your friend that your -- your expert conceded that? Page 61

1 MS. MAZZOCHI: Well, what he said is numerically 2 10 to 50 will -- can include tenths and hundredths. 3 That's not necessarily the same thing -- I don't 4 think -- as a person of ordinary skill in the art would 5 concede all of those to be the same. 6 But, nevertheless, if a person of ordinary skill 7 in the art is going to see a number 10 to 50 and see 8 tenths and hundredths and then they're going to see a 9 Number 40, then that also means you see tenths and 10 hundredths, and that's a range. 11 When it comes to the -- you know, what Dix says 12 about this class of VEGF antagonist and that, I think, 13 is actually where the Samsung decision that this Court 14 recently issued would, in fact, be relevant here. 15 So one of the things that my colleague argued is 16 that, "Well, Dix doesn't actually tell you about the 17 full sequence that we've got claimed in Claim 1." 18 Well, here's what Dix does do. 19 Dix, in its examples, always uses SEQ ID NO:4. 20 Dix in the specification has a clear preference 21 for SEQ ID NO:4. 22 And if we go to Dix, this is an A12595, under 23 the heading "VEGF Antagonist." So he's talking about 24 the fusion proteins. 25 Column 5, Lines 30 to 42. Page 62	1 invention. 2 So I think in this Court's claims, when we're 3 talking about is something arranged, as in the claim, 4 when we -- we clearly have an interrelated teaching. 5 Here's the fusion proteins. 6 Here's the ones that I prefer. 7 Here's what I most prefer. 8 So the District Court went wrong by not looking 9 at that particular thing, to say, "Oh, aflibercept is 10 something that Dix is specifically contemplating." 11 Similarly, if we then go to Dix's examples, the 12 '226 patent, Example 1. So that Dix -- this is at 13 A12596, Example 1. 14 What does Dix have there? 15 And now let's go to the '865 patent, Example 1. 16 What are the ingredients? 17 They're titled the same: "Stability of a 18 50 milligram per mL." 19 You know, the '865 patent says it's "VEGF Trap 20 Liquid Formulation." Dix just says "Liquid Formulation 21 of VEGF trap." 22 What's contained in it? 23 10 millimeter -- 10 millimoles of phosphate in 24 Dix; 10 millimoles of phosphate in the '865 patent. 25 50 millimoles of NaCl; also 50 millimoles of Page 64
1 He specifically says, "Here's what the VEGF 2 antagonists are. It includes fusion proteins. In a 3 preferred embodiment, the VEGF antagonist is the fusion 4 protein of 2 or 4, more preferably, SEQ ID NO:4." 5 And then further on -- then the next couple 6 lines. 7 This is the same thing that the Samsung decision 8 decided was going to be written description support for 9 Regeneron for its claims in the '865 patent relating to 10 the sequencing, like constellation patterns. 11 Dix has the same, identical language under the 12 same heading because Dix and the '865 patent are reading 13 almost verbatim on this. 14 It then says, "In a specific embodiment, the 15 fusion protein comprises amino acids 257 to 457 of SEQ 16 ID NO:4 and is glycosylated at asparagine residues 62, 17 94, 149, 122, and 308." 18 That is the single sequence that is claimed in 19 Claim 1 of the '865 patent here. 20 So Dix, if -- this is where the District Court 21 went wrong because the District Court only focused on 22 just that one description of Column 2 that's saying, 23 "Here's what the embodiment is for 10 to 50 milligrams," 24 but then he ignored where the specification then expands 25 on what it means to be a VEGF fusion protein of the Page 63	1 NaCl in the '865 patent. 2 Then we've got .1 percent Polysorbate 20. 3 JUDGE RAYMOND CHEN: Just so I can clarify, 4 which specific issue is what you're talking about 5 driving at? 6 MS. MAZZOCHI: Right. 7 This gets to the idea of -- my colleague from 8 Regeneron was saying that somehow there's other elements 9 that were missing from the Dix formulations that didn't 10 get you to the complete claim, and particularly the 11 stability elements. 12 Well, as you go down -- as you march through 13 these, you then get to Table 1 in Dix, Table 1 in the 14 '865 patent. You've got the same visual appearance, 15 turbidity, pH, and stability data, all above 98 percent. 16 So you've got the id- -- the near identical 17 ingredients, and both Dix's 50 milligram Example 1 that 18 meets each and every element of Claim 1 and Claim 4 and 19 all the other asserted claims here, it just doesn't have 20 the number 40 in it. 21 You go to the '865 patent. Yes, they've got a 22 50 milligram example, same stability numbers as in Dix; 23 They've got a 40 milligram number, same 24 stability results in Dix; 25 Then you look at the Dix 25 milligrams for Page 65

1 analysis. So you drop the concentration, and that's at 2 Column 12, and guess what? He uses those same 3 formulation ingredients, gets the same stability 4 outcome. 5 So -- 6 JUDGE RAYMOND CHEN: Do you have expert 7 testimony on this? 8 MS. MAZZOCHI: Yes. 9 JUDGE RAYMOND CHEN: And where is that? 10 MS. MAZZOCHI: That -- it is -- it is 11 throughout, I think. Let me pull out some of those. 12 I apologize, Your Honor. 13 I -- I will get you those. I know -- I know we 14 have the -- there citations in there where 15 they basic- -- where we basically did go back and forth 16 between matching each of these up. 17 So -- 18 JUDGE SHARON PROST: Okay. Can I 19 get [inaudible]? 20 MS. MAZZOCHI: Yeah. Couple other points, Your 21 Honor, that I did want to make. 22 JUDGE SHARON PROST: Well, I -- just -- 23 MS. MAZZOCHI: Sure. 24 JUDGE SHARON PROST: -- just one quick point. 25 As I -- I know so long ago that I don't Page 66	1 out, we did dispute below that this ranibizumab drug 2 was, in fact, the closest prior art. 3 Now, I know my colleague from Regeneron said, 4 "Well, you just talked about that in your briefing." 5 That's because our whole point was it's not legally 6 relevant. 7 The -- 8 JUDGE SHARON PROST: Well, did you ever say it's 9 not legally relevant? 10 MS. MAZZOCHI: Yes. 11 JUDGE SHARON PROST: Did you tell that to the 12 District Court -- 13 (Simultaneously speaking.) 14 MS. MAZZOCHI: Yes, that was in our proposed 15 findings of fact, conclusions, and law that the Court 16 had submitted, that -- that the closest prior art was 17 going to be the Dix formulation. It -- it was not going 18 to be ranibizumab because -- 19 And I think the Janssen v. Teva case that was 20 decided that we cited in our brief also bears this out, 21 is that you're not supposed to be looking at what's 22 happening with another drug to say, "Is this" -- you 23 know, to say, "This is how it's going to behave for 24 ours." 25 And then, additionally, I also wanted to point Page 68
1 remember, but I know your friend said something about a 2 grey brief and a citation to one of the experts, and 3 that your description of what he said was the exact 4 opposite, I think your friend said, of what he actually 5 said. 6 Do you have a response to that? 7 MS. MAZZOCHI: Right. I -- I did not get a 8 chance to check it. 9 JUDGE SHARON PROST: Okay. 10 MS. MAZZOCHI: If we did, then, you know, 11 obviously -- 12 JUDGE SHARON PROST: Okay. 13 MS. MAZZOCHI: -- we would withdraw that or see 14 if there was an error cite, and there's an additional 15 citation that needs to be made. 16 But on a certain level, I don't think it's 17 actually relevant because Dix already achieved 18 98 percent stability. He teaches it. He talks about 19 it. He specifically teaches one of ordinary skill in 20 the art how to get there. 21 So you don't even need to look at FDA's 22 motivations to get you there. He already got you there. 23 So once -- so there, again, that's where I get 24 to the enab- -- what is the enabling disclosure. 25 In addition, Your Honor, I did want to point Page 67	1 out that when it comes to this issue of criticality, we 2 do know, from Dix, that the desirable benefit of 3 stability was actually achieved not only for the lower 4 concentration but for even higher concentrations: 5 50 milligrams, 75, 100 milligrams per mL. 6 So under Abbott versus Baxter, 471 F.3d at 1368, 7 the fact that they may have found, even if we assume 8 from the District at -- Court's findings, we may have 9 found some additional property that we think is 10 beneficial, that doesn't change the fact, even -- and I 11 think Abbott even said, "Even if you put it in your 12 claims, that still doesn't change the fact that when 13 these are composition claims, and the compositions are 14 achieving the same outcomes, the same utilities, 15 there -- there just isn't any difference there, and 16 there's no anticipation." 17 And I think that Ineos, likewise, rejected the 18 idea that you can start having these little chains of 19 inferences to also get to criticality to somehow support 20 your claims. 21 All right. Thank you very much. 22 (Simultaneously speaking.) 23 JUDGE SHARON PROST: We'll close. 24 So we thank both sides. 25 Okay. This case is submitted. Page 69

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	(Whereupon, the audio recording concluded at timestamp 1:09:22.) --- oOo --- Page 70	
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	1 STATE OF CALIFORNIA) 2 COUNTY OF LOS ANGELES) SS. 3 4 I, Whitney Hester, CSR No. 14658, in 5 and for the State of California, do hereby certify: 6 That the foregoing is a true and accurate 7 transcription of the audio recording provided to me done 8 to the best of my ability; 9 That I am neither attorney or counsel for nor 10 related to any of the parties of said matter; 11 Furthermore, that I am not a relative or 12 employee of any attorney or counsel employed by the 13 parties hereto or financially interested in the action. 14 IN WITNESS WHEREOF, I have hereunder serve my 15 hand this 22nd day of April, 2025. 16 17 18  19 _____ 20 Certified Shorthand Reporter 21 for the State of California 22 23 24 25 Page 71	

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